

Avinger Inc  
Form 10-Q  
November 12, 2015  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

---

**FORM 10-Q**

---

(Mark One)

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

For the quarterly period ended September 30, 2015

or

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

For the transition period from    to

Edgar Filing: Avinger Inc - Form 10-Q

Commission File Number: 001-36817

---

**AVINGER, INC.**

(Exact name of registrant as specified in its charter)

---

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**20-8873453**  
(I.R.S. Employer  
Identification Number)

**400 Chesapeake Drive**

**Redwood City, California 94063**

(Address of principal executive offices and zip code)

**(650) 241-7900**

(Telephone number, including area code)

---

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Edgar Filing: Avinger Inc - Form 10-Q

(Do not check if a smaller reporting company)

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

As of November 2, 2015, the number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 12,622,074.

---

Table of Contents

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

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

- the outcome of our clinical studies and plans to conduct further clinical studies;
- our plans to modify our current products, or develop new products, to address additional indications;
- the expected timing of submission of a Special 510(k) to FDA for an enhanced version of Pantheris;
- the expected growth in our business and our organization;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to retain and recruit key personnel, including the continued development of a sales and marketing infrastructure;
- our ability to obtain and maintain intellectual property protection for our products;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for, or ability to obtain, additional financing;
- our expectations regarding the time during which we will be an emerging growth company under the

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

- our ability to identify and develop new and planned products and acquire new products;
- our financial performance; and
- developments and projections relating to our competitors or our industry.

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

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

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

---

Table of Contents

## AVINGER, INC.

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

## TABLE OF CONTENTS

	<b>Page</b>
<b>Part I</b>	
<b>Financial Information</b>	
<u>Item 1.</u>	1
<u>Unaudited Financial Statements</u>	1
<u>Condensed Balance Sheets</u>	2
<u>Condensed Statements of Operations and Comprehensive Loss</u>	3
<u>Condensed Statements of Cash Flows</u>	4
<u>Notes to Condensed Financial Statements</u>	19
<u>Item 2.</u>	19
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	27
<u>Item 3.</u>	27
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	27
<u>Item 4.</u>	27
<u>Controls and Procedures</u>	27
<b>Part II</b>	
<b>Other Information</b>	
<u>Item 1.</u>	28
<u>Legal Proceedings</u>	28
<u>Item 1A.</u>	28
<u>Risk Factors</u>	49
<u>Item 2.</u>	49
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	49
<u>Item 3.</u>	49
<u>Defaults Upon Senior Securities</u>	49
<u>Item 4.</u>	49
<u>Mine Safety Disclosures</u>	49
<u>Item 5.</u>	49
<u>Other Information</u>	49
<u>Item 6.</u>	49
<u>Exhibits</u>	49
<u>Signatures</u>	50

Avinger, Ocelot, Pantheris, and Lumivascular are trademarks of our company. Our logo and our other trade names, trademarks and service marks appearing in this Quarterly Report on Form 10-Q are our property. Other trade names, trademarks and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. Solely for convenience, our trademarks and trade names referred to in this Quarterly Report on Form 10-Q appear without the symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and trade names. Certain market and industry data used in this Quarterly Report on Form 10-Q, where noted, is attributable to Millennium Research Group, Inc. Millennium Research Group asserts copyright protection over the use of such information and reserves all rights with respect to its use. This information has been reprinted with Millennium Research Group's permission and the reproduction, distribution, transmission or publication of such information is prohibited without its consent.

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)*

	September 30, 2015	December 31, 2014
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 54,781	\$ 12,316
Accounts receivable, net	2,161	2,068
Inventories	3,205	3,991
Prepaid expenses and other current assets	680	425
Total current assets	60,827	18,800
Property and equipment, net	2,451	2,608
Other assets	196	3,029
Total assets	\$ 63,474	\$ 24,437
<b>Liabilities, convertible preferred stock and stockholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 464	\$ 1,013
Accrued compensation	2,333	1,147
Accrued expenses and other current liabilities	3,103	4,850
Borrowings, current portion		1,873
Total current liabilities	5,900	8,883
Borrowings, net of current portion	29,154	18,228
Convertible notes and accrued interest		8,609
Other long-term liabilities	1,677	325
Total liabilities	36,731	36,045
Commitments and contingencies (Note 8)		
Convertible preferred stock issuable in series, par value of \$0.001		
Shares authorized: none at September 30, 2015 and 6,819,197 at December 31, 2014		
Shares issued and outstanding: none at September 30, 2015 and 5,262,728 at December 31, 2014		
Liquidation preference: none at September 30, 2015		132,260
Stockholders' equity (deficit):		
Preferred stock issuable in series, par value of \$0.001		
Shares authorized: 5,000,000 at September 30, 2015 and none at December 31, 2014		
Shares issued and outstanding: none at September 30, 2015 and December 31, 2014		
Common stock, par value of \$0.001		
Shares authorized: 100,000,000 at September 30, 2015 and 15,555,555 at December 31, 2014		
Shares issued and outstanding: 12,620,682 at September 30, 2015 and 243,260 at December 31, 2014		13

Edgar Filing: Avinger Inc - Form 10-Q

Accumulated deficit	(182,805)	(146,533)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	\$ 63,474	\$ 24,437

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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenues	\$ 2,721	\$ 2,632	\$ 7,856	\$ 8,140
Cost of revenues	1,750	1,471	4,672	4,941
Gross profit	971	1,161	3,184	3,199
Operating expenses:				
Research and development	3,955	2,731	11,766	8,350
Selling, general and administrative	6,892	4,575	19,802	12,900
Total operating expenses	10,847	7,306	31,568	21,250
Loss from operations	(9,876)	(6,145)	(28,384)	(18,051)
Interest income	11		23	1
Interest expense	(1,334)	(1,712)	(4,002)	(4,905)
Other income (expense), net	(2,058)	(920)	(1,525)	(837)
Loss before provision for income taxes	(13,257)	(8,777)	(33,888)	(23,792)
Provision for income taxes	(7)	3		37
Net loss and comprehensive loss	(13,250)	(8,780)	(33,888)	(23,829)
Adjustment to net loss resulting from convertible preferred stock modification			(2,384)	
Net loss and comprehensive loss attributable to common stockholders	\$ (13,250)	\$ (8,780)	\$ (36,272)	\$ (23,829)
Net loss attributable to common stockholders per share, basic and diluted	\$ (1.08)	\$ (36.43)	\$ (3.32)	\$ (98.88)
Weighted average common shares used to compute net loss per share, basic and diluted	12,280	241	10,935	241

See accompanying notes.

Table of Contents

## AVINGER, INC.

## CONDENSED STATEMENTS OF CASH FLOWS

(unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2015	2014
<b>Cash flows from operating activities</b>		
Net loss	\$ (33,888)	\$ (23,829)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	961	1,132
Amortization of debt issuance costs and debt discount	152	167
Stock-based compensation	3,691	509
Remeasurement of warrant and embedded derivatives	(835)	(67)
Write off of embedded derivatives	1,066	
Noncash interest expense and other charges	1,735	2,999
Loss on extinguishment of convertible notes	86	892
Provision for excess and obsolete inventories	(57)	(47)
Changes in operating assets and liabilities:		
Accounts receivable	(93)	(271)
Inventories	332	1,298
Prepaid expenses and other current assets	(510)	69
Other assets	(6)	(326)
Accounts payable	(552)	104
Accrued compensation	1,185	279
Accrued expenses and other current liabilities	(994)	1,511
Other long-term liabilities and accrued interest	(1,637)	(168)
Net cash used in operating activities	(29,364)	(15,748)
<b>Cash flows from investing activities</b>		
Purchase of property and equipment	(288)	(37)
Restricted cash	255	
Net cash used in investing activities	(33)	(37)
<b>Cash flows from financing activities</b>		
Principal paydown of capital lease obligations	(15)	(14)
Payments on borrowing	(27,625)	
Proceeds from convertible notes, net of issuance costs		4,700
Proceeds from borrowing, net of issuance costs	29,124	11,074
Proceeds from the issuance of convertible preferred stock, net of issuance costs	6,176	
Proceeds from the issuance of common stock related to CRG loan, net of issuance costs	4,794	
Proceeds from initial public offering, net of issuance costs	58,746	
Proceeds from the exercise of common stock warrants	308	
Proceeds from the issuance of common stock	354	17
Net cash provided by financing activities	71,862	15,777
Net change in cash and cash equivalents	42,465	(8)
Cash and cash equivalents, beginning of period	12,316	12,221
Cash and cash equivalents, end of period	\$ 54,781	\$ 12,213

Edgar Filing: Avinger Inc - Form 10-Q

**Supplemental disclosure of cash flow information**

Cash paid for interest	\$	5,030	\$	1,743
<b>Noncash investing and financing activities:</b>				
Conversion of convertible preferred stock to common stock upon initial public offering	\$	137,632	\$	
Modification of convertible preferred stock		2,384		
Reclass of warrant liability to additional paid-in capital				34
Vesting of common stock subject to repurchase		17		7
Issuance of common stock warrants		804		129
Transfer between inventory and property and equipment		512		848
Conversion of convertible notes and accrued interest into Series E convertible preferred stock				7,794

See accompanying notes.

Table of Contents

**AVINGER, INC.**

**Notes to Financial Statements**

**1. Organization**

**Organization, Nature of Business**

Avinger, Inc. (the Company), a Delaware corporation, was founded in March 2007 by cardiologist and medical device entrepreneur Dr. John B. Simpson. The Company designs, manufactures and sells image-guided, catheter-based systems that are used by physicians to treat patients with peripheral arterial disease ( PAD ). Patients with PAD have a build-up of plaque in the arteries that supply blood to the arms and legs. The Company manufactures and sells a suite of products in the United States ( U.S. ) and in select European markets. The Company has developed its lumivascular platform, which integrates optical coherence tomography ( OCT ) visualization with interventional catheters and is the industry s only system that provides real-time intravascular imaging during the treatment portion of PAD procedures. The Company s lumivascular platform consists of a capital component, Lightbox, as well as a variety of disposable catheter products. The Company s current products include its non-imaging catheters, Wildcat and Kittycat, as well as its lumivascular platform products, Ocelot, Ocelot PIXL and Ocelot MVRX, all of which are designed to allow physicians to penetrate a total blockage in an artery, known as a chronic total occlusion ( CTO ). The Company is also developing Pantheris, its image-guided atherectomy device, designed to allow physicians to precisely remove arterial plaque in PAD patients. In October 2015, the Company received 510(k) clearance from the U.S. Food and Drug Administration ( FDA ) for commercialization of Pantheris. The Company intends to commence U.S. sales of Pantheris early in 2016, subject to obtaining FDA approval for an enhanced version of Pantheris. The Company is located in Redwood City, California.

**Initial Public Offering**

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

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

## Edgar Filing: Avinger Inc - Form 10-Q

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

The accompanying unaudited condensed financial statements have been prepared in accordance with United States generally accepted accounting principles ( U.S. GAAP ) and pursuant to the rules and regulations of the United States Securities and Exchange Commission ( SEC ). The accompanying unaudited condensed interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of our financial information. The results for the three and nine months ended September 30, 2015, are not necessarily indicative of results to be expected for the year ending December 31, 2015, or for any other interim period or for any future year. The December 31, 2014 condensed balance sheet data has been derived from audited financial statements. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to SEC rules and regulations relating to interim financial statements. These unaudited condensed financial statements and notes should be read in conjunction with the financial statements included in the Company's Form 10-K for the fiscal year ended December 31, 2014, which was filed with the SEC on March 27, 2015. The Company's significant accounting policies are more fully described in Note 2 of the Notes to the Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014.

Table of Contents

**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. Actual results could differ from those estimates.

**Fair Value of Financial Instruments**

The Company has evaluated the estimated fair value of its financial instruments as of September 30, 2015 and December 31, 2014. Financial instruments consist of cash and cash equivalents, accounts receivable and payable, and other current liabilities, borrowings, convertible notes and embedded derivatives. The carrying amounts of cash and cash equivalents, accounts receivable and payable, and other current liabilities approximate their respective fair values because of the short-term nature of those instruments. Based upon the borrowing terms and conditions currently available to the Company, the carrying values of its borrowings approximate fair value. Fair value accounting was applied to the warrant liabilities and embedded derivatives which were recorded at fair value in the financial statements. No warrant or embedded derivatives were outstanding as of September 30, 2015.

**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 September 30, 2015 and December 31, 2014, the Company's cash equivalents are entirely comprised of investments in money market funds. Any related unrealized gains and losses are recorded in other comprehensive income (loss) and included as a separate component of stockholders' equity (deficit). There were no unrealized gains and losses as of September 30, 2015 and December 31, 2014. Any realized gains and losses and interest and dividends on available-for-sale securities are included in interest income or expense and computed using the specific identification cost method.

**Restricted Cash**

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

**Concentration of Credit Risk, and Other Risks and Uncertainties**

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

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

The Company provides for uncollectible amounts when specific credit problems arise. Management's estimates for uncollectible amounts have been adequate, and management believes that all significant credit risks have been identified at September 30, 2015 and December 31, 2014.

The Company's accounts receivable are due from a variety of health-care organizations in the United States and select European markets. At September 30, 2015 and December 31, 2014, there were two customers and no customers that represented 10% or more of the Company's accounts receivable, respectively. For the three months ended September 30, 2015 and 2014 and the nine months ended September 30, 2015 and 2014, there were no customers that represented 10% or more of revenues. Disruption of sales orders or a deterioration of financial condition of its customers would have a negative impact on the Company's financial position and results of operations.

Table of Contents

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

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

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

**Inventories**

Inventories are valued at the lower of cost or market. Cost is determined using the first-in, first-out method for all inventories. The Company's policy is to write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value, and inventory in excess of expected requirements. The estimate of excess quantities is subjective and primarily dependent on the estimates of future demand for a particular product. If the estimate of future demand is too high, the Company may have to increase the reserve for excess inventory for that product and record a charge to the cost of revenues. Inventory used in clinical trials is expensed at the time of production and recorded as research and development expense.

As of September 30, 2015, inventories balance includes capitalized raw material costs of \$300,000 associated with the Company's Pantheris product. The decision to capitalize inventory costs associated with products prior to receiving regulatory approval was based on the Company's judgment of probable future commercial success and realizable value. Regulatory approval was received October 2015.

**Deferred Initial Public Offering Costs**

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

**Convertible Preferred Stock**

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

**Warrant Liability and Embedded Derivative Instruments**

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

Table of Contents

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

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

**Revenue Recognition**

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

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

1. **Lightbox sales:** The Company sells its products directly to hospitals and medical centers. Provided all other criteria for revenue recognition have been met, the Company recognizes revenue for Lightbox sales directly to end customers when delivery and acceptance occurs, which is defined as receipt by the Company of an executed form by the customer acknowledging that the training and installation process is complete.
2. **Sales of disposables:** Disposable revenues consist of sales of the Company's catheters and accessories and are recognized when the product has shipped, risk of loss and title has passed to the customer and collectability is reasonably assured.
3. **Service revenue:** Service revenue is recognized ratably over the term of the service period. To date service revenue has been insignificant.

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

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

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

Table of Contents

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

**Cost of Revenues**

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

**Product Warranty Costs**

The Company typically offers a one-year warranty for parts and labor on its products commencing upon the transfer of title and risk of loss to the customer. The Company accrues for the estimated cost of product warranties upon invoicing its customers, based on historical results. 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):

	<b>Amount</b>
Balance at December 31, 2014	\$ 167
Warranty provision	85
Usage	(97)
Balance at September 30, 2015	\$ 155

**Common Stock Valuation and Stock-Based Compensation**

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

Prior to completion of the Company's IPO the fair value of the Company's common stock was determined by its Board of Directors with assistance from management and third-party valuation specialists. Management's approach to estimating the fair value of the Company's common stock is consistent with the methods outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*. Management considered several factors to estimate enterprise value, including significant

milestones that would generally contribute to increases in the value of the Company's common stock. Following the closing of the Company's IPO in January 2015, the fair value of its common stock is determined based on the closing price of its common stock on The NASDAQ Stock Market.

**Net Loss per Share Attributable to Common Stockholders**

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, without consideration for potential dilutive common shares. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock and dilutive potential shares of common stock outstanding during the period. Common stock shares subject to repurchase are excluded from the calculations as the continued vesting of such shares is contingent upon the holders continued service to the Company. For the computation of net loss per share attributable to common stockholders, common stock shares subject to repurchase of 82 and 583 were excluded from the calculations as of September 30, 2015 and December 31, 2014, respectively. Since the Company was in a loss position for all periods presented, basic net loss per share attributable to common stockholders is the same as diluted net loss per share attributable to common stockholders as the inclusion of all potential dilutive common shares would have been anti-dilutive.

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

## Edgar Filing: Avinger Inc - Form 10-Q

### Table of Contents

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net loss	\$ (13,250)	\$ (8,780)	\$ (33,888)	\$ (23,829)
Adjustment to net loss resulting from convertible preferred stock modification			(2,384)	
Net loss attributable to common stockholders	\$ (13,250)	\$ (8,780)	\$ (36,272)	\$ (23,829)
Weighted average common stock outstanding	12,280	241	10,935	241
Net loss attributable to common stockholders per share, basic and diluted	\$ (1.08)	\$ (36.43)	\$ (3.32)	\$ (98.88)

In addition to the outstanding convertible notes as of September 30, 2014 (Note 6), the following potentially dilutive securities outstanding have been excluded from the computations of diluted weighted average shares outstanding because such securities have an anti-dilutive impact due to losses reported, in common stock equivalent shares:

	2015	September 30, 2014
Convertible preferred stock outstanding		4,259,998
Common stock options	3,056,207	316,733
Common stock warrants	2,213,395	1,050,971
	5,269,602	5,627,702

### **Comprehensive Loss**

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

### **Segment and Geographical Information**

The Company operates in one segment. Primarily all of the Company's long-lived assets are based in the United States. Long-lived assets are comprised of property and equipment. For the three months ended September 30, 2015 and 2014, 94% and 99% of the Company's revenues, were in the United States, based on the shipping location of the external customer, respectively. For the nine months ended September 30, 2015 and 2014, 98% and 99% of the Company's revenues, were in the United States, based on the shipping location of the external customer, respectively.

### **Change in Accounting Principle**

## Edgar Filing: Avinger Inc - Form 10-Q

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

During the third quarter of 2015, the Company elected early adoption of this accounting standard. The condensed balance sheet as of December 31, 2014 has been adjusted to reflect the retrospective application of the new method of presentation. Deferred debt issuance costs totaling \$343,000 that were included in the Company's assets as of December 31, 2014 were reclassified as a discount on borrowings. The Company has reflected these costs as a reduction of the debt on the balance sheet as of September 30, 2015 and will continue to do so in future periods. The adoption of this accounting standard had no impact on the Company's statements of operations, stockholders' equity (deficit) or cash flows.

### **Recent Accounting Pronouncements**

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

Table of Contents

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

In July 2015, the FASB issued an accounting standard which applies to all inventory that is measured using methods other than last-in, first-out or the retail inventory method, including inventory that is measured using first-in, first-out or average cost. The standard requires entities to measure inventory at the lower of cost and net realizable value, defined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance is effective for public entities for fiscal years beginning after December 15, 2016, and interim periods with fiscal years beginning after December 15, 2017. The amendments in the standard should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company does not expect the adoption of this standard to have a material effect on its financial statements.

**3. Fair Value Measurements**

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

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

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

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

As of September 30, 2015 and December 31, 2014, cash equivalents and restricted cash were all categorized as Level 1 and consisted of money market funds. In connection with the convertible notes issuances in 2013 and 2014 (Note 6), the Company agreed to issue warrants to purchase shares of its common stock. As the price per share of the common stock warrants was not fixed until the issuance of the Series E Convertible Preferred Stock in September 2014, they were classified as a derivative liability and were subject to remeasurement at each balance sheet date until September 2014. The convertible notes also contained redemption features which were determined to be a compound embedded derivative which, prior to their extinguishment in September 2015, required fair value accounting. The common stock warrant liability and embedded derivatives in the convertible notes were categorized as Level 3. When a determination is made to classify a financial instrument within Level 3,

## Edgar Filing: Avinger Inc - Form 10-Q

the determination is based upon the significance of the unobservable inputs to the overall fair value measurement. However, Level 3 financial instruments typically include, in addition to the unobservable inputs, observable inputs (that is, components that are actively quoted and can be validated to external sources). Any change in fair value is recognized as a component of other income (expense), net, on the statements of operations and comprehensive loss.

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

### *Common Stock Warrant Liability*

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

Table of Contents*Embedded Derivatives in Convertible Notes*

The following table sets forth a summary of the changes in the estimated fair value of the Company's compound embedded derivative associated with its convertible notes, which represented a financial instrument classified as Level 3. Upon the extinguishment of the convertible notes in September 2015, the current fair value of the compound embedded derivative was expensed to other income (expense), net. Accordingly, the income (expense) in the table below includes changes in fair value due in part to observable factors that are part of the Level 3 methodology (in thousands):

	<b>Amount</b>
Fair value at December 31, 2014	\$ 231
Issuance of convertible notes	
Change in fair value recorded in other income (expense), net	835
Reversal of fair value recorded in other income (expense), net	(1,066)
Fair value at September 30, 2015	\$

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

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

Subsequent to the Company's IPO and through the extinguishment of the convertible notes on September 22, 2015, the value of the compound derivative was determined utilizing a Black-Derman-Toy model. The inputs used to determine the estimated fair value of the derivative instrument include the term structure of yields which are observed in the market, the credit spread, which was estimated by the Company, and the volatility, which was estimated using an analysis of comparable bonds in the market. The fair value measurement is based upon significant inputs not observable in the market. These assumptions are inherently subjective and involve significant management judgment. The following table summarizes these various assumptions as of September 22, 2015, the date of extinguishment:

	<b>September 22, 2015</b>
Time to first call option (years)	
Credit spread	17.6%
Expected volatility	40.0%

## Edgar Filing: Avinger Inc - Form 10-Q

The compound embedded derivative asset was included in other long-term assets as of December 31, 2014, on the balance sheet.

### 4. Inventories

Inventories consisted of the following (in thousands):

	September 30, 2015		December 31, 2014	
Raw materials	\$	1,689	\$	2,265
Work-in-process				61
Finished products		1,516		1,665
Total inventories	\$	3,205	\$	3,991

Table of Contents

**5. Borrowings**

*CRG*

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

The Company may voluntarily prepay the loan in full, with a prepayment premium beginning at 5.0% and declining by 1.0% annually thereafter, with no premium being payable if prepayment occurs after the fifth year of the loan. Each tranche of borrowing requires the payment, on the borrowing date, of a financing fee equal to 1.5% of the borrowed loan principal, which is recorded as a discount to the debt. In addition, a facility fee equal to 7.0% of the amount borrowed plus any *PIK* is payable at the end of the term or when the loan is repaid in full. A long-term liability is being accreted using the effective interest method for the facility fee over the term of the Loan Agreement with a corresponding discount to the debt. The term loan is collateralized by a security interest in substantially all of the Company's assets.

The Loan Agreement requires that the Company adhere to certain affirmative and negative covenants, including financial reporting requirements, certain minimum financial covenants for pre-specified liquidity and revenue requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the Loan Agreement. In particular, the covenants of the Loan Agreement include a covenant that the Company maintains a minimum of \$5,000,000 of cash and certain cash equivalents, and the Company must achieve minimum revenue of \$7,000,000 in 2015, with the target minimum revenue increasing in each year thereafter until reaching \$70,000,000 in 2020 and in each year thereafter, as applicable. If the Company fails to meet the applicable minimum revenue target in any calendar year, the Loan Agreement provides the Company a cure right if it prepays a portion of the outstanding principal equal to 2.0 times the revenue shortfall. In addition, the Loan Agreement prohibits the payment of cash dividends on the Company's capital stock and also places restrictions on mergers, sales of assets, investments, incurrence of liens, incurrence of indebtedness and transactions with affiliates. CRG may accelerate the payment terms of the Loan Agreement upon the occurrence of certain events of default set forth therein, which include the failure of the Company to make timely payments of amounts due under the Loan Agreement, the failure of the Company to adhere to the covenants set forth in the Loan Agreement, the insolvency of the Company or upon the occurrence of a material adverse change. As of September 30, 2015, the Company was in compliance with all applicable covenants.

## Edgar Filing: Avinger Inc - Form 10-Q

As of September 30, 2015, principal and PIK payments under the Loan Agreement follows (in thousands):

Period Ending December 31,	<b>Principal and PIK Loan Repayments</b>	
2015	\$	
2016		
2017		
2018		
2019 and thereafter		30,000
		30,000
Add: PIK		26
		30,026
Less: Amount representing debt financing costs		(872)
Borrowings, net of current portion	\$	29,154

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

Table of Contents

In connection with the Loan Agreement, the Company recorded a debt discount of \$876,000. The debt discount comprised financing fees of \$450,000, paid directly to CRG, and an allocation of the common stock premium of \$115,000 and of the other costs directly attributable to the Loan Agreement and Security Purchase Agreement with CRG of \$541,000 based on the relative fair values of each security. The debt discount is being amortized as non-cash interest expense using the effective interest method over the term of the Loan Agreement. As of September 30, 2015, the balance of the debt discount was \$872,000.

*PDL BioPharma*

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

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

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

In addition to the interest and principal payments, the Company also paid a royalty, referred to as Assigned Interests, equal to 1.8% of the Company's quarterly net revenues. Upon the prepayment of the Term Note, the Company's obligations relating to Assigned Interests continue, and are payable through the maturity date at a reduced rate of 0.9% of the quarterly net revenues, subject to certain quarterly minimum mandatory amounts, which are payable quarterly. The ongoing obligation was determined to be an embedded element of the Agreement and cannot be bifurcated from the Term Note for accounting purposes. Accordingly, the Company continued to account for the Assigned Interest obligation relating to future royalties as a debt instrument by applying the retrospective approach. 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 September 30, 2015, was used to adjust the carrying amount to the present value of the revised estimated cash flows, discounted at the new effective interest rate. The resulting increase in the carrying value of the Assigned Interests, of \$942,000, was recognized as a component of other income (expense), net, on the statements of operations and comprehensive loss. The Company has an aggregate accrual for its Assigned Interest obligations of \$2,500,000, representing the net present value of the future minimum royalty obligation as of September 30, 2015. The Assigned Interest liability was included within accrued expenses and other current liabilities and within other long-term liabilities as of September 30, 2015, on the balance sheet. Prior to the repayment of the Term Note, the Assigned Interests liability was included within borrowings and borrowings, net of current portion as of December 31, 2014, on the balance sheet.

Additionally, until there are no further obligations to periodically pay PDL a percentage of our net revenue, the Company must comply with certain affirmative covenants and negative covenants limiting its ability to, among other things, undergo a change in control or dispose of assets, in each case subject to certain exceptions. The Company was in compliance with the covenants under the Agreement as of September 30, 2015.

The remaining unamortized costs relating to the PDL agreement were trued up through application of the retrospective method and will continue to be amortized over the remaining term using the effective interest method.

Table of Contents**6. Convertible Notes**

On October 29, 2013, the Company entered into a Note and Warrant Purchase Agreement (the Convertible Note Agreement ), as amended in May 2014, with certain existing convertible preferred stockholders, third-parties and employees for the issuance of convertible notes for up to an aggregate principal amount of \$25,000,000. Under the terms of the Convertible Note Agreement, the Company issued convertible notes in October and November 2013 for total proceeds of \$13,472,000, and in May and July 2014 for additional total proceeds of \$4,720,000. The convertible notes bear interest at a rate of 30-day LIBOR, plus 6% per annum subject to a minimum internal rate of return of 20%. The notes will mature and the accrued interest thereon will become payable on the earlier of: (i) October 29, 2018, (ii) an event of default, or (iii) a change of control event.

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

**7. Capital Leases**

Capital lease obligations consist of leased office equipment. As of September 30, 2015 and December 31, 2014, the aggregate amount of capital leases recorded within property and equipment, net, on the accompanying balance sheet is \$45,000 and \$12,000, respectively. The current portion of the capital lease obligations is included in accrued liabilities and the balance included within other long-term liabilities represents the long-term portion.

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

<u>Period ending December 31,</u>	<b>Future Minimum Lease Payments</b>	
2015	\$	7
2016		19
2017		18
2018		4
Total minimum payments		48
Less: Amount representing future interest		3
Present value of minimum lease payments	\$	45

**8. Commitments and Contingencies****Lease Commitments**

## Edgar Filing: Avinger Inc - Form 10-Q

The Company's operating lease obligations primarily consist of leased office, laboratory, and manufacturing space under a non-cancelable operating lease that expires in November 2016. The lease agreement includes two renewal provisions allowing the Company to extend this lease for additional periods of three years each. In addition to the minimum future lease commitments presented below, the lease requires the Company to pay property taxes, insurance, maintenance, and repair costs. The lease includes a rent holiday concession and escalation clauses for increased rent over the lease term. Rent expense is recognized using the straight-line method over the term of the lease. The Company records deferred rent calculated as the difference between rent expense and the cash rental payments. In connection with the facility lease, the landlord also provided incentives of \$369,000 to the Company in the form of leasehold improvements. These amounts have been reflected as deferred rent and are being amortized as a reduction to rent expense over the term of the Company's operating lease. Rent expense was \$231,000 and \$230,000 for the three months ended September 30, 2015 and 2014, and \$708,000 and \$691,000 for the nine months ended September 30, 2015 and 2014, respectively.

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

	<b>Future Minimum Lease Payments</b>	
<u>Period ending December 31,</u>		
2015	\$	283
2016		1,060
Total minimum lease payments	\$	1,343

Table of Contents

**Purchase Obligations**

Purchase obligations consist of agreements to purchase goods and services entered into in the ordinary course of business. The Company had noncancellable commitments to suppliers for purchases totaling \$3,158,000 and \$1,334,000 as of September 30, 2015 and December 31, 2014, respectively.

**Indemnification**

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

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

**Legal Proceedings**

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

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

**9. Convertible Preferred Stock**

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

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

On January 9, 2015, the Company issued a total of 490,472 shares of Series E Convertible Preferred Stock at \$12.60 per share for total cash proceeds of \$6,180,000. Upon the closing of the IPO, all shares of convertible preferred stock then outstanding converted into an aggregate of 6,967,925 shares of common stock. As of September 30, 2015, the Company does not have any convertible preferred stock issued or outstanding.

Table of Contents

**10. Stockholders Equity (Deficit)**

**Preferred Stock**

At September 30, 2015, the Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 5,000,000 shares of preferred stock with \$0.001 par value per share, of which no shares were issued and outstanding.

**Common Stock**

At September 30, 2015, the Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 100,000,000 shares of common stock with \$0.001 par value per share, of which 12,620,682 shares were issued and outstanding.

**Restricted Stock**

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

As of September 30, 2015 and December 31, 2014, a total of 82 and 583 shares, respectively, were subject to repurchase, at cost, under these Restricted Stock Purchase Agreements.

**Common Stock Warrants**

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

## Edgar Filing: Avinger Inc - Form 10-Q

The warrants are immediately exercisable, at an exercise price per share of \$12.60, and expire upon the earlier of September 2, 2019 or upon the consummation of a change of control of the Company. The Company determined that these common stock warrants meet the requirements for equity classification. As of December 31, 2014, in connection with the issuance of its Series E Convertible Preferred Stock, the Company issued warrants to purchase an aggregate of 1,335,779 shares of common stock. The common stock warrants were recorded at their allocated fair value of \$175,000 within stockholders' equity (deficit).

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

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

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

Table of Contents**Stock Plans**

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

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

Activity under the Plans is set forth below:

	Shares Available for Grant	Number of Shares	Options Outstanding Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2014	21,705	3,010,373	\$ 5.78	\$ 13,188
Additional shares reserved	1,320,000			
Granted	(261,288)	261,288	\$ 12.83	
Exercised		(277)	\$ 4.50	
Cancelled	215,177	(215,177)	\$ 9.54	
Balance at September 30, 2015	1,295,594	3,056,207	\$ 6.12	\$ 27,142

The weighted-average grant date fair value of stock options granted during the nine months ended September 30, 2015 and 2014 was \$6.56 and \$0.13 per share, respectively. As of September 30, 2015, the aggregate intrinsic value of options outstanding and vested was \$630,000. The aggregate intrinsic value of options exercised was \$3,000 and none during the nine months ended September 30, 2015 and 2014, respectively. The aggregate intrinsic value was calculated as the difference between the exercise prices of the underlying options and the estimated fair value of the common stock on the date of exercise. Because of the Company's net operating losses, the Company did not realize any tax benefits from share-based payment arrangements for the three and nine months ended September 30, 2015 and 2014.

## Edgar Filing: Avinger Inc - Form 10-Q

At September 30, 2015 and at December 31, 2014, there were 252,016 and 201,018 shares, respectively, vested with a weighted-average exercise price of \$14.31 and \$5.38 per share, respectively, and a weighted average contractual life of 6.55 and 7.03 years, respectively.

### **2015 Employee Stock Purchase Plan**

In January 2015, the Company's Board of Directors adopted and the Company's stockholders approved the 2015 Employee Stock Purchase Plan ( ESPP ) under which eligible employees are permitted to purchase common stock at a discount through payroll deductions. 500,000 shares of common stock are reserved for issuance and will be increased on the first day of each fiscal year, commencing in 2016, by an amount equal to the lesser of (i) 493,000 shares (ii) 1.5% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (iii) an amount as determined by the Board of Directors. The price of the common stock purchased will be the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. The ESPP is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Internal Revenue Code of 1986, as amended. The first offering under the ESPP began in February 2015. As of September 30, 2015, approximately 468,000 shares of common stock remained reserved for issuance under the ESPP. The Company incurred \$45,000 and \$112,000 in stock-based compensation expense related to the ESPP for the three and nine months ended September 30, 2015, respectively.

Table of Contents

**11. Stock-Based Compensation**

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Expected term (years)	6.3		6.3	7.0
Expected volatility	50.6%		52.2%	50.0%
Risk-free interest rate	1.8%		1.7%	2.1%
Dividend rate				

As of September 30, 2015 and December 31, 2014, the total unamortized compensation expense related to stock-based awards granted to employees and directors was \$15,758,000 and \$18,938,000, which is expected to be amortized over the next 3.23 and 3.92 years, respectively.

The fair value of the shares to be issued under the Company's ESPP was estimated using the Black-Scholes valuation model with the following average assumptions for the three and nine months ended September 30, 2015:

	Three Months and Nine months Ended September 30, 2015
Expected term (years)	0.5
Expected volatility	45.2% to 47.2%
Risk-free interest rate	0.07% to 0.26%
Dividend rate	

## Edgar Filing: Avinger Inc - Form 10-Q

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Cost of revenues	\$ 57	\$ 19	\$ 173	\$ 46
Research and development expenses	564	54	1,673	127
Selling, general and administrative expenses	590	119	1,845	336
	\$ 1,211	\$ 192	\$ 3,691	\$ 509

Table of Contents

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

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

**Overview**

We are a commercial-stage medical device company that designs, manufactures and sells image-guided, catheter-based systems that are used by physicians to treat patients with peripheral arterial disease, or PAD. Patients with PAD have a build-up of plaque in the arteries that supply blood to the arms and legs. Our mission is to dramatically improve the treatment of vascular disease through the introduction of products based on our lumivascular platform, the only intravascular image-guided system available in this market. We manufacture and sell a suite of products in the United States and select European markets. Our current products include our Lightbox imaging console, as well as our Wildcat, Kittycat, and the Ocelot family of catheters, which are designed to allow physicians to penetrate a total blockage in an artery, known as a chronic total occlusion, or CTO. Pantheris, our image-guided atherectomy device, is designed to allow physicians to precisely remove arterial plaque in PAD patients. In October 2015, we received 510(k) clearance from the U.S. Food and Drug Administration, or FDA, for commercialization of Pantheris. We believe that Pantheris will significantly enhance our market opportunity within PAD and can expand the overall addressable market for PAD endovascular procedures. We intend to commence U.S. sales of Pantheris early in 2016, subject to obtaining FDA approval for an enhanced version of Pantheris.

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 effectiveness endpoints. We believe the data from VISION will also allow us to demonstrate that avoiding disruption of the membrane between the outermost layers of the artery, which we refer to as the black line, reduces the likelihood of restenosis, or re-narrowing, of the diseased artery. We plan to commercialize Pantheris as part of our lumivascular platform in the United States early in 2016 and in select European countries after obtaining any required marketing authorizations.

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

## Edgar Filing: Avinger Inc - Form 10-Q

Prior to the introduction of our lumivascular platform, our non-imaging catheter products were manufactured by third parties. All of our products are now manufactured in-house at our facilities in Redwood City, California using components and sub-assemblies manufactured both in-house and by outside vendors. We expect our current manufacturing facility will be sufficient to meet our anticipated growth through at least 2016. We assemble all of our products at our manufacturing facility, but certain critical processes such as coating and sterilization are done by outside vendors.

We began commercializing our initial non-lumivascular platform products in 2009 and introduced our lumivascular platform products in the United States in late 2012. We have not been profitable since inception, and as of September 30, 2015, our accumulated deficit was \$182.8 million. Since inception, we have financed our operations primarily through private placements of our preferred securities and, to a lesser extent, debt financing arrangements. In January 2015, we completed an initial public offering of 5.0 million shares. As a result of our initial public offering, which closed in February 2015, we received net proceeds of approximately \$56.9 million, after underwriting discounts and commissions of approximately \$4.5 million and other expenses associated with our initial public offering of approximately \$3.6 million.

In September 2015, we entered into a Term Loan Agreement, or Loan Agreement, with CRG Partners III L.P. and certain of its affiliated funds, collectively CRG, under which we may borrow up to \$50.0 million on or before March 29, 2017. We borrowed \$30.0 million on September 22, 2015. Upon FDA approval of our 510(k) for Pantheris we are now eligible to borrow an additional \$10.0 million, on or prior to June 30, 2016. We may also borrow an additional \$10.0 million, on or prior to March 29, 2017, upon achievement of certain revenue milestones, among other conditions.

Table of Contents

Contemporaneous with the execution of the Loan Agreement, we entered into a Securities Purchase Agreement with CRG, pursuant to which CRG purchased 348,262 shares of common stock on September 22, 2015 at a price of \$14.357 per share, which represents the 10-day average of closing prices of our common stock ending on September 21, 2015. Pursuant to the securities purchase agreement, Avinger must file a registration statement covering the resale of the shares sold to CRG and must comply with certain affirmative covenants during the time that such registration statement remains in effect.

We used the proceeds from the CRG borrowing and securities purchase to retire our outstanding principal and accrued interest with PDL Biopharma, or PDL, and to retire the principal and accrued interest underlying our outstanding promissory notes, or the notes.

**Components of Our Results of Operations**

***Revenues***

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

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

***Cost of Revenues and Gross Profit***

Cost of revenues consists primarily of costs related to manufacturing overhead, materials and direct labor. A significant portion of our cost of revenues currently consists of manufacturing overhead costs. These overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. We expect overhead costs as a percentage of revenues to become less significant as our production volume increases. Cost of revenues also includes depreciation expense for production equipment, depreciation and related maintenance expense for leased equipment held by customers and certain direct costs such as those incurred for shipping our products. We expect cost of revenues to increase in absolute dollars to the extent our revenues grow and as we continue to invest in our operational infrastructure to support anticipated growth.

## Edgar Filing: Avinger Inc - Form 10-Q

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

### ***Research and Development Expenses***

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

Table of Contents

***Selling, General and Administrative Expenses***

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

Selling, general and administrative, or SG&A, expenses consist primarily of compensation for personnel, including stock-based compensation, related to selling and marketing functions, physician education programs, business development, finance, information technology and human resource functions. Other SG&A expenses include commissions, training, travel expenses, educational and promotional activities, marketing initiatives, market research and analysis, conferences and trade shows, professional services fees, including legal, audit and tax fees, insurance costs, a 2.3% tax on U.S. sales of medical devices, general corporate expenses and allocated facilities-related expenses. We expect to grow our sales force in preparation for the commercial launch of Pantheris in order to increase the base of customers using our lumivasular platform products. We believe that expanding our U.S. sales infrastructure and establishing distributor relationships in select regions outside the United States will drive further adoption of our lumivasular platform. We expect SG&A expenses to continue to increase in absolute dollars and as a percentage of revenues through at least 2015 as we expand our infrastructure to both drive and support anticipated growth in revenues and due to additional legal, accounting, insurance and other expenses associated with being a public company.

***Interest Income (Expense), net***

Interest income (expense), net consists primarily of interest incurred on our outstanding indebtedness and non-cash interest related to the amortization of debt discount and issuance costs associated with our various debt agreements. Due to the conversion of \$7.8 million and \$3.8 million in principal amount of the notes and related accrued interest into shares of our Series E preferred stock in September and November 2014, respectively, we expect that for 2015 our interest expense will decrease.

***Other Income (Expense), net***

Other income (expense), net primarily consists of gains and losses resulting from the remeasurement of the fair value of our common stock warrant liability and the compound embedded derivative instrument associated with the notes and the loss on the extinguishment of our notes. We continued to record adjustments to the estimated fair value of the common stock warrants until the Series E preferred stock issuance in September 2014, upon which the common stock warrant exercise price was fixed at \$12.60 per share. At this time we re-evaluated the terms of the common stock warrants and determined that the common stock warrants issued with the convertible notes met the requirements for equity classification and the fair value of the warrant liability was reclassified to additional paid-in capital. We continued to record adjustments to the estimated fair value of the compound embedded derivative instrument associated with the notes until the notes were repaid in September 2015. Upon extinguishment of the notes, the associated current fair value of the embedded derivative asset was expensed to other income (expense), net. Additionally, for the nine months ended September 30, 2015, other income (expense), net includes charges to reflect the carrying value of our ongoing royalty obligation to PDL.

**Results of Operations:**

Edgar Filing: Avinger Inc - Form 10-Q

	Three Months Ended September 30,				Nine Months Ended September 30,			
		2015	2014		2015	2014		2014
Revenues	\$	2,721	\$	2,632	\$	7,856	\$	8,140
Cost of revenues		1,750		1,471		4,672		4,941
Gross profit		971		1,161		3,184		3,199
		36%		44%		41%		39%
Operating expenses:								
Research and development		3,955		2,731		11,766		8,350
Selling, general and administrative		6,892		4,575		19,802		12,900
Total operating expenses		10,847		7,306		31,568		21,250
Loss from operations		(9,876)		(6,145)		(28,384)		(18,051)
Interest income (expense), net		(1,323)		(1,712)		(3,979)		(4,904)
Other income (expense), net		(2,058)		(920)		(1,525)		(837)
Loss before provision for income taxes		(13,257)		(8,777)		(33,888)		(23,792)
Provision for income taxes		(7)		3				37
Net loss and comprehensive loss	\$	(13,250)	\$	(8,780)	\$	(33,888)	\$	(23,829)

Table of Contents

*Comparison of Three Months Ended September 30, 2015 and 2014*

*Revenues.* Revenues increased \$0.1 million, or 3%, to \$2.7 million during the three months ended September 30, 2015, compared to \$2.6 million during the three months ended September 30, 2014. For the three months ended September 30, 2015, sales of our Lightbox imaging console increased by 16% to \$0.9 million while sales of our disposable catheters decreased by 2% to \$1.8 million. The decrease in disposable catheter revenues in 2015 and changes in revenue mix is related to our continuing commercial focus on our lumivascular programs to broaden physician exposure to optical coherence tomography (OCT) image interpretation and build the installed base of the Lightbox imaging console prior to the commercial launch of Pantheris, which we expect to occur in the first quarter of 2016.

*Cost of Revenues and Gross Margin.* Cost of revenues increased \$0.3 million, or 19%, to \$1.8 million during the three months ended September 30, 2015, compared to \$1.5 million during the three months ended September 30, 2014. This increase was attributable to increases in manufacturing overhead costs as we invest in operational infrastructure to support anticipated growth. Gross margin for the three months ended September 30, 2015 was 36%, compared to 44% in the three months ended September 30, 2014. This decrease was primarily attributable to the decreased proportion of revenue coming from our disposable catheters, the continued investment in our operational infrastructure to support growth and the proportion of revenue coming from our products sold under agreement with an international distributor.

*Research and Development Expenses.* R&D expenses increased \$1.3 million, or 45%, to \$4.0 million during the three months ended September 30, 2015, compared to \$2.7 million during the three months ended September 30, 2014. This increase was primarily due to a \$0.9 million increase in personnel-related expenses, an increase of \$0.2 million in outside services and a \$0.1 million increase in product development materials and related costs. Personnel-related expenses included stock-based compensation expense of \$0.6 million compared to \$34,000 for the three months ended September 30, 2015 and 2014, respectively. The remaining increase in personnel-related expenses and increase in outside services were attributable to our VISION clinical trial.

*Selling, General and Administrative Expenses.* SG&A expenses increased \$2.3 million, or 51%, to \$6.9 million during the three months ended September 30, 2015, compared to \$4.6 million during the three months ended September 30, 2014. This increase was primarily due to a \$1.7 million increase in personnel-related expenses and an increase of \$0.5 million in consulting, legal and professional fees. Personnel-related expenses increased due to an increase in headcount and stock-based compensation expense. Personnel-related expenses included stock-based compensation expense of \$0.6 million compared to \$0.1 million for the three months ended September 30, 2015 and 2014, respectively. Increases in our consulting, legal and professional fees were associated with the review of our financial statements and other costs associated with operating as a public company.

*Interest Income (Expense), Net.* Interest income (expense), net decreased \$0.4 million, or 23%, to an expense of \$1.3 million during the three months ended September 30, 2015, compared to an expense of \$1.7 million during the three months ended September 30, 2014. This decrease in expense was attributable to the conversion of certain of our then outstanding notes into shares of Series E preferred stock during the third and fourth quarter of 2014.

*Other Income (Expense), Net.* Other income (expense), net increased \$1.2 million to an expense of \$2.1 million, during the three months ended September 30, 2015, compared to an expense of \$0.9 million during the three months ended September 30, 2014. Other expense for the three months ended September 30, 2015, was primarily attributable to the reversal of the current fair value of the embedded derivative asset of \$1.1 million upon the repayment of our notes in September 2015, expense of \$0.9 million to reflect the carrying value of our ongoing royalty obligation to PDL and non-cash charges related to the amortization of debt discount and issuance costs associated with the notes and the credit agreement upon their repayment in September 2015, partially offset by the remeasurement of the fair value of the derivative instruments associated with our notes through the date of their repayment. Other expense for the three months ended September 30, 2014, was primarily attributable to the \$0.9 million loss on the extinguishment of certain of our then-outstanding notes that were converted into Series E preferred stock in September 2014, partially offset by the remeasurement of the fair value of our common stock warrant liability through the issuance of the Series E preferred stock in September 2014, and the derivative instruments associated with our notes which are accounted for as a compound embedded derivative instrument and marked-to-market at each reporting date.

***Comparison of Nine months Ended September 30, 2015 and 2014***

*Revenues.* Revenues decreased \$0.2 million, or 3%, to \$7.9 million during the nine months ended September 30, 2015, compared to \$8.1 million during the nine months ended September 30, 2014. For the nine months ended September 30, 2015, sales of our Lightbox imaging console increased by 21% to \$2.9 million while sales of our disposable catheters decreased by 14% to \$5.0 million. The decrease in disposable catheter revenues in 2015 and changes in revenue mix related to the Company's continuing commercial focus on its lumivascular programs to broaden physician exposure to optical coherence tomography (OCT) image interpretation and build the installed base of the Lightbox imaging console prior to commercial launch of Pantheris, which we expect to occur in the first quarter of 2016.

Table of Contents

*Cost of Revenues and Gross Margin.* Cost of revenues decreased \$0.2 million, or 5%, to \$4.7 million during the nine months ended September 30, 2015, compared to \$4.9 million during the nine months ended September 30, 2014. This decrease was attributable to the decrease in revenues from sales of our disposable catheters. Gross margin for the nine months ended September 30, 2015 was 41%, up from 39% compared to the nine months ended September 30, 2014. This increase was primarily attributable to the increasing proportion of revenue coming from our lumivasular products partially offset by increases in manufacturing overhead costs as we invest in operational infrastructure to support anticipated growth.

*Research and Development Expenses.* R&D expenses increased \$3.4 million, or 41%, to \$11.8 million during the nine months ended September 30, 2015, compared to \$8.4 million during the nine months ended September 30, 2014. This increase was primarily due to a \$2.6 million increase in personnel-related expenses and an increase of \$0.8 million in outside services. Personnel-related expenses included stock-based compensation expense of \$1.7 million compared to \$0.1 million for the nine months ended September 30, 2015 and 2014, respectively. The remaining increase in personnel-related expenses and increase in outside services were attributable to our VISION clinical trial.

*Selling, General and Administrative Expenses.* SG&A expenses increased \$6.9 million, or 54%, to \$19.8 million during the nine months ended September 30, 2015, compared to \$12.9 million during the nine months ended September 30, 2014. This increase was primarily due to a \$4.8 million increase in personnel-related expenses and an increase of \$1.8 million in consulting, legal and professional fees. Personnel-related expenses increased due to an increase in headcount and stock-based compensation expense. Personnel-related expenses included stock-based compensation expense of \$1.8 million compared to \$0.3 million for the nine months ended September 30, 2015 and 2014, respectively. Increases in our consulting, legal and professional fees were associated with the audit and reviews of our financial statements and other costs associated with operating as a public company.

*Interest Income (Expense), Net.* Interest income (expense), net decreased \$0.9 million, or 20%, to an expense of \$4.0 million during the nine months ended September 30, 2015, compared to an expense of \$4.9 million during the nine months ended September 30, 2014. This decreased expense was attributable to the conversion of certain of our then-outstanding notes into shares of Series E preferred stock during the third and fourth quarter of 2014.

*Other Income (Expense), Net.* Other income (expense), net increased \$0.7 million, or 82%, to an expense of \$1.5 million during the nine months ended September 30, 2015, compared to an expense of \$0.8 million during the nine months ended September 30, 2014. Other expense for the nine months ended September 30, 2015, was primarily attributable to the reversal of the current fair value of the embedded derivative asset of \$1.1 million upon the repayment of our notes in September 2015, expense of \$0.9 million to reflect the carrying value of our ongoing royalty obligation to PDL and non-cash charges related to the amortization of debt discount and issuance costs associated with the notes and the credit agreement upon their repayment in September 2015, partially offset by the remeasurement of the fair value of the derivative instruments associated with our notes through the date of their repayment. During the nine months ended September 30, 2014, other expense was primarily attributable to the \$0.9 million loss on the extinguishment of certain of our then-outstanding notes that were converted into Series E preferred stock in

September 2014, partially offset by the remeasurement of the fair value of our common stock warrant liability through the issuance of the Series E preferred stock in September 2014, and the derivative instruments associated with our notes which are accounted for as a compound embedded derivative instrument and marked-to-market at each reporting date.

### **Liquidity and Capital Resources**

As of September 30, 2015, we had cash and cash equivalents of \$54.8 million and an accumulated deficit of \$182.8 million, compared to cash and cash equivalents of \$12.3 million and an accumulated deficit of \$146.5 million as of December 31, 2014. We currently believe our existing cash and cash equivalents, expected revenues and debt financing currently available under our Loan Agreement with CRG, will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months. If these sources are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or obtain an additional credit facility. Prior to our initial public offering in January 2015, our primary sources of capital have been private placements of preferred stock and debt financing agreements. In September 2015, we entered into a Loan Agreement with CRG, under which we could borrow up to \$50.0 million, of which \$30.0 million was immediately available and drawn down by us. Of the remaining \$20.0 million, \$10.0 million is currently available to us until June 30, 2016 and the remaining \$10.0 million is available based upon the achievement of certain net revenue milestones prior to March 29, 2017. As of September 30, 2015, we had \$29.2 million outstanding under the Loan Agreement. See section titled Contractual Obligations.

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

Table of Contents**Cash Flows**

	2015	September 30, (unaudited) (in thousands)	2014
Net cash (used in) provided by:			
Operating activities	\$	(29,364)	\$ (15,748)
Investing activities		(33)	(37)
Financing activities		71,862	15,777
Net (decrease) increase in cash and cash equivalents	\$	42,465	\$ (8)

***Net Cash Used in Operating Activities***

Net cash used in operating activities for the nine months ended September 30, 2015 was \$29.4 million, consisting primarily of a net loss of \$33.9 million and an increase in net operating assets of \$2.3 million, partially offset by non-cash charges of \$6.8 million. The increase in net operating assets was primarily due to an increase in prepaids and other current assets, decreases in accounts payable and in accrued expenses and other current liabilities due to timing of payments relating to our initial public offering costs, and decreases in other liabilities related to the repayment of accrued interest on our notes, partially offset by an increase in accrued compensation. The non-cash charges primarily consisted of depreciation, stock-based compensation, non-cash interest expense and other charges related to our credit agreement with PDL and its repayment, and the reversal of the current fair value of the embedded derivative upon repayment of the notes, partially offset by the change in fair value of the embedded compound derivative associated with the notes.

During the nine months ended September 30, 2014, net cash used in operating activities was \$15.7 million, consisting primarily of a net loss of \$23.8 million, partially offset by a decrease in net operating assets of \$2.5 million and by non-cash charges of \$5.6 million. The decrease in net operating assets was primarily due to decreases in inventory, and an increase in accrued expenses and other current liabilities related to interest payable to PDL and transaction fees related to our Series E preferred stock financing. The non-cash charges primarily consisted of depreciation, stock-based compensation, non-cash interest expense related to our credit agreement with PDL, and losses on the extinguishment of our notes.

***Net Cash Used in Investing Activities***

Net cash used in investing activities in the nine months ended September 30, 2015 was \$33,000 consisting of \$255,000 from the release of a restriction against our cash, offset by purchases of property and equipment of \$288,000.

Net cash used in investing activities in the nine months ended September 30, 2014 was \$37,000 consisting of purchases of property and equipment.

*Net Cash Provided by Financing Activities*

Net cash provided by financing activities in the nine months ended September 30, 2015 was \$71.9 million, consisting of net proceeds of \$58.7 million from the issuance of common stock related to our IPO, net proceeds of \$6.2 million from the issuance of our Series E preferred stock, net proceeds of \$5.5 million from the issuance of our common stock and net proceeds of \$29.1 million from the debt financing under the Loan Agreement with CRG, partially offset by the payment of \$27.6 million to retire our debt with PDL and outstanding notes. As of December 31, 2014, cash paid for deferred IPO costs was \$1.8 million.

During the nine months ended September 30, 2014, net cash provided by financing activities was \$15.8 million, consisting of net proceeds of \$4.7 million from the issuance of convertible notes and net proceeds of \$11.1 million from the issuance of our Series E preferred stock.

**Off-Balance Sheet Arrangements**

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

Table of Contents**Contractual Obligations**

Our principal obligations consist of the operating lease for our facilities, capital leases related to office equipment, our ongoing royalty obligations with PDL, our Loan Agreement with CRG and non-cancellable purchase commitments. We used the proceeds from the debt financing under the Loan Agreement and securities purchase with CRG to retire our outstanding principal and accrued interest with PDL, and to retire the principal and accrued interest underlying our outstanding notes. Accordingly, there have been material changes to our contractual obligations from those described in our Annual Report on Form 10-K, as filed with the SEC on March 27, 2015. The following table sets out as of September 30, 2015, our contractual obligations due by period (in thousands):

	Payments Due by Period				Total
	Less Than 1 Year	1 - 3 Years	3-5 Years	More Than 5 Years	
Operating lease obligations	\$ 1,150	\$ 193	\$	\$	\$ 1,343
Capital lease obligations	21	24			45
Credit agreement with PDL	1,180	1,998			3,178
CRG Loan			21,832	13,100	34,932
Noncancellable purchase commitments	3,158				3,158
	\$ 5,509	\$ 2,215	\$ 21,832	\$ 13,100	\$ 42,656

**CRG**

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

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

## Edgar Filing: Avinger Inc - Form 10-Q

any PIK is payable at the end of the term or when the loan is repaid in full. The term loan is collateralized by a security interest in substantially all of our assets.

The Loan Agreement requires that we adhere to certain affirmative and negative covenants, including financial reporting requirements, certain minimum financial covenants for pre-specified liquidity and revenue requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the Loan Agreement. In particular, the covenants of the Loan Agreement include a covenant that we maintain a minimum of \$5.0 million of cash and certain cash equivalents, and we must achieve minimum revenue of \$7.0 million in 2015, with the target minimum revenue increasing in each year thereafter until reaching \$70,000,000 in 2020 and in each year thereafter, as applicable. If we fail to meet the applicable minimum revenue target in any calendar year, the Loan Agreement provides a cure right if we prepay a portion of the outstanding principal equal to 2.0 times the revenue shortfall. In addition, the Loan Agreement prohibits the payment of cash dividends on our capital stock and also places restrictions on mergers, sales of assets, investments, incurrence of liens, incurrence of indebtedness and transactions with affiliates. CRG may accelerate the payment terms of the Loan Agreement upon the occurrence of certain events of default set forth therein, which include our failure to make timely payments of amounts due under the Loan Agreement, the failure to adhere to the covenants set forth in the Loan Agreement, our insolvency or upon the occurrence of a material adverse change. We were in compliance with the covenants under the Loan Agreement as of September 30, 2015.

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.

Table of Contents

***Convertible Promissory Notes***

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

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

***Lease Agreement***

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

***PDL Credit and Security Agreements***

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

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

Following the retirement of the PDL debt, our royalty obligations under the PDL credit agreement continue and are payable through the maturity date at the higher of a reduced rate of 0.9% of our quarterly revenues or certain minimum amounts, starting at \$65,000 per quarter in 2013 and increasing annually to \$310,000 per quarter in 2018. Additionally, until there are no further obligations to periodically pay to lender a percentage of our net revenue, we must comply with certain affirmative covenants and negative covenants limiting our ability to, among other things,

undergo a change in control or dispose of assets, in each case subject to certain exceptions. We were in compliance with the covenants under the credit agreement as of September 30, 2015.

***Indemnification***

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

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

Table of Contents

**Critical Accounting Policies and Estimates**

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenues, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. There have been no significant and material changes in our critical accounting policies during the three and nine months ended September 30, 2015, as compared to those disclosed in Management's Discussion and Analysis of Financial Conditions and Results of Operations - Critical accounting policies and significant judgments and estimates in our most recent Annual Report on Form 10-K, as filed with the SEC on March 27, 2015.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

*Interest Rate Risk*

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

*Credit Risk*

As of September 30, 2015 and December 31, 2014, our cash and cash equivalents were maintained with one financial institution in the United States, and our current deposits are likely in excess of insured limits. We have reviewed the financial statements of this institution and believe it has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us.

Our accounts receivable primarily relate to revenues from the sale of our lumivascular platform products to hospitals and medical centers in the United States. Two and no customers represented more than 10% of our accounts receivable as of September 30, 2015 and December 31, 2014, respectively.

*Foreign Currency Risk*

Our business is primarily conducted in U.S. dollars. Any transactions that may be conducted in foreign currencies are not expected to have a material effect on our results of operations, financial position or cash flows.

**ITEM 4. CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures**

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

As required by Rule 13a-15(b) under the Exchange Act, our management, under the supervision and with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2015. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of September 30, 2015, our disclosure controls and procedures were effective.

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal controls over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the third quarter of 2015 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

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

**ITEM 1A. RISK FACTORS**

*We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition, results of operations and future growth prospects. Our business could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Quarterly Report on Form 10-Q, including our financial statements and related notes. Please also see Special Notes Regarding Forward-Looking Statements.*

**Risks Related to Our Business**

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

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

- our ability to obtain and maintain FDA clearance and approval from foreign regulatory authorities for our products, including the version of Pantheris that we expect to commercialize;
- market acceptance of our lumivascular platform;

Edgar Filing: Avinger Inc - Form 10-Q

- the availability of reimbursement for our lumivascular platform products;
- our ability to attract new customers and grow our business with existing customers;
- results of our clinical trials;
- the timing and success of new product and feature introductions by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;
- the amount and timing of costs and expenses related to the maintenance and expansion of our business and operations;
- changes in our pricing policies or those of our competitors;
- general economic, industry and market conditions;
- the regulatory environment;
- the hiring, training and retention of key employees, including our ability to expand our sales team;
- litigation or other claims against us;
- our ability to obtain additional financing; and
- advances and trends in new technologies and industry standards.

Table of Contents

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

We have incurred significant losses in each period since our inception in 2007, including net losses of \$39.9 million and \$32.0 million in for the years ended December 31, 2013 and 2014, respectively, and \$33.9 million for the nine months ended September 30, 2015. As of September 30, 2015, we had an accumulated deficit of approximately \$182.8 million. These losses and our accumulated deficit reflect the substantial investments we have made to develop our lumivasular platform and acquire customers.

We expect our costs and expenses to increase in the future due to anticipated increases in cost of revenues, sales and marketing expenses, research and development expenses and general and administrative expenses and, therefore, we expect our losses to continue for the foreseeable future as we continue to make significant future expenditures to develop and expand our business. In addition, as a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. Accordingly, we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability would negatively impact the market price of our common stock.

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

We were incorporated in 2007, began commercializing our initial non-lumivasular platform products in 2009 and introduced our first lumivasular platform products in the United States in late 2012. Our limited commercialization experience and number of approved products make it difficult to evaluate our current business and predict our future prospects. We have encountered and will continue to encounter risks and difficulties frequently experienced by companies in rapidly-changing industries. These risks and uncertainties include the risks inherent in clinical trials and increasing and unforeseen expenses as we continue to attempt to grow our business.

Our short commercialization experience and limited number of approved products also make it difficult for us to forecast our future financial performance and growth and such forecasts are limited and subject to a number of uncertainties, including our ability to obtain FDA clearance for the version of Pantheris that we expect 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 our ability to obtain FDA clearance for the version of Pantheris that we expect to commercialize and our successful commercialization of this device. The version of Pantheris we expect to commercialize has been used in only a limited number of procedures and there is no long-term data on its safety and efficacy.***

The long-term viability of our company is largely dependent on the successful development and commercialization of Pantheris. In March 2015, we completed enrollment of patients in a clinical study called VISION that was used to support regulatory clearance of Pantheris. In October 2015, we received 510(k) clearance from the FDA to commercialize Pantheris but the version we expect to commercialize will still require separate FDA approval before we can market it. There can be no guarantee that the FDA will grant this approval. Because we are depending heavily on sales of Pantheris to achieve our revenue goals,

delays related to receiving FDA approval for the version of the device that we expect to commercialize will harm our financial results and ability to become profitable. We do not have significant long-term data on Pantheris' safety and efficacy. Our ability to successfully market this product will be limited due to a number of factors including regulatory restrictions in our labeling. In addition, there can be no guarantee that Pantheris will be accepted by the medical community as a valid alternative to currently available devices. If we cannot sell Pantheris as planned, our financial results will be harmed.

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

We believe that our cash and cash equivalents at September 30, 2015, expected revenues from operations and debt financing currently available under our Loan Agreement with CRG will be sufficient to satisfy our capital requirements and fund our operations for at least the next 12 months. We will likely need additional funds to meet our operational needs and capital requirements for product development, clinical trials and commercialization.

Table of Contents

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

- the costs, timing and outcomes of clinical trials and regulatory reviews associated with our future products;
  
- the costs and expenses of expanding our sales and marketing infrastructure and our manufacturing operations;
  
- the costs and timing of developing variations of our lumivasular platform products, especially Pantheris, and, if necessary, obtaining FDA clearance of such variations;
  
- the degree of success we experience in commercializing our lumivasular platform products, particularly Pantheris;
  
- the extent to which our lumivasular platform is adopted by hospitals for use by interventional cardiologists, vascular surgeons and interventional radiologists in the treatment of PAD;
  
- the number and types of future products we develop and commercialize;
  
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
  
- the extent and scope of our general and administrative expenses.

## Edgar Filing: Avinger Inc - Form 10-Q

We may raise funds in equity or debt financings or enter into credit facilities in order to access funds for our capital needs. Any debt financing obtained by us in the future would cause us to incur additional debt service expenses and could include restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and pursue business opportunities. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution in their percentage ownership of our company, and any new equity securities we issue could have rights, preferences and privileges senior to those of holders of our common stock. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, delay clinical trials necessary to market our products, or delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products. If this were to occur, our ability to continue to grow and support our business and to respond to business challenges could be significantly limited.

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

As of September 30, 2015, we had \$29.2 million in principal and interest outstanding under our Loan Agreement with CRG. Our debt with CRG is collateralized by substantially all of our assets and contains customary financial and operating covenants limiting our ability to, among other things, dispose of assets, undergo a change in control, merge or consolidate, enter into certain transactions with affiliates, make acquisitions, incur debt, incur liens, pay dividends, repurchase stock and make investments, in each case subject to certain exceptions. We are also subject to standard event of default provisions both 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, the covenants to which we are bound and the obligation to pay a certain percentage of our future revenues to PDL, even though the PDL debt has been repaid, may prevent us from being able to secure additional debt or equity financing on favorable terms, or at all, or to pursue business opportunities, including potential acquisitions.

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

Ocelot, Ocelot PIXL, Ocelot MVRX, Lightbox, Wildcat, 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 lumivasular platform products. We expect that sales of our current and future lumivasular platform products in the United States will account for substantially all of our revenues for the foreseeable future. Because of their recent commercial introduction, our lumivasular platform products have limited product and brand recognition. We do not know if our lumivasular platform products will be successful over the long term and market acceptance may be hindered if physicians are not presented with compelling data from long-term studies of the safety and efficacy of our lumivasular platform products compared to alternative procedures, such as angioplasty, stenting, bypass surgery or other atherectomy procedures. For example, if patients undergoing treatment with our lumivasular 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 lumivasular platform products. Any studies we may conduct comparing our lumivasular 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 lumivasular platform products may decline or may not increase as quickly as we expect. Failure of our lumivasular platform products to significantly penetrate current or new markets 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, the current model of Pantheris may require two physicians to operate the catheter and a technician to operate the Lightbox, making it less financially attractive for physicians. It may take significant time and expense to modify our products to allow a single physician to operate the entire system and we can provide no guarantee that we will be able to make such modifications, or obtain any additional and necessary regulatory clearances for such modifications. Also, although the OCT images created by our Lightbox may make it possible for physicians to reduce the degree to which fluoroscopy and contrast dye are used when using our lumivascular platform products compared to competing endovascular products, physicians are still using both fluoroscopy and contrast dye, particularly with Pantheris. As a result, risks of complications from radiation and contrast dye are still present and may limit the commercial success of our products. Finally, it will require training for technicians and physicians to effectively operate our lumivascular platform products, including interpreting the OCT images created by our Lightbox, which may affect adoption of our products by physicians. These or other characteristics and features of our lumivascular platform may cause our products not to be widely adopted and harm our business, financial condition and results of operation.

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

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

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

Table of Contents

***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 not FDA-cleared or approved for use in the carotid, cerebral, coronary, iliac, or renal arteries. Our sales force does not promote the use of our products for off-label indications, and our U.S. instructions for use specify that our lumivascular platform products are not intended for use in the carotid, cerebral, coronary, iliac or renal arteries. However, we cannot prevent a physician from using our lumivascular platform products for these off-label applications. The application of our lumivascular platform products to coronary arteries, as opposed to peripheral arteries, is more likely to result in complications that have serious consequences. For example, if excised plaque were not captured properly in our device, it could be carried by the bloodstream to a more narrow location, blocking a coronary artery, leading to a heart attack, or blocking an artery to the brain, leading to a stroke. If our lumivascular platform products are defectively designed, manufactured or labeled, contain defective components or are misused, we may become subject to costly litigation initiated by our customers or their patients. Product liability claims are especially prevalent in the medical device industry and could harm our reputation, divert management's attention from our core business, be expensive to defend and may result in sizable damage awards against us. Although we maintain product liability insurance, the amount or breadth of our coverage may not be adequate for the claims that are made against us.

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

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

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

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

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

The medical device market is characterized by extensive research and development and rapid technological change. Technological progress or new developments in our industry could harm sales of our products. Our products could be rendered obsolete because of future innovations in the treatment of PAD. In order to remain competitive, we must continue to develop new product offerings and enhancements to our existing lumivascular platform products. Maintaining adequate research and development personnel and resources to meet the demands of the market is essential. If we are unable to develop products, applications or features due to certain constraints, such as insufficient cash resources, inability to raise sufficient cash in future equity or debt financings, high employee turnover, inability to hire sufficient research and development personnel or a lack of other research and development resources, we may miss market opportunities. Furthermore, many of our competitors expend a considerably greater amount of funds on their research and development programs than we do, and those that do not may be acquired by larger companies that would allocate greater resources to our competitors' research and development programs. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our competitors could harm our business.

Table of Contents

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

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

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

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

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

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

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

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

- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing which may be expensive and time consuming;
- trial results may not meet the level of statistical significance required by FDA or other regulatory authorities;

Table of Contents

- FDA or similar foreign regulatory authorities may find the product is not sufficiently safe for investigational use in humans;
- FDA or similar foreign regulatory authorities may interpret data from preclinical testing and clinical trials in different ways than we do;
- there may be delays or failure in obtaining approval of our clinical trial protocols from FDA or other regulatory authorities;
- there may be delays in obtaining institutional review board approvals or government approvals to conduct clinical trials at prospective sites;
- FDA or similar foreign regulatory authorities may find our or our suppliers' manufacturing processes or facilities unsatisfactory;
- FDA or similar foreign regulatory authorities may change their review policies or adopt new regulations that may negatively affect or delay our ability to bring a product to market or receive approvals or clearances to treat new indications;
- we may have trouble in managing multiple clinical sites;
- we may experience delays in agreeing on acceptable terms with third-party research organizations and trial sites that may help us conduct the clinical trials; and
- we, or regulators, may suspend or terminate our clinical trials because the participating patients are being exposed to unacceptable health risks.

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

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

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

*We have no long-term data regarding the safety and efficacy of our lumivasular platform products. Any long-term data that is generated by clinical trials involving our lumivasular 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 lumivasular 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 lumivasular platform products will be measured are long-term data on the rate of restenosis following our procedure, and the corresponding duration of patency, or openness of the artery, and publication of that data in peer-reviewed journals. Another important factor that physicians will consider is the rate of reintervention, or retreatment, following the use of our lumivasular platform products. The long-term clinical benefits of procedures that use our lumivasular platform products are not known.

Table of Contents

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

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

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

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

The development, marketing, and sale of our products, including Pantheris, depends upon our ability to maintain strong working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. Physicians assist us in clinical trials and as researchers, marketing and product consultants and public speakers. If we 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 Health and Human Services Office of Inspector General, or OIG, the Department of Justice, or DOJ, state attorneys general, and other foreign and domestic government agencies. Our failure to comply with laws, rules and regulations governing our relationships with physicians, or an investigation into our compliance by the OIG, DOJ, state attorneys general and other government agencies, could significantly harm our business.

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

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

Table of Contents

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

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

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

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

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

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

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

- we intend to significantly expand our manufacturing capacity, and our production processes may have to change to accommodate this growth;
- key components and sub-assemblies of our lumivasular platform products are currently provided by a single supplier or limited number of suppliers, and we do not maintain large inventory levels of these components and sub-assemblies; if we experience a shortage in any of these components or sub-assemblies, we would need to identify and qualify new supply sources, which could increase our expenses and result in manufacturing delays;

- we may experience a delay in completing validation and verification testing for new controlled-environment rooms at our manufacturing facilities;
- we have limited experience in complying with FDA's Quality System Regulation, which applies to the manufacture of our lumivasular platform products; and
- to increase our manufacturing output significantly, we will have to attract and retain qualified employees, who are in short supply, for our manufacturing operations.

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

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

Table of Contents

***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 lumivasular platform products and to pursue our research and development efforts may be jeopardized.***

We currently manufacture and assemble our lumivasular 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 lumivasular 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 Quality System regulations enforced by the FDA and state regulatory authorities;
- inability to control the quality of products manufactured by third parties;
- production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications; and
- delays in delivery by our suppliers due to changes in demand from us or their other customers.

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

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

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

Table of Contents

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

We intend to educate physicians on the capabilities of our lumivasular 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 lumivasular platform products, they may not refer patients to interventional cardiologists, vascular surgeons and interventional radiologists for treatment using our lumivasular 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 lumivasular platform products, our ability to increase our revenues may be impaired.

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

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

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

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

Marketing our lumivasular platform outside of the United States would require substantial additional sales and marketing, regulatory and personnel expenses. As part of our product development and regulatory strategy, we plan to expand into select European markets, but we do not currently intend to devote significant additional resources to market our lumivasular platform internationally in order to focus our resources and

## Edgar Filing: Avinger Inc - Form 10-Q

efforts on the U.S. market. Our decision to market our products primarily in the United States in the near-term will limit our ability to reach all of our potential markets and will limit our potential sources of revenue. In addition, our competitors will have an opportunity to further penetrate and achieve market share outside of the United States until such time, if ever, that we devote significant additional resources to market our lumivascular platform products or other products internationally.

Table of Contents

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

As of December 31, 2014, we had federal and state net operating loss carryforwards, or NOLs, due to prior period losses of \$133.9 million and \$134.2 million, respectively, which if not utilized will begin to expire in 2027 for federal purposes and 2015 for state purposes. We may use these NOLs to offset against taxable income for U.S. federal income tax purposes. However, Section 382 of the Internal Revenue Code of 1986, as amended, may limit the NOLs we may use in any year for U.S. federal income tax purposes in the event of certain changes in ownership of our company. A Section 382 ownership change generally occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. This offering or future issuances or sales of our stock (including certain transactions involving our stock that are outside of our control) could cause an ownership change. If an ownership change occurs, Section 382 would impose an annual limit on the amount of pre-ownership change NOLs and other tax attributes we can use to reduce our taxable income, potentially increasing and accelerating our liability for income taxes, and also potentially causing those tax attributes to expire unused. Any limitation on using NOLs could (depending on the extent of such limitation and the NOLs previously used) result in our retaining less cash after payment of U.S. federal income taxes during any year in which we have taxable income (rather than losses) than we would be entitled to retain if such NOLs were available as an offset against such income for U.S. federal income tax reporting purposes, which could harm our profitability.

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

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

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

**Risks Related to Our Intellectual Property**

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

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

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

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

Table of Contents

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

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

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

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

In order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. We rely on a combination of patents, copyrights, trademarks, trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. As of September 30, 2015, we held six issued U.S. patents and had 18 U.S. utility patent applications and 4 PCT applications pending. As of September 30, 2015, we also had 10 issued patents outside of the United States. As of September 30, 2015, we had 34 pending patent applications outside of the United States, including in Australia, Canada, Europe, India, China and Japan. Our patents and patent applications include claims covering key aspects of the design, manufacture and therapeutic use of OCT imaging catheters, occlusion-crossing catheters, atherectomy devices and our imaging console. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Any patents issued to us may be challenged by third parties as being invalid, or third parties may independently develop similar or competing technology that avoids our patents. Should such challenges be successful, competitors might be able to market products and use manufacturing processes that are substantially similar to ours. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors or former or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology. To the extent our intellectual property protection is incomplete, we are exposed to a greater risk of direct competition. In addition, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our lumivascular platform, brand and business.

## Edgar Filing: Avinger Inc - Form 10-Q

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

Table of Contents

**Risks Related to Government Regulation**

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

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

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

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

- product design, development and manufacture;
- laboratory, preclinical and clinical testing, labeling, packaging storage and distribution;
- premarketing clearance or approval;
- record keeping;
- product marketing, promotion and advertising, sales and distribution; and

- post-marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals.

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

In addition, we are required to timely file various reports with the FDA, including reports required by the medical device reporting regulations, or MDRs, that require that we report to the regulatory authorities if our devices may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not filed timely, regulators may impose sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business. For example, to date we have submitted to the FDA five MDRs regarding our Ocelot family of catheters, which included four perforations and one related to removal of the guidewire coating.

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

Table of Contents

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

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

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

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

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

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

## Edgar Filing: Avinger Inc - Form 10-Q

may be subject to significant enforcement actions. We plan to make further modifications to the design of Pantheris prior to widespread commercialization, which will require regulatory clearances or approvals.

***If we or our suppliers fail to comply with FDA's Quality System Regulation, our manufacturing operations could be delayed or shut down and lumivascular platform sales could suffer.***

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

Table of Contents

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

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

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

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

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

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

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

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

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of health care may harm:

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

Table of Contents

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

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

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

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

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could harm our ability to operate our business and our results of operations. In addition, the clearance or approval and commercialization of any of our products outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

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

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

Table of Contents

**Risks related to ownership of our common stock**

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

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

- the results of our clinical trials;
- changes in analysts estimates, investors perceptions, recommendations by securities analysts or our failure to achieve analysts estimates;
- quarterly variations in our or our competitors results of operations;
- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors;
- changes in operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular;
- the loss of key personnel, including changes in our board of directors and management;
- legislation or regulation of our business;

- lawsuits threatened or filed against us;
- the announcement of new products or product enhancements by us or our competitors;
- announcements related to patents issued to us or our competitors and to litigation; and
- developments in our industry.

In addition, the stock prices of many companies in the medical device industry have experienced wide fluctuations that have often been unrelated to the operating performance of those companies. In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and harm our business, results of operations, financial condition, reputation and cash flows. These factors may materially and adversely affect the market price of our common stock.

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

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

Table of Contents

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

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

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

As of November 2, 2015, our directors, officers and each stockholder holding more than 5% of our common stock collectively control approximately 41.9% of our outstanding common stock, assuming the exercise of all options and warrants held by such persons. As a result, these stockholders, if they act together, would be able to exert significant influence over the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control, might adversely affect the market price of our common stock and may not be in the best interests of our other stockholders.

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

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

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

For a discussion of our remediation and the actions that we have executed during 2014 to remediate the material weakness see our most recent Annual Report on Form 10-K, as filed with the SEC on March 27, 2015. We believe the measures described remediated the material weakness we previously identified and strengthened our internal control over financial reporting. The actions we have taken are subject to continued review, supported by confirmation and testing by management as well as audit committee oversight. While we have remediated this weakness, we cannot assure you that additional material weaknesses or significant deficiencies in our internal control over financial reporting will not be

identified in the future. Any failure to maintain or implement required new or improved controls, or any difficulties we encounter in their implementation, could result in additional material weaknesses or significant deficiencies, cause us to fail to meet our periodic reporting obligations or result in material misstatements in our financial statements. Any such failure could also adversely affect the results of periodic management evaluations regarding the effectiveness of our internal control over financial reporting. The existence of a material weakness or significant deficiency could result in errors in our financial statements that could result in a restatement of financial statements, cause us to fail to meet our reporting obligations and cause investors to lose confidence in our reported financial information, leading to a decline in our stock price.

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

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of The NASDAQ Stock Market and other applicable securities laws, rules and regulations. Compliance with these laws, rules and regulations have increased our legal and financial compliance costs and will make some activities more difficult, time-consuming or costly and increase demand on our systems and resources, particularly after we are no longer an emerging growth company. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. Our management and other personnel now need to devote a substantial amount of time to these compliance initiatives. As a result, management's attention may be diverted from other business concerns and our costs and expenses will increase, which could harm our business and operating results. We may need to hire more employees in the future or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

Table of Contents

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

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

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

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

We are an emerging growth company and a smaller reporting company. For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions from reporting requirements that are applicable to other public companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain eligible for these exemptions, other than with respect to stockholder approval of golden parachute payments, after we are no longer an emerging growth company for as long as we remain a smaller reporting company. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile or decline.

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



Table of Contents

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

**Unregistered Sales of Equity Securities**

We have issued and sold the following securities from July 1, 2015 to September 30, 2015:

1. On September 22, 2015 we issued and sold to CRG 348,262 shares of common stock at a purchase price per share of \$14.357.

The sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act. The recipients of securities in each such transaction represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the share certificates issued in such transactions. All recipients had adequate access, through their relationships with us, to information about us.

**Use of Proceeds from Public Offering of Common Stock**

## Edgar Filing: Avinger Inc - Form 10-Q

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

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

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

### **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

### **ITEM 5. OTHER INFORMATION**

None.

### **ITEM 6. EXHIBITS**

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

Table of Contents

**SIGNATURES**

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

**Avinger, Inc.**  
(Registrant)

Date: November 12, 2015

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

Date: November 12, 2015

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

Table of Contents

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Exhibit Title</b>
6.1	Term Loan Agreement, dated as of September 22, 2015, by and among Avinger, Inc., certain of its subsidiaries from time to time party thereto as guarantors and CRG Partners III L.P. and certain of its affiliated funds, as lenders.
6.2	Securities Purchase Agreement, dated as of September 22, 2015, by and among Avinger, Inc., and CRG Partners III L.P. and certain of its affiliated funds, as purchasers.
31.1	Certification of the Chief Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document