

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Avinger Inc

Form: 10-Q

Date Filed: 2019-11-05

Corporate Issuer CIK: 1506928

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, 2019

or

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

For the transition period from to

Commission File Number: 001-36817

AVINGER, INC.

(Exact name of registrant as specified in its charter)

Delaware

(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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each
class:

Common Stock, par value \$0.001 per share

Trading
Symbol(s):

AVGR

Name of each exchange on which registered:

The Nasdaq Capital Market

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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 1, 2019, the number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 10,351,959.

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

- the outcome of and expectations regarding our clinical studies, including our INSIGHT trial and plans to conduct further clinical studies;
 - our plans to modify our current products, or develop new products, to address additional indications;
 - our ability to obtain additional financing through future equity or debt financings;
 - the expected growth in our business and our organization;
 - our expectations regarding government and third-party payor coverage and reimbursement, including the ability of Pantheris to qualify for reimbursement codes used by other atherectomy products;
 - our ability to continue as a going concern;
 - our ability to retain and recruit key personnel, including the continued development of our sales and marketing infrastructure;
 - our ability to obtain and maintain intellectual property protection for our products;
 - our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for, or ability to obtain, additional financing;
 - our expectations regarding revenue, cost of revenue, gross margins, and expenses, including research and development and selling, general and administrative expenses;
 - our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act;
 - our ability to identify and develop new and planned products and acquire new products;
 - our financial performance;
 - our ability to remain in compliance with laws and regulations that currently apply or become applicable to our business, both in the United States and internationally; and
 - developments and projections relating to our competitors or our industry.
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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 the "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 6, 2019. We urge you to consider these factors carefully in evaluating the forward-looking statements. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. We assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

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

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

AVINGER, INC.
AS OF AND FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2019

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"Avinger," "Pantheris," and "Lumivascular" are trademarks of our company. Our logo and our other trade names, trademarks and service marks appearing in this Quarterly Report on Form 10-Q are our property. Other trade names, trademarks and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. Solely for convenience, our trademarks and trade names referred to in this Quarterly Report on Form 10-Q appear without the TM 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.

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, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 14,461	\$ 16,410
Accounts receivable, net of allowance for doubtful accounts of \$185 and \$260 at September 30, 2019 and December 31, 2018, respectively	1,301	1,154
Inventories	4,112	3,422
Prepaid expenses and other current assets	489	635
Total current assets	20,363	21,621
Right of use asset	5,192	—
Property and equipment, net	1,873	2,078
Other assets	579	—
Total assets	\$ 28,007	\$ 23,699
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 919	\$ 1,148
Accrued compensation	1,189	1,197
Accrued expenses and other current liabilities	681	1,449
Leasehold liability, current portion	855	—
Borrowings	8,578	7,486
Preferred stock dividends payable	2,685	2,918
Total current liabilities	14,907	14,198
Leasehold liability, long-term portion	4,337	—
Other long-term liabilities	9	41
Total liabilities	19,253	14,239
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Convertible preferred stock issuable in series, par value of \$0.001;		
Shares authorized: 5,000,000 at September 30, 2019 and December 31, 2018;		
Shares issued and outstanding: 44,923 and 45,671 at September 30, 2019 and December 31, 2018, respectively; aggregate liquidation preference of \$47,430 and \$44,718 at September 30, 2019 and December 31, 2018, respectively		
	—	—
Common stock, par value of \$0.001;		
Shares authorized: 100,000,000 at September 30, 2019 and December 31, 2018;		
Shares issued and outstanding: 10,342,179 and 3,492,200 at September 30, 2019 and December 31, 2018, respectively		
	10	3
Additional paid-in capital	351,958	338,342
Accumulated deficit	(343,214)	(328,885)
Total stockholders' equity	8,754	9,460
Total liabilities and stockholders' equity	\$ 28,007	23,699

See accompanying notes.

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,	
	2019	2018	2019	2018
Revenues	\$ 2,410	\$ 2,020	\$ 6,569	\$ 5,887
Cost of revenues	1,563	1,477	4,629	5,061
Gross profit	847	543	1,940	826
Operating expenses:				
Research and development	1,371	1,404	4,120	4,340
Selling, general and administrative	4,091	4,499	12,168	13,443
Total operating expenses	5,462	5,903	16,288	17,783
Loss from operations	(4,615)	(5,360)	(14,348)	(16,957)
Interest income	70	54	242	137
Interest expense	(377)	(324)	(1,091)	(5,358)
Other income net	299	242	868	710
Net loss and comprehensive loss	(4,623)	(5,388)	(14,329)	(21,468)
Accretion of preferred stock dividends	(895)	(836)	(2,685)	(2,082)
Deemed dividend arising from beneficial conversion feature of convertible preferred stock	—	—	—	(5,216)
Net loss attributable to common stockholders	\$ (5,518)	\$ (6,224)	\$ (17,014)	\$ (28,766)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.70)	\$ (5.56)	\$ (2.75)	\$ (43.00)
Weighted average common shares used to compute net loss per share, basic and diluted	7,900	1,119	6,189	669

See accompanying notes.

AVINGER, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited)
(In thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance at June 30, 2019	44,923	\$ —	6,421,317	\$ 6	\$ 348,505	\$ (338,591)	\$ 9,920
Issuance of common stock under officers and directors purchase plan	—	—	10,947	—	18	—	18
Issuance of common stock upon vesting of restricted stock units	—	—	96,356	—	—	—	—
Employee stock-based compensation	—	—	—	—	523	—	523
Issuance of common stock in August public offering, net of commissions and issuance costs	—	—	3,813,559	4	3,807	—	3,811
Accretion of Series A Preferred Stock dividends	—	—	—	—	(895)	—	(895)
Net and comprehensive loss	—	—	—	—	—	(4,623)	(4,623)
Balance at September 30, 2019	44,923	\$ —	10,342,179	\$ 10	\$ 351,958	\$ (343,214)	\$ 8,754
	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance at June 30, 2018	43,501	\$ —	930,587	\$ 1	\$ 323,991	\$ (317,400)	\$ 6,592
Employee stock-based compensation	—	—	—	—	768	—	768
Issuance of common stock in July public offering, net of commissions and issuance costs	—	—	216,618	—	3,021	—	3,021
Issuance of common stock under officers' and directors' purchase plan	—	—	209	—	5	—	5
Accretion of Series A Preferred Stock dividends	—	—	—	—	(836)	—	(836)
Issuance of common stock to a vendor	—	—	8,000	—	—	—	—
Net and comprehensive loss	—	—	—	—	—	(5,388)	(5,388)
Balance at September 30, 2018	43,501	\$ —	1,155,414	\$ 1	\$ 326,949	\$ (322,788)	\$ 4,162

See accompanying notes.

AVINGER, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (CONTINUED)
(unaudited)
(In thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2018	45,671	\$ —	3,492,200	\$ 3	\$ 338,342	\$ (328,885)	\$ 9,460
Issuance of common stock under officers and directors purchase plan	—	—	18,735	—	54	—	54
Issuance of common stock upon vesting of restricted stock units	—	—	96,356	—	—	—	—
Employee stock-based compensation	—	—	—	—	1,532	—	1,532
Exercises of warrants for common stock	—	—	1,998,079	2	7,991	—	7,993
Issuance of common stock in August public offering, net of commissions and issuance costs	—	—	3,813,559	4	3,807	—	3,811
Conversion of Series B Preferred Stock into common stock	(1,523)	—	380,750	—	—	—	—
Conversion of Series C Preferred Stock into common stock	(2,170)	—	542,500	1	(1)	—	—
Issuance of Series A Preferred stock to pay dividends	2,945	—	—	—	2,918	—	2,918
Accretion of Series A Preferred Stock dividends	—	—	—	—	(2,685)	—	(2,685)
Net and comprehensive loss	—	—	—	—	—	(14,329)	(14,329)
Balance at September 30, 2019	44,923	\$ —	10,342,179	\$ 10	\$ 351,958	\$ (343,214)	\$ 8,754

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2017	—	\$ —	83,359	\$ —	\$ 265,630	\$ (301,320)	\$ (35,690)
Issuance of common stock	—	—	4,220	—	337	—	337
Employee stock-based compensation	—	—	—	—	2,027	—	2,027
Exercises of warrants for common stock	—	—	29,050	—	581	—	581
Issuance of common stock in July public offering, net of commissions and issuance costs	—	—	216,618	—	3,021	—	3,021
Conversion of CRG into Series A Preferred Stock	41,800	—	—	—	41,800	—	41,800
Issuance of Series B Preferred Stock, net of commissions and issuance costs	17,979	—	—	—	15,525	—	15,525
Conversion of Series B Preferred Stock into common stock	(16,278)	—	813,958	1	(1)	—	—
Accretion of Series A Preferred Stock dividends	—	—	—	—	(2,082)	—	(2,082)
Issuance of common stock under officers and directors purchase plan	—	—	209	—	5	—	5
Issuance of common stock to a vendor	—	—	8,000	—	106	—	106
Net and comprehensive loss	—	—	—	—	—	(21,468)	(21,468)
Balance at September 30, 2018	43,501	\$ —	1,155,414	\$ 1	\$ 326,949	\$ (322,788)	\$ 4,162

See accompanying notes

AVINGER, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2019	2018
Cash flows from operating activities		
Net loss	\$ (14,329)	\$ (21,468)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	654	735
Amortization of debt issuance costs and debt discount	129	87
Stock-based compensation	1,532	2,028
Noncash interest expense and other charges	1,146	5,330
Common stock to be issued for services	—	106
Provision for doubtful accounts receivable	—	45
Gain on sale of property and equipment	—	(28)
Provision for excess and obsolete inventories	80	630
Changes in operating assets and liabilities:		
Accounts receivable	(147)	(378)
Other long-term assets	427	104
Inventories	(1,149)	776
Prepaid expenses and other current assets	(59)	(91)
Accounts payable	(229)	297
Accrued compensation	(8)	123
Leasehold liability	(984)	—
Accrued expenses and other current liabilities	(768)	(2,618)
Other long-term liabilities and accrued interest	(32)	(115)
Net cash used in operating activities	(13,737)	(14,437)
Cash flows from investing activities		
Purchases of property and equipment	(88)	(411)
Proceeds from sale of property and equipment	18	28
Net cash used in investing activities	(70)	(383)
Cash flows from financing activities		
Proceeds from the issuance of convertible preferred stock, net of issuance costs	—	15,534
Proceeds from the issuance of common stock related to warrant exercises	7,993	581
Proceeds from the issuance of common stock in public offerings, net of issuance costs	3,811	3,539
Proceeds from the issuance of common stock under officers and directors purchase plan	54	—
Payment of debt discount in connection with loan amendment	—	(155)
Payment of accrued interest	—	(60)
Net cash provided by financing activities	11,858	19,439
Net change in cash and cash equivalents	(1,949)	4,619
Cash and cash equivalents, beginning of period	16,410	5,389
Cash and cash equivalents, end of period	\$ 14,461	\$ 10,008
Supplemental disclosure of cash flow information		
Cash paid for interest	\$ —	\$ 60
Noncash investing and financing activities:		
Conversion of CRG loan principal into Series A Preferred Stock	\$ —	\$ 38,000
Accretion of Series A Preferred Stock dividends	\$ 2,685	\$ 2,082
Issuance of Series A Preferred Stock as dividend payment	\$ 2,918	\$ —
Reclassification of right of use asset to prepaid rent	\$ 358	\$ —
Increase to right of use asset and leasehold liability arising from lease amendment	\$ 4,680	\$ —
Transfers between inventory and property and equipment	\$ 380	\$ 103
Deemed dividend arising from beneficial conversion feature of convertible preferred stock	\$ —	\$ 5,216

See accompanying notes.

Notes to Condensed Financial Statements

1. Organization**Organization, Nature of Business**

Avinger, Inc. (the "Company"), a Delaware corporation, was incorporated in March 2007. The Company designs, manufactures and sells image-guided, catheter-based systems that are used by physicians to treat patients with peripheral artery disease ("PAD"). Patients with PAD have a build-up of plaque in the arteries that supply blood to areas away from the heart, particularly the pelvis and legs. The Company manufactures and sells a suite of products in the United States ("U.S.") and in select international markets. The Company has developed its Lumivascular platform, which integrates optical coherence tomography ("OCT") visualization with interventional catheters and is the industry's only system that provides real-time intravascular imaging during the treatment portion of PAD procedures. The Company's Lumivascular platform consists of a capital component, Lightbox, as well as a variety of disposable catheter products. The Company's current products include its non-imaging catheters, Wildcat and Kittycat, as well as its Lumivascular platform products, Ocelot, Ocelot PIXL and Ocelot MVRX, all of which are designed to allow physicians to penetrate a total blockage in an artery, known as a chronic total occlusion ("CTO"). In March 2016, the Company received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") for commercialization of Pantheris, the Company's image-guided atherectomy system, designed to allow physicians to precisely remove arterial plaque in PAD patients. In May 2018, the Company also received 510(K) clearance from the FDA for its next-generation of Pantheris. In April 2019, the Company further received FDA clearance for Pantheris SV, a lower profile Pantheris, and commenced sales in August 2019. The Company has sales in the U.S. and select international markets. The Company is located in Redwood City, California.

Liquidity Matters

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

In the course of its activities, the Company has incurred losses and negative cash flows from operations since its inception. As of September 30, 2019, the Company had an accumulated deficit of \$343.2 million. The Company expects to incur losses for the foreseeable future. The Company believes that its cash and cash equivalents of \$14.5 million at September 30, 2019 and expected revenues and funds from operations will be sufficient to allow the Company to fund its current operations through at least the second quarter of 2020. Even though we received net proceeds of \$3.8 million from the sales of our common stock in our August 2019 offering, net proceeds of \$10.2 million from the sale of our Series C Preferred Stock and common stock in our November 2018 offering, net proceeds of \$3.0 million from the sale of common stock and warrants in our July 2018 offering, net proceeds of \$15.5 million from the sale of our Series B preferred stock and warrants in our February 2018 offering, and proceeds from issuance of common stock upon the exercise of warrants in the nine months ended September 30, 2019 of \$8.0 million, the Company will need to raise additional funds through future equity or debt financings within the next twelve months to meet its operational needs and capital requirements for product development, clinical trials and commercialization and may subsequently require additional fundraising. The Company can provide no assurance that it will be successful in raising funds pursuant to additional equity or debt financings or that such funds will be raised at prices that do not create substantial dilution for our existing stockholders. Given the recent decline in the Company's stock price, any financing that we undertake in the next twelve months could cause substantial dilution to our existing stockholders, there can be no assurance that the Company will be successful in acquiring additional funding at levels sufficient to fund its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. If the Company is unable to raise additional capital in sufficient amounts or on terms acceptable to it, the Company may have to significantly reduce its operations or delay, scale back or discontinue the development of one or more of its products. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. The Company's ultimate success will largely depend on its continued development of innovative medical technologies, its ability to successfully commercialize its products and its ability to raise significant additional funding.

Additionally, due to the substantial doubt about the Company's ability to continue operating as a going concern and the material adverse change clause in the Loan Agreement with CRG, the entire amount of borrowings at September 30, 2019 and December 31, 2018 has been classified as current in these financial statements. CRG has not invoked the material adverse change clause.

Public Offerings

On February 16, 2018, we completed a public offering of 17,979 shares of Series B preferred stock and warrants to purchase 1,797,900 shares of common stock. As a result, we received net proceeds of approximately \$15.5 million after underwriting discounts, commissions, legal and accounting fees. The Series B preferred stock has a liquidation preference of \$0.001 per share, full ratchet price based anti-dilution protection, has no voting rights and is subject to certain ownership limitations. The Series B preferred stock is immediately convertible at the option of the holder, has no stated maturity, and does not pay regularly stated dividends or interest. Each share of Series B preferred stock is accompanied by one Series 1 warrant that expires on the seventh anniversary of the date of issuance to purchase up to 50 shares of common stock and one Series 2 warrant that expires on the earlier of (i) the seventh anniversary of the date of issuance or (ii) the 60th calendar day following the receipt and announcement of FDA clearance of our Pantheris below-the-knee device (or the same or similar product with a different name) to purchase up to 50 shares of common stock; provided, however, if at any time during such 60-day period the volume weighted average price for any trading day is less than the then effective exercise price, the termination date shall be extended to the seven year anniversary of the initial exercise date. FDA clearance of Pantheris SV was received in April 2019, triggering this 60-day period. During the entire 60-day period following clearance, the volume weighted average price was less than the then effective exercise price. As such, all Series 2 warrants are currently deemed to expire on the seventh anniversary of the date of issuance. In addition, pursuant to the Series A Purchase Agreement, we issued to CRG 41,800 shares of Series A preferred stock at the closing of the Series B Offering. The Series A preferred stock was issued in exchange for the conversion of \$38.0 million of the outstanding principal amount of their senior secured term loan (plus the back-end fee and prepayment premium applicable thereto), totaling approximately \$41.8 million. The Series A Preferred Stock is initially convertible into 2,090,000 shares of common stock subject to certain limitations contained in the Series A Purchase Agreement.

On July 12, 2018, we entered into a securities purchase agreement with certain investors pursuant to which we agreed to sell and issue, in a registered direct offering, an aggregate of 216,618 shares of our common stock at an offering price of \$16.425 per share. In a concurrent private placement, or the Private Placement, we agreed to issue to these investors warrants exercisable for one share of our common stock for each two shares purchased in the registered direct offering, which equals an aggregate of 108,309 shares of common stock. The closing of such registered direct offering and the concurrent Private Placement occurred on July 16, 2018, in connection with which we received net proceeds of approximately \$3.0 million after deducting placement agent fees and other expenses payable by us. The warrants have an exercise price of \$15.80 per share of our common stock and expire on July 16, 2021.

On November 1, 2018, we completed a public offering of 728,500 shares of common stock and 8,586 shares of Series C convertible preferred stock (the "Series C preferred stock"). As a result, we received net proceeds of approximately \$10.2 million after underwriting discounts, commissions, legal and accounting fees. Upon any dissolution, liquidation or winding up, whether voluntary or involuntary, holders of Series C preferred stock will be entitled to receive distributions out of our assets, whether capital or surplus, of an amount equal to \$0.001 per share of Series C preferred stock before any distributions shall be made on the common stock but after distributions shall be made on any outstanding Series A preferred stock and any of our existing or future indebtedness. The Series C preferred stock has no voting rights.

On August 26, 2019, we completed a public offering of 3,813,559 shares of common stock at an offering price of \$1.18 per share. As a result, we received net proceeds of approximately \$3.8 million after underwriting discounts, commissions, legal and accounting fees and the conversion price of the outstanding shares of Series B preferred stock, issued in our February 2018 offering, was reduced to \$1.18 per share as a result.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") and pursuant to the rules and regulations of the SEC. The accompanying unaudited condensed interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the Company's financial information. The results for the three and nine months ended September 30, 2019 are not necessarily indicative of results to be expected for the year ending December 31, 2019, or for any other interim period or for any future year. The December 31, 2018 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, 2018, which was filed with the SEC on March 6, 2019. The Company's significant accounting policies are more fully described in Note 2 of the Notes to Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

On January 30, 2018, the Company's Board of Directors approved an amendment to the Company's amended and restated certificate of incorporation to effect a 1-for-40 reverse stock split of the Company's common stock. Further, on June 19, 2019, the Company's Board of Directors approved an amendment to the Company's amended and restated certificate of incorporation to effect an additional 1-for-10 reverse stock split of the Company's common stock. The reverse stock split became effective on June 21, 2019. The par value of the common stock and convertible preferred stock was not adjusted as a result of the reverse stock split. All common stock, stock options, and restricted stock units, and per share amounts in the financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock splits.

Use of Estimates

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

Fair Value of Financial Instruments

The Company has evaluated the estimated fair value of its financial instruments as of September 30, 2019 and December 31, 2018. Financial instruments consist of cash and cash equivalents, accounts receivable and payable, and other current liabilities and borrowings. The carrying amounts of cash and cash equivalents, accounts receivable and payable, and other current liabilities approximate their respective fair values because of the short-term nature of those instruments. Based upon the borrowing terms and conditions currently available to the Company, the carrying values of the borrowings approximate their fair value.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the time of purchase to be cash equivalents. Cash equivalents are considered available-for-sale marketable securities and are recorded at fair value, using level 1 inputs, based on quoted market prices. As of September 30, 2019 and December 31, 2018, 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, 2019 and December 31, 2018. Any realized gains and losses and interest and dividends on available-for-sale securities are included in interest income or expense and computed using the specific identification cost method.

Concentration of Credit Risk, and Other Risks and Uncertainties

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

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

The Company provides for uncollectible amounts when specific credit problems arise. Management's estimates for uncollectible amounts have been adequate, and management believes that all significant credit risks have been identified at September 30, 2019 and December 31, 2018.

The Company's accounts receivable are due from a variety of healthcare organizations in the United States and select international markets. At September 30, 2019 and December 31, 2018, there were no customers that represented 10% or more of the Company's accounts receivable. For the three and nine months ended September 30, 2019 and 2018, there were no customers that represented 10% or more of revenues. Disruption of sales orders or a deterioration of financial conditions of customers would have a negative impact on the Company's financial position and results of operations.

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

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

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

Revenue Recognition

The Company's revenues are derived from (1) sale of Lightboxes, (2) sale of disposables, which consist of catheters and accessories, and (3) sale of customer service contracts. The Company sells its products directly to hospitals and medical centers as well as through distributors. The Company accounts for a contract with a customer when there is a legally enforceable contract between the Company and the customer, the rights of the parties are identified, the contract has commercial substance, and collectability of the contract consideration is probable. The Company's revenues are measured based on consideration specified in the contract with each customer, net of any sales incentives and taxes collected from customers that are remitted to government authorities. For all sales, the Company uses either a signed agreement or a binding purchase order as evidence of an arrangement. The Company's revenue recognition policies generally result in revenue recognition at the following points:

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

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

The Company evaluates its lease and commercial evaluation program agreements and accounts for these contracts under the guidance in Accounting Standards Codification ("ASC") 840, *Leases* and ASU No. 2014 09, *Revenue from Contracts with Customers (Topic 606)*. The guidance requires arrangement consideration to be allocated between a lease deliverable and a non-lease deliverable based upon the relative selling-price of the deliverables, using a specific hierarchy. The hierarchy is as follows: vendor-specific objective evidence of fair value of the respective elements, third-party evidence of selling price, or best estimate of selling price ("BESP"). The Company allocates arrangement consideration using BESP.

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

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

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

Cost of Revenues

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

Product Warranty Costs

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

Balance at December 31, 2018	\$	272
Warranty provision		70
Usage/release		(128)
Balance at September 30, 2019	\$	<u>214</u>

Net Loss per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, without consideration for potential dilutive common shares. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock and dilutive potential shares of common stock outstanding during the period. Any common stock shares subject to repurchase are excluded from the calculations as the continued vesting of such shares is contingent upon the holders' continued service to the Company. As of September 30, 2019 and December 31, 2018, there were no shares subject to repurchase. Since the Company was in a loss position for all periods presented, basic net loss per share attributable to common stockholders is the same as diluted net loss per share attributable to common stockholders as the inclusion of all potentially dilutive common shares would have been anti-dilutive.

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

	Three Months Ended September		Nine Months Ended September	
	30,		30,	
	2019	2018	2019	2018
Net loss attributable to common stockholders	\$ (5,518)	\$ (6,224)	\$ (17,014)	\$ (28,766)
Weighted average common stock outstanding	7,900	1,119	6,189	669
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.70)	\$ (5.56)	\$ (2.75)	\$ (43.00)

The following potentially dilutive securities outstanding have been excluded from the computations of diluted weighted average shares outstanding because such securities have an anti-dilutive impact due to losses reported:

	Three Months Ended September		Nine Months Ended September	
	30,		30,	
	2019	2018	2019	2018
Common stock warrant equivalents	2,757,741	1,867,226	3,346,568	1,511,832
Common stock options	7,444	8,472	7,596	7,246
Convertible preferred stock	44,923	4,450	45,046	3,969
Unvested restricted stock units	371,651	84,848	316,575	374
	<u>3,181,759</u>	<u>1,964,996</u>	<u>3,715,785</u>	<u>1,523,421</u>

Segment and Geographical Information

The Company operates and manages its business as one reportable and operating segment. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. Primarily all of the Company's long-lived assets are based in the United States. Long-lived assets are comprised of property and equipment. For the three months ended September 30, 2019 and 2018, 96% and 94%, respectively, of the Company's revenues were in the United States based on the shipping location of the external customer. For the nine months ended September 30, 2019 and 2018, 94% and 94%, respectively, of the Company's revenues were in the United States based on the shipping location of the external customer.

Recent Accounting Pronouncements

Adopted:

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

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

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

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

The Company adopted ASC 606 and related ASUs on January 1, 2018, using the modified retrospective approach. The adoption did not have a material impact on the Company's financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting*, which provides guidance on determining which changes to the terms and conditions of share-based payment awards require an entity to apply modification accounting under Topic 718. The amendments in this ASU should be applied prospectively to an award modified on or after the adoption date. The Company adopted this guidance on January 1, 2018 and such adoption did not have a material impact on the Company's financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. This update clarifies how certain cash receipts and cash payments are presented and classified in the statement of cash flows. This ASU is effective for public business entities for fiscal years beginning after December 15, 2017, and for interim periods therein with early adoption permitted and must be applied retrospectively to all periods presented. The Company adopted this guidance on January 1, 2018 and such adoption did not have a material impact on the Company's financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. Topic 842 amends a number of aspects of lease accounting, including requiring lessees to recognize leases with a term greater than one year as a right-of-use asset and corresponding liability, measured at the present value of the lease payments. In July, the FASB issued supplemental adoption guidance and clarification to Topic 842 within ASU No. 2018-10, *Codification Improvements to Topic 842, Leases* and ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*. The guidance became effective for us beginning in the first quarter of 2019 and was required to be adopted using a modified retrospective approach. The Company adopted this guidance on January 1, 2019. This adoption resulted in the recognition of a right of use asset and a corresponding leasehold liability related to the Company's building lease on the balance sheet of approximately \$1.8 million with no material impact on the statements of operations and comprehensive loss. To maintain comparability between periods, the Company reclassified sublease payments received of approximately \$240,000 and \$720,000 that were netted against rent expense in the three and nine months ended September 30, 2018 to other income on the condensed statement of operations and comprehensive loss. In addition, the Company elected to take advantage of the available practical expedients.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which expands the scope of Topic 718 to include share based payment transactions for acquiring goods and services from nonemployees and applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606. This update is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company adopted this guidance on July 1, 2018 and such adoption did not have a material impact on the Company's 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, 2019 and December 31, 2018, cash equivalents were all categorized as Level 1 and consisted of money market funds. As of September 30, 2019 and December 31, 2018, there were no financial assets and liabilities categorized as Level 2 or 3. There were no transfers between fair value hierarchy levels during the three and nine months ended September 30, 2019 and 2018.

4. Inventories

Inventories consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Raw materials	\$ 1,898	\$ 2,102
Work-in-process	544	158
Finished products	1,670	1,162
Total inventories	<u>\$ 4,112</u>	<u>\$ 3,422</u>

5. Borrowings

CRG

On September 22, 2015, the Company entered into a Term Loan Agreement, as amended (the "Loan Agreement") with CRG under which, subject to certain conditions, the Company had the right to borrow up to \$50,000,000 in principal amount from CRG on or before March 29, 2017. The Company borrowed \$30,000,000 on September 22, 2015. The Company borrowed an additional \$10,000,000 on June 15, 2016 under the Loan Agreement.

On February 14, 2018, the Company and CRG amended the Loan Agreement concurrent with the conversion of \$38,000,000 of the principal amount of the senior secured term loan (plus \$3,800,000 in back-end fees and prepayment premium applicable thereto) into a newly authorized Series A convertible preferred stock (see Note 7, below).

Under the Loan Agreement, as amended, no cash payments for either principal or interest are due until the first quarter of 2020. Beginning in the first quarter of 2020 accrued interest will be partially paid and partially accrued and included in the debt balance based (to the extent not paid) on principal amounts outstanding at the beginning of the quarter at an interest rate of 12.5%. Beginning in the third quarter of 2021, the Company will be required to make quarterly principal payments (in addition to the interest) of \$1.2 million with total principal payments of \$2.4 million in 2021, \$4.8 million in 2022 and \$2.4 million in 2023.

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

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

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

- extend the interest only payment period and the period during which the Company may elect to pay a portion of the interest in PIK interest payments through June 30, 2021;
- provide for a 15% facility fee to be paid on the maturity date ("final facility fee");
- permit the Company to make the entire interest payment for payment dates in 2018 and 2019 in PIK interest payments, provided no default has occurred and is continuing;
- extend the maturity date to June 30, 2023;
- modify certain of the covenants, including the indebtedness covenant, lien covenant and restricted payments covenant, to eliminate or modify permitted exceptions to the restrictions in those covenants;
- modify the financial covenants to reduce the minimum liquidity requirement to \$3,500,000 at all times, to eliminate the minimum revenue requirements for 2018 and 2019, and to reduce the minimum revenue requirements to \$15,000,000 million for 2020, \$20,000,000 for 2021 and \$25,000,000 for 2022; and
- provide CRG with board observer rights.

As of September 30, 2019, the Company was in compliance with all applicable covenants under the Loan Agreement.

As of September 30, 2019, principal, final facility fee and PIK payments due under the Loan Agreement are as follows (in thousands):

Year Ending December 31,

2019 (remaining three months of the year)	\$	—
2020		799
2021		3,403
2022		5,522
2023		3,981
		<u>13,705</u>
Less: Amount of PIK additions and final facility fee to be accreted subsequent to September 30, 2019		(4,497)
Less: Amount representing debt financing costs		(630)
Borrowings, as of September 30, 2019	\$	<u>8,578</u>

In connection with drawdowns under the Loan Agreement, the Company recorded aggregate debt discounts of \$1.3 million as contra-debt. The debt discounts are being amortized as non-cash interest expense using the effective interest method over the term of the Loan Agreement. As of September 30, 2019 and December 31, 2018, the balance of the aggregate debt discount was approximately \$630,000 and \$757,000, respectively. The Company's interest expense associated with the amortization of debt discount amounted to \$42,000 and \$30,000 during the three months ended September 30, 2019 and 2018, respectively, and \$127,000 and \$84,000 during the nine months ended September 30, 2019 and 2018, respectively. For the three months ended September 30, 2019 and 2018, the Company incurred interest expense of approximately \$377,000 and \$362,000, respectively, and for the nine approximately \$1.1 million and \$5.4 million, respectively.

Due to the substantial doubt about the Company's ability to continue operating as a going concern and the material adverse change clause in the Loan Agreement with CRG, the entire amount of borrowings at September 30, 2019 and December 31, 2018 is classified as current in these financial statements. CRG has not invoked the material adverse change clause.

6. Commitments and Contingencies

Lease Commitments

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

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

Upon the adoption of Topic 842 on January 1, 2019, the Company recognized a right of use asset and a corresponding leasehold liability related to this lease of approximately \$1.8 million, representing the present value of the remaining minimum lease payments as of that date. The asset was being reduced over the remaining period of the lease on a straight-line basis. The leasehold liability is being reduced as payments are made.

On April 1, 2019, we entered into an amendment to the lease which extended the lease term for an additional period of five years subsequent to the original expiration of November 30, 2019. As amended, the lease will expire on November 30, 2024. Under the terms of the amendment, we will be obligated to pay approximately \$5.8 million in base rent payments through November 2024, beginning on December 1, 2019. This amendment does not extend the term of the lease with respect to the building being subleased.

In connection with the amendment the Company adjusted its right-of-use asset and lease liability to \$6.0 million. As of the date of the amendment, the operating lease was included on the balance sheet at the present value of the future base payments discounted at a 6.5% discount rate using the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term and amount equal to the lease payments in a similar economic environment as the leases do not provide an implicit rate.

For the three and nine months ended September 30, 2019, our operating lease expense, excluding variable maintenance fees and other expenses paid by the Company on a monthly basis, was approximately \$314,000 and \$1.1 million, respectively. Rent expense for the three and nine months ended September 30, 2018 was approximately \$481,000 and \$1.4 million, respectively. Operating right-of-use asset amortization for the three and nine months ended September 30, 2019 was approximately \$225,000 and \$444,000, respectively. Due to payments being made in excess of operating lease expense recognized, the Company recorded approximately \$358,000 as prepaid rent included in other assets on the condensed balance sheet as of September 30, 2019.

The following table presents the future operating lease payments and lease liability included on the condensed balance sheet related to the Company's operating lease as of September 30, 2019 (in thousands):

Year Ending December 31,	
2019 (remaining three months of the year)	\$ 418
2020	1,085
2021	1,123
2022	1,162
2023	1,203
Thereafter	1,138
	<u>6,128</u>
Less: Imputed interest	(937)
Leasehold liability as of September 30, 2019	<u>\$ 5,192</u>

Indemnification

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

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

Legal Proceedings

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

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

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

On October 11, 2017, the Federal Court appointed a lead plaintiff and approved the selection of a lead counsel in the Federal Action. On November 21, 2017, an amended complaint was filed in the Federal Action. Defendants filed a motion to dismiss that complaint on January 26, 2018. On March 19, 2018, plaintiff in the Federal Action filed a further amended complaint, on behalf of a class of purchasers of our common stock in and/or traceable to our IPO, as well as purchasers of our common stock during the period January 30, 2015, to April 10, 2017.

The Company and its directors believe that the foregoing lawsuits were without merit; however, in the interest of avoiding the cost and disruption of continuing to defend against these lawsuits, the Company entered into a settlement of the actions. The settlement is for a total of \$5 million. The Company's total contribution to the settlement fund is \$1.76 million, which the Company paid in March 2018. On October 24, 2018, the court approved the settlement.

7. Stockholders' Equity (Deficit)

Convertible Preferred Stock

The Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 5,000,000 shares of convertible preferred stock with \$0.001 par value per share, of which 44,923 shares were issued and outstanding as of September 30, 2019.

Series A Convertible Preferred Stock

On February 14, 2018, the Company entered into a Series A Purchase Agreement with CRG, pursuant to which it agreed to convert \$38.0 million of the outstanding principal amount of its senior secured term loan (plus \$3.8 million in back-end fees, accrued interest, debt discount and prepayment premium applicable thereto), totaling \$41.8 million, into a newly authorized Series A convertible preferred stock (the "Series A preferred stock"). The Series A preferred stock was initially convertible into 2,090,000 shares of common stock subject to certain limitations contained in the Series A Purchase Agreement. Under the terms of the Series A Purchase Agreement, the holders of Series A preferred stock are entitled to receive annual accruing dividends at a rate of 8%, payable in additional shares of Series A preferred stock or cash, at the Company's option. The shares of Series A preferred stock have no voting rights and rank senior to all other classes and series of the Company's equity in terms of repayment and certain other rights. In January 2019, 2,945 additional shares were issued to CRG as payment of dividends accrued through December 31, 2018. As of September 30, 2019, 44,745 shares of Series A preferred stock were outstanding. The Series A preferred stock accrued additional dividends of approximately \$895,000 and \$836,000 during the three months ended September 30, 2019 and 2018, respectively, and \$2.7 million and \$2.1 million during the nine months ended September 30, 2019 and 2018, respectively.

Series B Convertible Preferred Stock

On February 16, 2018, the Company completed a public offering of 17,979 shares of Series B convertible preferred stock (the "Series B preferred stock"). As a result, the Company received net proceeds of approximately \$15.5 million after underwriting discounts, commissions, legal and accounting fees. The Series B preferred stock has a liquidation preference of \$0.001 per share, full ratchet price based anti-dilution protection, has no voting rights and is subject to certain ownership limitations. The Series B preferred stock is immediately convertible at the option of the holder, has no stated maturity, and does not pay regularly stated dividends or interest. As of December 31, 2018, there were 1,701 shares of Series B preferred stock outstanding. During the nine months ended September 30, 2019, 1,523 of these shares converted into 380,750 shares of common stock and 178 shares of Series B preferred stock remained outstanding.

The Company evaluated the Series B convertible preferred stock issuance in accordance with the provisions of ASC 815, *Derivatives and Hedging*, including consideration of embedded derivatives requiring bifurcation. The issuance of the convertible preferred stock could generate a beneficial conversion feature ("BCF"), which arises when a debt or equity security is issued with an embedded conversion option that is beneficial to the investor or in the money at inception because the conversion option has an effective conversion price that is less than the market price of the underlying stock at the commitment date. The Company recognized the BCF by allocating the intrinsic value of the conversion option, which is the number of shares of common stock available upon conversion multiplied by the difference between the effective conversion price per share and the fair value of common stock per share on the commitment date, to additional paid-in capital, resulting in a discount on the convertible preferred stock. As the Series B convertible preferred stock may be converted immediately, the Company recognized a BCF of \$5.2 million as a deemed dividend in the statements of operations as of February 16, 2018.

Series C Convertible Preferred Stock

On November 1, 2018, the Company completed a public offering of 728,500 shares of common stock and 8,586 shares of Series C convertible preferred stock (the "Series C preferred stock"). As a result, we received net proceeds of approximately \$10.2 million after underwriting discounts, commissions, legal and accounting fees. Upon any dissolution, liquidation or winding up, whether voluntary or involuntary, holders of Series C preferred stock will be entitled to receive distributions out of our assets, whether capital or surplus, of an amount equal to \$0.001 per share of Series C preferred stock before any distributions shall be made on the common stock but after distributions shall be made on any outstanding Series A preferred stock and any of our existing or future indebtedness. The Series C preferred stock has no voting rights. As of December 31, 2018, there were 2,170 shares of Series C preferred stock outstanding. During the nine months ended September 30, 2019, all 2,170 of these shares were converted into 542,500 shares of common stock and no shares remained outstanding.

Common Stock

As of September 30, 2019, 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 10,342,179 shares were issued and outstanding.

Common Stock Warrants

In connection with the issuance of the Company's Series E convertible preferred stock in September 2014 through January 2015, the Company issued warrants to purchase an aggregate of up to the number of shares of common stock equal to 50% of the number of shares of the Company's Series E Convertible preferred stock purchased by such investor. As of June 30, 2019, there were warrants outstanding to purchase an aggregate of 5,380 shares of common stock with an exercise price of \$5,040.00 per share. These warrants expired on September 2, 2019.

On February 16, 2018, in connection with the Company's completed public offering of Series B preferred stock, the Company issued two series of warrants that together provide for the purchase, by the investors in that offering, of an aggregate of 1,797,900 shares of common stock (the "Series B Warrants"). Each share of Series B preferred stock is accompanied by one warrant to purchase one share of common stock at \$4.00 per share that expires on the seventh anniversary of the date of issuance to purchase up to 50 shares of common stock and one warrant that expires on the earlier of (i) the seventh anniversary of the date of issuance or (ii) the 60th calendar day following the receipt and announcement of FDA clearance of the Company's Pantheris below-the-knee device (or the same or similar product with a different name) to purchase up to 50 shares of common stock; provided, however, if at any time during such 60-day period the volume weighted average price for any trading day is less than the then effective exercise price, the termination date shall be extended to the seven year anniversary of the initial exercise date. FDA clearance of Pantheris SV was received in April 2019, triggering this 60-day period. During the entire 60-day period following clearance, the volume weighted average price was less than the then effective exercise price. As such, all Series 2 warrants are currently deemed to expire on the seventh anniversary of the date of issuance. The Company determined that the Series B Warrants should be classified as equity. As of September 30, 2019, Series B Warrants to purchase an aggregate of 1,768,850 shares of common stock remain outstanding.

On July 13, 2018, in connection with the Company's completed public offering of 216,618 shares of common stock, the Company issued warrants that provide for the purchase of 108,309 shares of common stock at \$15.80 per share. Each share of common stock is accompanied by one half of one warrant that expires on the third anniversary of the date of issuance. The Company determined that these warrants should be classified as equity. As of September 30, 2019 all of these warrants remain outstanding.

On November 1, 2018, in connection with the Company's completed public offering of 728,500 shares of common stock and 8,586 shares of Series C convertible preferred stock, the Company issued warrants to provide for the purchase of 2,875,000 shares of common stock. Each share of common stock is accompanied by one warrant to purchase one share of common stock at \$4.00 per share. These warrants expire on the 5th anniversary of the date of issuance. Each share of preferred stock is accompanied by one warrant to purchase 250 shares of common stock. The Company determined that the warrants should be classified as equity. As of December 31, 2018 all 28,750,000 of these warrants were outstanding at a conversion rate of ten warrants for each share of common stock. During the nine months ended September 30, 2019, warrants were exercised for an aggregate of 1,998,079 shares of common stock with proceeds to the Company of approximately \$8.0 million. As of September 30, 2019, warrants to purchase an aggregate of 876,840 shares of common stock remain outstanding.

The Company accounted for the common stock warrants issued during the year ended December 31, 2018 as issuance costs relating to the respective equity financing, and used the Black-Scholes method to estimate their fair value. The fair value of the common stock warrants issued in July 2018 and November 2018 was not significant. The assumptions used to estimate the fair value of the common stock warrants issued in February 2018 were as follows:

Expected term (years)	7
Expected volatility	55%
Risk-free interest rate	2%
Dividend rate	—

As of September 30, 2019 and December 31, 2018, warrants to purchase an aggregate of 2,753,999 and 4,757,539 shares of common stock were outstanding, respectively.

Stock Plans

In January 2015, the Board of Directors adopted and the Company's stockholders approved the 2015 Equity Incentive Plan ("2015 Plan"). The 2015 Plan replaced the 2009 Stock Plan (the "2009 Plan") which was terminated immediately prior to consummation of the Company's IPO (collectively the "Plans.") The 2015 Plan provides for the grant of incentive stock options ("ISOs") to employees and for the grant of non-statutory stock options ("NSOs"), restricted stock, RSUs, stock appreciation rights, performance units and performance shares to employees, directors and consultants. Initially a total of 3,300 shares of common stock were reserved for issuance pursuant to the 2015 Plan. The shares reserved for issuance under the 2015 Plan included shares reserved but not issued under the 2009 Plan, plus any share awards granted under the 2009 Plan that expire or terminate without having been exercised in full or that are forfeited or repurchased. In addition, the number of shares available for issuance under the 2015 Plan includes an automatic annual increase on the first day of each fiscal year beginning in fiscal 2016, equal to the lesser of 4,225 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. In addition, during fiscal 2018, the Board of Directors approved an additional 300,000 shares of common stock for issuance under the 2015 Plan. The Company's stockholders approved this increase on June 8, 2018. On June 19, 2019, the Company's stockholders approved an additional 800,000 increase to the 2015 Plan. As of September 30, 2019, 68,954 shares were available for grant under the 2015 Plan.

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

Stock option activity under the Plans is set forth below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Intrinsic Value
Balance at December 31, 2018	7,954	\$ 1,707.30	7.69	\$ —
Options expired	(433)	3,015.01		
Options forfeited	(105)	\$ 1,929.52		
Balance at September 30, 2019	7,416	\$ 1,316.32	7.05	\$ —
Exercisable at September 30, 2019	7,181	\$ 1,300.40	7.05	\$ —
Vested and expected to vest at September 30, 2019	7,416	\$ 1,316.32	7.05	\$ —

There were no options exercised during the nine months ended September 30, 2019. As of September 30, 2019, there was approximately \$142,000 of remaining unamortized stock-based compensation expense associated with unvested stock options, which will be expensed over a weighted average remaining service period of approximately 1.0 years. 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 month periods ended September 30, 2019 and 2018.

The Company's RSUs generally vest annually over three or four years in equal increments. The Company measures the fair value of RSUs using the closing stock price of a share of the Company's common stock on the grant date and is recognized as expense on a straight-line basis over the vesting period of the award. A summary of all RSU activity is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term
Awards outstanding at December 31, 2018	294,066	\$ 17.34	3.1
Awarded	764,151	\$ 1.24	
Released	(96,444)	\$ 17.86	
Forfeited	(20,205)	\$ 20.46	
Awards outstanding at September 30, 2019	941,568	\$ 4.15	2.0

As of September 30, 2019, there was approximately \$3.6 million of remaining unamortized stock-based compensation expense associated with RSUs, which will be expensed over a weighted average remaining service period of approximately 2.0 years. The 941,568 outstanding non-vested and expected to vest RSUs have an aggregate intrinsic value of approximately \$782,000. The Company used the closing market price of \$0.83 per share at September 30, 2019, to determine the aggregate intrinsic value for the RSUs outstanding at that date. For the nine months ended September 30, 2019 and 2018, the fair value of RSUs vested was approximately \$110,000 and \$1,000, respectively. For the nine months ended September 30, 2018, the weighted average grant date fair value of RSUs granted was \$15.80.

2018 Officer and Director Share Purchase Plan

On August 22, 2018, the Board of Directors of the Company approved the adoption of an Officer and Director Share Purchase Plan ("ODPP"), which allows executive officers and directors to purchase shares of our common stock at fair market value in lieu of salary or, in the case of directors, director fees. Eligible individuals may voluntarily participate in the ODPP by authorizing payroll deductions or, in the case of directors, deductions from director fees for the purpose of purchasing common stock. Elections to participate in the ODPP may only be made during open trading windows under our insider trading policy when the participant does not otherwise possess material non-public information concerning the Company. The Board of Directors authorized 20,000 shares to be made available for purchase by officers and directors under the ODPP. Effective on August 28, 2019, the Board of Directors approved an additional 40,000 shares to be made available under the ODPP. Common stock issued under the ODPP during the nine months ended September 30, 2019 totaled 18,543 shares. As of September 30, 2019, there were 37,056 shares reserved for issuance under the ODPP.

8. Stock-Based Compensation

Total noncash stock-based compensation expense relating to the Company's stock options and RSUs recognized during the three and nine months ended September 30, 2019 and 2018, is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Cost of revenues	\$ 40	\$ 20	\$ 128	\$ 56
Research and development expenses	122	137	339	353
Selling, general and administrative expenses	361	611	1,065	1,619
	<u>\$ 523</u>	<u>\$ 768</u>	<u>\$ 1,532</u>	<u>\$ 2,028</u>

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

You should read the following discussion and analysis of our financial condition and results of operations together with the unaudited financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q. This discussion and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions, that are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the "Risk Factors" section of this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K filed with the SEC on March 6, 2019.

Overview

We are a commercial-stage medical device company that designs, manufactures and sells image-guided, catheter-based systems that are used by physicians to treat patients with peripheral artery disease, or PAD. Patients with PAD have a build-up of plaque in the arteries that supply blood to areas away from the heart, particularly the pelvis and legs. Our mission is to significantly improve the treatment of vascular disease through the introduction of products based on our Lumivascular platform, the only intravascular image-guided system available in this market. We manufacture and sell a suite of products in the United States and select international markets. Our current products include our Lightbox imaging console, the Ocelot family of catheters, which are designed to allow physicians to penetrate a total blockage in an artery, known as a chronic total occlusion, or CTO, and Pantheris, our image-guided atherectomy device which is designed to allow physicians to precisely remove arterial plaque in PAD patients. We received 510(k) clearance from the U.S. Food and Drug Administration, or FDA, for commercialization of Pantheris in October 2015. We received an additional 510(k) clearance for an enhanced version of Pantheris in March 2016 and commenced sales of Pantheris in the United States and select European countries promptly thereafter. In May 2018, the Company also received 510(K) clearance from the FDA for its current next-generation version of Pantheris. In April 2019, the Company received 510(K) clearance from the FDA for its Pantheris SV, a lower profile Pantheris, and commenced sales in August 2019. The Company has sales in the U.S. and select international markets. The Company is located in Redwood City, California. We also offer the Wildcat and Kittycat 2 catheters, which are used for crossing CTOs but do not contain on-board imaging technology.

We completed development of our next-generation Pantheris which we believe represents a significant improvement over our prior product. Our next-generation Pantheris includes new features and design improvements to the handle, shaft, balloon and nose cone that we believe improves usability and reliability. Our next-generation Pantheris received CE Marking approval in December 2017 and was cleared by the FDA in May 2018. The next-generation Pantheris is available for commercial sale in the EU and United States. In addition, in April 2019 we obtained FDA 510(K) clearance of a next-generation version of our Pantheris atherectomy device, Pantheris SV, a lower profile Pantheris. Pantheris SV is available for commercial sale in the EU and United States. The lower profile Pantheris has a smaller diameter and longer length that we believe will optimize it for use in smaller vessels.

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

During the fourth quarter of 2017, we began enrolling patients in INSIGHT, a clinical trial designed to support a filing with the FDA to expand the indication for our Pantheris atherectomy device to include in-stent restenosis. Patient enrollment began in October 2017 and is expected to continue through 2020. Patient outcomes will be evaluated at thirty days, six months and one year following treatment. We plan to submit a 510(k) application with the FDA seeking a specific indication for treating in-stent restenosis with Pantheris once the trial is fully enrolled and follow-up data through six months are available and analyzed.

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

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

In addition to commercialization of Pantheris in the United States and select international markets in March 2016, we began commercializing our initial non-Lumivascular platform products in 2009 and introduced our Lumivascular platform products in the United States in late 2012. We generated revenues of \$7.9 million in the year ended December 31, 2018 and \$9.9 million in the year ended December 31, 2017. During the years ended December 31, 2018 and 2017, our net loss and comprehensive loss was \$27.6 million and \$48.7 million, respectively. We have not been profitable since inception, and as of September 30, 2019, our accumulated deficit was \$343.2 million. Since inception, we have financed our operations primarily through private and public placements of our preferred and common securities and, to a lesser extent, debt financing arrangements. In January 2015, we completed an initial public offering, or IPO, of 12,500 shares. As a result of our IPO, which closed in February 2015, we received net proceeds of approximately \$56.9 million, after underwriting discounts and commissions of approximately \$4.5 million and other expenses associated with our IPO of approximately \$3.6 million.

In September 2015, we entered into a Term Loan Agreement, or Loan Agreement, with CRG Partners III L.P. and certain of its affiliated funds, collectively CRG, under which we were able to borrow up to \$50.0 million on or before March 29, 2017, subject to certain terms and conditions. We borrowed \$30.0 million on September 22, 2015 and an additional \$10.0 million on June 15, 2016 under the Loan Agreement. Contingent on achievement of certain revenue milestones, among other conditions, we would have been eligible to borrow an additional \$10.0 million, on or prior to March 29, 2017; however, we did not achieve the level of revenues required to borrow the final \$10.0 million. Contemporaneously with the execution of the Loan Agreement, we entered into a Securities Purchase Agreement with CRG, pursuant to which CRG purchased 870 shares of our common stock on September 22, 2015 at a price of \$5,596.40 per share, which represents the 10-day average of closing prices of our common stock ending on September 21, 2015. Pursuant to the Securities Purchase Agreement, we filed a registration statement covering the resale of the shares sold to CRG and must comply with certain affirmative covenants during the time that such registration statement remains in effect. We used the proceeds from the CRG borrowing and securities purchase to retire our outstanding principal and accrued interest with PDL Biopharma, or PDL, and to retire the principal and accrued interest underlying our outstanding promissory notes, or the notes.

On February 3, 2016, we filed a universal shelf registration statement to offer up to \$150.0 million of our securities and entered into an “at-the-market” program pursuant to a Sales Agreement with Cowen and Company, or Cowen, through which we may, from time to time, issue and sell shares of common stock having an aggregate offering value of up to \$50.0 million. The shelf registration statement also covers the resale of the shares sold to CRG. The registration statement was declared effective by the SEC on March 8, 2016. During the year ended December 31, 2016, we sold 2,737 shares of common stock through the “at-the-market” program at an average price of \$1,947.40 and raised net proceeds of \$5.2 million, after payment of \$0.2 million in commissions and fees to Cowen. During the year ended December 31, 2017, we sold 18,968 shares of common stock through the “at-the-market” program at an average price of \$176.80 and raised net proceeds of \$3.2 million, after payment of \$0.1 million in commissions and fees to Cowen. In addition, in August 2016 we completed a follow-on public offering of 24,644 shares of our common stock for net proceeds of approximately \$31.5 million after deducting underwriting discounts and commissions of approximately \$2.4 million and other expenses of approximately \$0.6 million. The 24,644 shares include the exercise in full by the underwriters of their option to purchase an additional 3,214 shares of our common stock.

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

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

In addition, on February 14, 2018, we entered into a Series A preferred stock Purchase Agreement (the "Series A Purchase Agreement") with CRG, pursuant to which it agreed to convert \$38.0 million of the outstanding principal amount of its senior secured term loan (plus the back-end fee and prepayment premium applicable thereto) under the Loan Agreement into a newly authorized Series A preferred stock. As discussed in the section of this report titled "Dividend Policy," the holders of Series A preferred stock are entitled to receive annual accruing dividends at a rate of 8%, payable in additional shares of Series A preferred stock or cash, at our option. The shares of Series A preferred stock have no voting rights and rank senior to all other classes and series of the Company's equity in terms of repayment and certain other rights.

On February 16, 2018, we completed a public offering of 17,979 shares of Series B preferred stock and warrants to purchase 1,797,900 shares of common stock. As a result, we received net proceeds of approximately \$15.5 million after underwriting discounts, commissions, legal and accounting fees. The Series B preferred stock has a liquidation preference of \$0.001 per share, full ratchet price based anti-dilution protection, has no voting rights and is subject to certain ownership limitations. The Series B preferred stock is immediately convertible at the option of the holder, has no stated maturity, and does not pay regularly stated dividends or interest. Each share of Series B preferred stock is accompanied by one Series 1 warrant that expires on the seventh anniversary of the date of issuance to purchase up to 50 shares of common stock and one Series 2 warrant that expires on the earlier of (i) the seventh anniversary of the date of issuance or (ii) the 60th calendar day following the receipt and announcement of FDA clearance of our Pantheris below-the-knee device (or the same or similar product with a different name) to purchase up to 50 shares of common stock; provided, however, if at any time during such 60-day period the volume weighted average price for any trading day is less than the then effective exercise price, the termination date shall be extended to the seven year anniversary of the initial exercise date. FDA clearance of Pantheris SV was received in April 2019, triggering this 60-day period. During the entire 60-day period following clearance, the volume weighted average price was less than the then effective exercise price. As such, all Series 2 warrants are currently deemed to expire on the seventh anniversary of the date of issuance. In addition, pursuant to the Series A Purchase Agreement, we issued to CRG 41,800 shares of Series A preferred stock at the closing of the Series B Offering. The Series A preferred stock was issued in exchange for the conversion of \$38.0 million of the outstanding principal amount of their senior secured term loan (plus the back-end fee and prepayment premium applicable thereto), totaling approximately \$41.8 million. The Series A Preferred Stock is initially convertible into 2,090,000 shares of common stock subject to certain limitations contained in the Series A Purchase Agreement.

On July 12, 2018, we entered into a securities purchase agreement with certain investors pursuant to which we agreed to sell and issue, in a registered direct offering, an aggregate of 216,618 shares of our common stock at an offering price of \$16.425 per share. In a concurrent private placement, or the Private Placement, we agreed to issue to these investors warrants exercisable for one share of our common stock for each two shares purchased in the registered direct offering, which equals an aggregate of 108,309 shares of common stock. The closing of such registered direct offering and the concurrent Private Placement occurred on July 16, 2018, in connection with which we received net proceeds of approximately \$3.0 million after deducting placement agent fees and other expenses payable by us. The warrants have an exercise price of \$15.80 per share of our common stock and may be exercised from time to time beginning on January 17, 2019 and expire on July 16, 2021.

On November 1, 2018, we completed a public offering of 728,500 shares of common stock and 8,586 shares of Series C convertible preferred stock (the "Series C preferred stock"). As a result, we received net proceeds of approximately \$10.2 million after underwriting discounts, commissions, legal and accounting fees. Upon any dissolution, liquidation or winding up, whether voluntary or involuntary, holders of Series C preferred stock will be entitled to receive distributions out of our assets, whether capital or surplus, of an amount equal to \$0.001 per share of Series C preferred stock before any distributions shall be made on the common stock but after distributions shall be made on any outstanding Series A preferred stock and any of our existing or future indebtedness. The Series C preferred stock has no voting rights.

On March 7, 2019, we filed a universal shelf registration statement (the "Shelf Registration Statement") to offer up to \$50.0 million of our securities. We have established, and may in the future establish, "at-the-market" programs pursuant to which we may offer and sell shares of our common stock pursuant to the Shelf Registration Statement. Due to the SEC's "baby shelf rules," which prohibit companies with a public float of less than \$75 million from issuing securities under a shelf registration statement in excess of one-third of such company's public float in a twelve-month period, we are only able to issue a limited number of shares using the Shelf Registration Statement at this time. In addition, pursuant to our Securities Purchase Agreement with CRG, the Shelf Registration Statement also registered for resale 870 shares of common stock held by CRG, which may be sold freely in the public market. Under the Shelf Registration Statement, on August 26, 2019, we completed a public offering of 3,813,559 shares of common stock at an offering price of \$1.18 per share. As a result, we received net proceeds of approximately \$3.8 million after underwriting discounts, commissions, legal and accounting fees and the conversion price of the outstanding shares of Series B preferred stock, issued in our February 2018 offering, was reduced to \$1.18 per share as a result.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenues, expenses and related disclosures of contingent assets and liabilities. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. There have been no significant and material changes in our critical accounting policies during the nine months ended September 30, 2019, 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 6, 2019.

Components of Our Results of Operations

Revenues

All of our revenues are currently derived from sales and rentals of our Lightbox console and sales of our various PAD catheters, as well as related services in the United States and select international markets. Our revenues were adversely affected by the product performance issues we have experienced with the previous version of Pantheris as well as our strategic decision to reduce the size of our sales force in April 2017 and September 2017. For the three and nine months ended September 30, 2019 and 2018, there were no customers that represented 10% or more of revenues.

Revenues may fluctuate from quarter to quarter due to a variety of factors including capital equipment purchasing patterns that are typically increased towards the end of the calendar year and decreased in the first quarter. In addition, our results can be harmed by adverse weather and by resetting of annual patient healthcare insurance plan deductibles, both of which may cause patients to delay elective procedures. In the 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 Margin

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

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

Research and Development Expenses

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

Selling, General and Administrative Expenses

Selling, general and administrative, or SG&A, expenses consist primarily of compensation for personnel, including stock-based compensation, related to selling and marketing functions, physician education programs, business development, finance, information technology and human resource functions. Other SG&A expenses include commissions, training, travel expenses, educational and promotional activities, marketing initiatives, market research and analysis, conferences and trade shows, professional services fees, including legal, audit and tax fees, insurance costs, general corporate expenses and allocated facilities-related expenses. We expect SG&A expenses to increase compared with the prior year due to expansion of our sales and marketing efforts.

Interest Income (Expense), net

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

Other Income (Expense), net

Other income (expense), net primarily consists of sublease income and gains and losses resulting from the remeasurement of foreign exchange transactions.

Results of Operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands, except percentages)			
Revenues	\$ 2,410	\$ 2,020	\$ 6,569	\$ 5,887
Cost of revenues	1,563	1,477	4,629	5,061
Gross profit (loss)	847	543	1,940	826
Gross margin	35%	27%	30%	14%
Operating expenses:				
Research and development	1,371	1,404	4,120	4,340
Selling, general and administrative	4,091	4,499	12,168	13,443
Total operating expenses	5,462	5,903	16,288	17,783
Loss from operations	(4,615)	(5,360)	(14,348)	(16,957)
Interest income (expense), net	(307)	(270)	(849)	(5,221)
Other income (expense), net	299	242	868	710
Net loss and comprehensive loss	\$ (4,623)	\$ (5,388)	\$ (14,329)	\$ (21,468)

Comparison of Three Months Ended September 30, 2019 and 2018*Revenues.*

Revenues increased by 19% to \$2.4 million for the three months ended September 30, 2019, compared to \$2.0 million for the three months ended September 30, 2018. The increase in revenues was primarily due to increased sales of our Pantheris product following the limited and commercial release of our Pantheris SV device in the third quarter of 2019.

Cost of Revenues and Gross Margin.

Cost of revenues increased by 6% to \$1.6 million for the three months ended September 30, 2019, compared to \$1.5 million for the three months ended September 30, 2018. The increase in cost of revenues was primarily due to the increase in revenues compared to the prior year period.

Gross margin 2019 increased to 35% for the three months ended September 30, compared to 27% in the three months ended September 30, 2018. The increase in gross margin was primarily due to the increase in revenues and higher facility utilization compared to the prior year period.

Research and Development Expenses ("R&D").

R&D expenses were flat, at \$1.4 million for the three months ended September 30, 2019 and 2018.

Stock-based compensation expense within R&D totaled approximately \$0.1 million during both of the three months ended September 30, 2019 and 2018.

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

SG&A expenses decreased by 9% to \$4.1 million for the three months ended September 30, 2019, compared to \$4.5 million during the three months ended September 30, 2018. The decrease was primarily due to lower professional services expenses.

Stock-based compensation expense within SG&A totaled approximately \$0.4 million and \$0.6 million during the three months ended September 30, 2019 and 2018, respectively.

Interest Income (Expense), Net.

Interest income (expense), net for the three months ended September 30, 2019 was flat compared to the three months ended September 30, 2018.

Other Income (Expense), Net.

Other income (expense), net primarily consists of sublease income and gains and losses resulting from the remeasurement of foreign exchange transactions.

Comparison of Nine Months Ended September 30, 2019 and 2018

Revenues.

For the nine months ended September 30, 2019, revenue increased 12% to \$6.6 million compared to \$5.9 million for the nine months ended September 30, 2018. The increase in revenues was primarily due to additional sales of our Pantheris Next-Generation device in 2019 after commercial release in May 2018 and higher sales of our Pantheris SV device following the limited and commercial release in the third quarter of 2019.

Cost of Revenues and Gross Margin.

Cost of revenues decreased 9% to \$4.6 million for the nine months ended September 30, 2019, compared to \$5.1 million during the nine months ended September 30, 2018. The decrease in cost of revenues was primarily due to lower charges for inventory excess and obsolescence relating to our consoles in the nine months ended September 30, 2019.

Gross margin for the nine months ended September 30, 2019 increased to 30%, compared to 14% in the nine months ended September 30, 2018. The increase in gross margin was primarily due to the lower charges for inventory excess and obsolescence compared to the prior year period.

Research and Development Expenses ("R&D").

R&D expenses decreased by 5% to \$4.1 million for the nine months ended September 30, 2019, compared to \$4.3 million during the nine months ended September 30, 2018. The decrease was primarily due to lower project related expenses associated with development activities.

Stock-based compensation expense within R&D totaled approximately \$0.3 million and \$0.4 million during the nine months ended September 30, 2019 and 2018, respectively.

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

SG&A expenses decreased by 9% to \$12.2 million for the nine months ended September 30, 2019, compared to \$13.4 million during the nine months ended September 30, 2018. The decrease was primarily due to lower personnel-related expenses including compensation expense and professional services expenses.

Stock-based compensation expense within SG&A totaled approximately \$1.1 million and \$1.6 million during the nine months ended September 30, 2019 and 2018, respectively.

Interest Income (Expense), Net. Interest income (expense), net decreased \$4.4 million to \$0.8 million during the nine months ended September 30, 2019, compared to an expense of \$5.2 million during the nine months ended September 30, 2018. The decrease was due to the conversion of the CRG note ("CRG Conversion") in February 2018 that decreased the debt outstanding.

Other Income (Expense), Net. Other income (expense), net primarily consists of sublease income and gains and losses resulting from the remeasurement of foreign exchange transactions.

Liquidity and Capital Resources

As of September 30, 2019, we had cash and cash equivalents of \$14.5 million and an accumulated deficit of \$343.2 million, compared to cash and cash equivalents of \$16.4 million and an accumulated deficit of \$328.9 million as of December 31, 2018. The Company expects to incur losses for the foreseeable future. The Company believes that its cash and cash equivalents of \$14.5 million at September 30, 2019 and expected revenues and funds from operations will be sufficient to allow the Company to fund its current operations through at least the second quarter of 2020. We do not know when or if our operations will generate sufficient cash to fund our ongoing operations. Additional debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any additional debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders and require significant debt service payments, which divert resources from other activities. Additional financing may not be available at all, or if available, may not be in amounts or on terms acceptable to us. If we are unable to obtain additional financing, we may be required to delay the development, commercialization and marketing of our products and we may be required to significantly scale back our business and operations.

To date, we have financed our operations primarily through sales of our products and net proceeds from the issuance of our preferred stock and debt financings, our “at-the-market” program, our initial public offering, or IPO, our follow-on public offerings and other post-IPO private offerings, primarily of warrants. The warrants issued pursuant to the Series B Purchase Agreement entered into in connection with the Series B preferred stock follow-on in February 2018, or the Series B Offering, prohibit us from entering into certain transactions involving the issuance of securities for a price determined by reference to the trading price of our common stock or otherwise subject to modification following the date of issuance, in each case for a period of three years from the closing date of the Series B Offering (and excluding purchases pursuant to the Series B Purchase Agreement, which may be made on the 120 day anniversary of the closing date of the offering). This prohibition may be waived by holders of two-thirds of the outstanding Series 1 and Series 2 warrants at any time.

On September 22, 2015, the Company entered into a Term Loan Agreement (the “Loan Agreement”), with CRG under which, subject to certain conditions, the Company had the right to borrow up to \$50,000,000 in principal amount from CRG on or before March 29, 2017. The Company borrowed \$30,000,000 on September 22, 2015. The Company borrowed an additional \$10,000,000 on June 15, 2016 under the Loan Agreement.

On February 14, 2018, the Company and CRG amended the Loan Agreement concurrent with the conversion of \$38,000,000 of the principal amount of the senior secured term loan (plus \$3,800,000 in back-end fees and prepayment premium applicable thereto) into shares of a newly authorized Series A convertible preferred stock. To date, the Company has elected to make payment-in-kind for the majority of the 12.5% interest rate and plans to continue doing so until such time as cash payments are required. As of March 31, 2019, the balance due under the loan, including payment-in-kind, is \$7.9 million. No cash payments will be made until the final two years of the loan, which matures in June 2023. On February 11, 2019, our board of directors declared a dividend on our Series A Preferred Stock, and we issued 2,945 shares of Series A Preferred Stock to pay the preferred dividend to the holder of Series A Preferred Stock.

On February 3, 2016, we filed a universal shelf registration statement to offer up to \$150.0 million of our securities and entered into an “at-the-market” program pursuant to a Sales Agreement with Cowen, as sales agent, through which we issued and sold common stock with an aggregate value of approximately \$8.7 million between the registration statement’s effectiveness on March 8, 2016 and September 2017. During the year ended December 31, 2016, we sold 2,737 shares of common stock through the “at-the-market” program at an average price of \$1,947.40 and raised net proceeds of \$5.2 million, after payment of \$0.2 million in commissions and fees to Cowen. During the year ended December 31, 2017, we sold 18,968 shares of common stock through the “at-the-market” program at an average price of \$176.80 and raised net proceeds of \$3.2 million, after payment of \$0.1 million in commissions and fees to Cowen. In addition, in August 2016, we issued and sold 24,644 shares of our common stock in a follow-on public offering at a public offering price of \$1,400.00 per share, for net proceeds of approximately \$31.5 million after deducting underwriting discounts and commissions of approximately \$2.4 million and other expenses of approximately \$0.6 million. The 24,644 shares include the exercise in full by the underwriters of their option to purchase an additional 3,214 shares of our common stock.

On February 16, 2018, we completed a public offering of 17,979 shares of Series B preferred stock and warrants to purchase 1,797,900 shares of common stock. As a result, we received net proceeds of approximately \$15.5 million after underwriting discounts, commissions, legal and accounting fees. The Series B preferred stock has a liquidation preference of \$0.001 per share, full ratchet price based anti-dilution protection, has no voting rights and is subject to certain ownership limitations. The Series B preferred stock is immediately convertible at the option of the holder, has no stated maturity, and does not pay regularly stated dividends or interest. Each share of Series B preferred stock is accompanied by one Series 1 warrant that expires on the seventh anniversary of the date of issuance to purchase up to 50 shares of common stock and one Series 2 warrant that expires on the earlier of (i) the seventh anniversary of the date of issuance or (ii) the 60th calendar day following the receipt and announcement of FDA clearance of our Pantheris below-the-knee device (or the same or similar product with a different name) to purchase up to 50 shares of common stock; provided, however, if at any time during such 60-day period the volume weighted average price for any trading day is less than the then effective exercise price, the termination date shall be extended to the seven year anniversary of the initial exercise date. FDA clearance of Pantheris SV was received in April 2019, triggering this 60-day period. During the entire 60-day period following clearance, the volume weighted average price was less than the then effective exercise price. As such, all Series 2 warrants are currently deemed to expire on the seventh anniversary of the date of issuance. In addition, pursuant to the Series A Purchase Agreement, we issued to CRG 41,800 shares of Series A preferred stock at the closing of the Series B Offering. The Series A preferred stock was issued in exchange for the conversion of \$38.0 million of the outstanding principal amount of their senior secured term loan (plus the back-end fee and prepayment premium applicable thereto), totaling approximately \$41.8 million. The Series A Preferred Stock is initially convertible into 2,090,000 shares of common stock subject to certain limitations contained in the Series A Purchase Agreement.

On July 12, 2018, we entered into a securities purchase agreement with certain investors pursuant to which we agreed to sell and issue, in a registered direct offering, an aggregate of 216,618 shares of our common stock at an offering price of \$16.425 per share. In a concurrent private placement, or the Private Placement, we agreed to issue to these investors warrants exercisable for one share of our common stock for each two shares purchased in the registered direct offering, which equals an aggregate of 108,309 shares of common stock. The closing of such registered direct offering and the concurrent Private Placement occurred on July 16, 2018, in connection with which we received net proceeds of approximately \$3.0 million after deducting placement agent fees and other expenses payable by us and the conversion price of the outstanding shares of Series B preferred stock, issued in our February 2018 offering, was reduced to \$15.80 per share as a result. The warrants have an exercise price of \$15.80 per share of our common stock and may be exercised from time to time beginning on January 17, 2019 and expire on July 16, 2021.

On November 1, 2018, we completed a public offering of 728,500 shares of common stock and 8,586 shares of Series C convertible preferred stock (the "Series C preferred stock"). As a result, we received net proceeds of approximately \$10.2 million after underwriting discounts, commissions, legal and accounting fees. Upon any dissolution, liquidation or winding up, whether voluntary or involuntary, holders of Series C preferred stock will be entitled to receive distributions out of our assets, whether capital or surplus, of an amount equal to \$0.001 per share of Series C preferred stock before any distributions shall be made on the common stock but after distributions shall be made on any outstanding Series A preferred stock and any of our existing or future indebtedness. The Series C preferred stock has no voting rights.

On March 7, 2019, we filed a universal shelf registration statement (the "Shelf Registration Statement") to offer up to \$50.0 million of our securities. We have established, and may in the future establish, "at-the-market" programs pursuant to which we may offer and sell shares of our common stock pursuant to the Shelf Registration Statement. Due to the SEC's "baby shelf rules," which prohibit companies with a public float of less than \$75 million from issuing securities under a shelf registration statement in excess of one-third of such company's public float in a twelve-month period, we are only able to issue a limited number of shares using the Shelf Registration Statement at this time. In addition, pursuant to our Securities Purchase Agreement with CRG, the Shelf Registration Statement also registered for resale 870 shares of common stock held by CRG, which may be sold freely in the public market. Under the Shelf Registration Statement, on August 26, 2019, we completed a public offering of 3,813,559 shares of common stock at an offering price of \$1.18 per share. As a result, we received net proceeds of approximately \$3.8 million after underwriting discounts, commissions, legal and accounting fees.

During the nine months ended September 30, 2019, we received proceeds of approximately \$8.0 million from the issuance of 1,998,079 shares of common stock related to warrant exercises.

Cash Flows

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	\$ (13,737)	\$ (14,437)
Investing activities	(70)	(383)
Financing activities	11,858	19,439
Net increase (decrease) in cash and cash equivalents	<u>\$ (1,949)</u>	<u>\$ 4,619</u>

Net Cash Used in Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2019 was \$13.7 million, consisting primarily of a net loss of \$14.3 million and an increase in net operating assets of \$3.0 million, offset by non-cash charges of \$3.5 million. The increase in net operating assets was due to fluctuations in inventories, prepaid expenses, other assets, leasehold liability, accounts payable, accrued compensation and other accrued expenses, due to timing of payments and reduction of leasehold liability. The non-cash charges primarily consisted of depreciation and amortization of \$0.8 million, stock-based compensation of \$1.5 million and non-cash interest expense of \$1.1 million.

Net cash used in operating activities for the nine months ended September 30, 2018 was \$14.4 million, consisting primarily of a net loss of \$21.5 million and an increase in net operating assets of \$2.2 million, offset by non-cash charges of \$8.9 million. The decrease in net operating assets was due to a decrease in other liabilities related to the payment of litigation settlement expense of \$1.8 million, assigned interest to PDL, partially offset by fluctuations in inventories, accounts receivable, prepaid expenses and accounts payable, due to timing of payments. The non-cash charges primarily consisted of depreciation and amortization of \$0.8 million, stock-based compensation of \$2.0 million, non-cash interest expense of \$5.3 million and an increased reserve for excess and obsolete inventories of \$0.6 million.

Net Cash Used in Investing Activities

Net cash used in investing activities in the nine months ended September 30, 2019 was \$70,000 consisting of purchases of property and equipment of \$88,000, offset by proceeds from the sale of property and equipment.

Net cash used in investing activities in the nine months ended September 30, 2018 was \$0.4 million consisting of purchases of property and equipment offset by \$28,000 of proceeds from the sale of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities in the nine months ended September 30, 2019 of \$11.9 million primarily relates to proceeds of \$8.0 million from warrant exercises and proceeds of \$3.8 million from issuance of common stock in a public offering.

Net cash provided by financing activities in the nine months ended September 30, 2018 of \$19.4 million primarily relates to proceeds from issuances of convertible preferred stock of \$15.5 million and common stock of \$3.5 million and warrant exercises of \$0.6 million.

Off-Balance Sheet Arrangements

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

Contractual Obligations

Our principal obligations consist of the operating lease of our facilities, our Loan Agreement with CRG and non-cancellable purchase commitments. The following table sets out, as of September 30, 2019, 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	
Non-cancellable purchase commitments	\$ 1,601	\$ 463	\$ 7	\$ —	\$ 2,071
CRG Loan	595	7,804	5,305	—	13,704
Operating lease obligations	1,230	2,266	2,427	205	6,128
	<u>\$ 3,426</u>	<u>\$ 10,533</u>	<u>\$ 7,739</u>	<u>\$ 205</u>	<u>\$ 21,903</u>

The total CRG Loan amount, shown as borrowings on the condensed balance sheet as of September 30, 2019, is \$8.6 million, which includes contra-debt amounts relating to debt discount and debt issuance costs that are being amortized. The contractual obligation in the table above of \$13.7 million under the CRG Loan includes future interest to be accrued but not paid in cash as well as a \$1.5 million back-end fee to be paid in June 2023 on maturity of the CRG Loan which is being accreted.

We lease our headquarters in Redwood City, California pursuant to a lease agreement with HCP LS Redwood City, LLC (the "Landlord") dated July 30, 2010, as amended by the First Amendment to Lease dated September 30, 2011 and the Second Amendment to Lease dated March 4, 2016 (the "Lease"). The Lease has a rental commencement date of December 1, 2011 and, prior to the amendment described below, expires on November 30, 2019. The Lease is for an aggregate of approximately 44,200 square feet, comprised of one building containing approximately 19,600 square feet located at 400 Chesapeake Drive, Redwood City, California 94063 (the "400 Building") and one building containing 24,600 square feet located at 600 Chesapeake Drive, Redwood City, California 94063 (the "600 Building"). We previously subleased the 600 Building to a subtenant.

On April 1, 2019, we entered into the Third Amendment to Lease with the Landlord (the "Third Amendment"), which amended the Lease to extend the lease term with respect to the 400 Building for a period of five years. As amended by the Third Amendment, the Lease, with respect to the 400 Building, will expire on November 30, 2024. Under the terms of the Third Amendment, we are obligated to pay approximately \$5.8 million in base rent payments from December 2019 through November 2024. The Third Amendment does not extend the term of the Lease with respect to the 600 Building and, therefore, the Company's lease of the 600 Building will terminate on November 30, 2019.

There have been no other material changes to our contractual obligations from those described in our Annual Report on Form 10-K, as filed with the SEC on March 6, 2019.

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, 2019 and December 31, 2018, our cash and cash equivalents were maintained with one financial institution in the United States, and our current deposits are likely in excess of insured limits. We have reviewed the financial statements of this institution and believe it has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us.

Our accounts receivable primarily relates to revenues from the sale and rental of our Lumivascular platform products to hospitals and medical centers in the United States. None of our customers represented more than 10% of our accounts receivable as of September 30, 2019 and December 31, 2018.

Foreign Currency Risk

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended (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, 2019. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of September 30, 2019, 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 2019 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

Except as described below, there have been no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 6, 2019.

Risks Related to Our Business

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

We were incorporated in 2007, began commercializing our initial non-Lumivasular platform products in 2009 and introduced our first Lumivasular platform products in the United States in late 2012. We received 510(k) clearance from the FDA, for commercialization of Pantheris in October 2015, an additional 510(k) clearance for an enhanced version of Pantheris in March 2016 and commenced sales of Pantheris in the United States and select international markets promptly thereafter. Our current next-generation version of Pantheris received FDA clearance in May 2018. Our Pantheris SV received FDA clearance in April 2019 and commenced sales in August 2019. Our limited commercialization experience and number of approved products make it difficult to evaluate our current business and predict our future prospects. We have encountered and will continue to encounter risks and difficulties frequently experienced by companies in rapidly-changing industries. These risks and uncertainties include the risks inherent in clinical trials, market acceptance of our products, and increasing and unforeseen expenses as we continue to attempt to grow our business.

In addition, we have in the past, and may in the future, become aware of performance issues with our products. For example, prior to becoming commercially available on March 1, 2016, Pantheris had been used in clinical trials mainly in controlled situations. Since its commercialization and as more physicians have used Pantheris, we have received additional feedback on its performance, both positive and negative. We have attempted to address certain of these concerns with our current version of Pantheris. However, there can be no assurance that the changes and improvements will fully address the performance issues that have been raised by earlier versions of Pantheris. Even if these issues are resolved and physician concerns addressed, future product performance issues may occur and our reputation could suffer, which could lead to decreased sales of our products. Our revenue has been and continues to be adversely impacted by these product performance issues. We also had to incur additional expenses to make product changes and improvements, and to replace products in accordance with our warranty policy. This additional expense, and any future expense that we may incur as a result of future product performance issues, will negatively impact our financial performance and results of operations. If we are unable to improve the performance of our products to meet the concerns of physicians our revenue may decline further or fail to increase.

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

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

Ocelot, Ocelot PIXL, Ocelot MVRX, Lightbox, Wildcat, Kittycat 2 and Pantheris are our only products currently cleared for sale, and our current revenues are wholly dependent on them. Sales of Wildcat and Kittycat 2 have declined and are continuing to decline as we focus on the promotion of our Lumivasular platform products. In addition, the long-term viability of our company is largely dependent on the successful commercialization and continued development of Pantheris and we expect that sales of our next-generation Pantheris and Pantheris SV and our other current and future Lumivasular platform products in the United States will account for substantially all of our revenues for the foreseeable future. Accordingly, our success depends on the continued and growing acceptance and use of Pantheris and our other Lumivasular platform products by the medical community. All of our products have a limited commercial history. For example, we received 510(k) clearance from the FDA to commercialize Pantheris in October 2015 as well as a separate FDA clearance to market enhanced versions of Pantheris in March 2016 and May 2018 and FDA clearance to market Pantheris SV in April 2019 and those versions of Pantheris became or will become commercially available in the United States and select international markets promptly thereafter. As such acceptance among physicians of these products may not increase or may decline.

Our ability to successfully market Pantheris will also be limited due to a number of factors including regulatory restrictions in our labeling. We cannot assure you that demand for Pantheris and our other Lumivasular platform products will continue to grow and our products may not significantly penetrate current or new markets. Market demand for Pantheris and physician adoption of this product also may be negatively impacted by product performance issues that we have experienced and the need to replace certain products in accordance with our warranty policy. Utilization of our products has been less than we anticipated historically. If demand for Pantheris and our other Lumivasular platform products does not increase and we cannot sell our products as planned, our financial results will be harmed. In addition, market acceptance may be hindered if physicians are not presented with compelling data from long-term studies of the safety and efficacy of our 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, or our failure to successfully commercialize Pantheris, would harm our business, financial condition and results of operations.

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

Risks Related to Our Intellectual Property

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, 2019, we held 29 issued and allowed U.S. patents and had 27 U.S. utility patent applications and 1 PCT applications pending. As of September 30, 2019, we also had 54 issued and allowed patents outside of the United States. As of September 30, 2019, we had 44 pending patent applications outside of the United States, including in Australia, Canada, China, Europe, India and Japan. Our patents and patent applications include claims covering key aspects of the design, manufacture and therapeutic use of OCT imaging catheters, occlusion-crossing catheters, atherectomy devices and our imaging console. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Any patents issued to us may be challenged by third parties as being invalid, or third parties may independently develop similar or competing technology that avoids our patents. Should such challenges be successful, competitors might be able to market products and use manufacturing processes that are substantially similar to ours. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors or former or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property rights to the same extent as the laws of the United States.

Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology. To the extent our intellectual property protection is incomplete, we are exposed to a greater risk of direct competition. In addition, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our Lumivasular platform, brand and business.

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

Risks Related to Government Regulation

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

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

In March 2019, we successfully transferred all current product certificates from BSI-UK to BSI-Netherlands in anticipation of a no-deal Brexit. Our products currently CE marked and distributed in the EU will be subject to the new EU MDR regulations (replacing the current MDD) starting in May 2020 with a transitional period extending to May 27, 2024 or the length of the currently issued Notified Body certification, whichever comes first. While we have multiple ongoing efforts to update our Quality Management System and product Technical Documentation to be fully compliant with the new requirements and intend to be certified to MDR before the deadline, (as required by our Notified Body BSI) during the transition period, and until such time as we are fully certified to the new MDR, we will be highly limited in our ability to make significant product changes to existing design and intended purposes of products (EU only) and/or will be unable to launch new products in the EU. If we do not become fully certified, such limitations could harm our business, financial condition and operating results.

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

Our Lumivasular 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;
- pre-marketing 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 pre-marketing 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 and Pantheris SV, our image-guided atherectomy devices, 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. We obtained 510(k) clearance for our next-generation Pantheris in May 2018 and for Pantheris SV in April 2019 and we are currently selling both of these devices. 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 medical device reports, or MDRs, 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 MDRs 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.

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 publicly 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 that could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

The FDA and the Federal Trade Commission, or FTC, also regulate the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances, that there are adequate and reasonable scientific 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, adverse publicity, and we may be required to revise our promotional claims and make other corrections or restitutions.

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

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

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

Risks Related to Our Common Stock and Preferred Stock

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

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

We will need to raise additional funds through future equity or debt financings to meet our operational needs and capital requirements for product development, clinical trials and commercialization. We can provide no assurance that we will be successful in raising funds pursuant to additional equity or debt financings or that such funds will be raised at prices that do not create substantial dilution for our existing stockholders. Given the recent decline in our stock price, any financing that we undertake in the next nine months could cause substantial dilution to our existing stockholders.

The warrants issued in connection with the Series B preferred stock prohibit us from entering into certain transactions involving the issuance of securities for a variable price determined by reference to the trading price of our common stock or otherwise subject to modification following the date of issuance, in each case until February 17, 2021. This prohibition may be waived by holders of two-thirds of the outstanding Series 1 and Series 2 warrants at any time. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. Sales of newly issued securities under any registration statement will result in dilution of our stockholders and could cause our stock price to fall.

On March 7, 2019, we filed a universal shelf registration statement (the "Shelf Registration Statement") to offer up to an aggregate of \$50.0 million of our securities, including common stock, preferred stock, depositary shares, warrants, debt securities, subscription rights, units or any combination of the foregoing. However, we may not be able to raise additional funds on favorable terms, or at all. In addition, due to the SEC's "baby shelf rules," which prohibit companies with a public float of less than \$75 million from issuing securities under a shelf registration statement in excess of one-third of such company's public float in a twelve-month period, we are only able to issue a limited number of shares using the Shelf Registration Statement at this time. Further, pursuant to our Securities Purchase Agreement with CRG, the Shelf Registration Statement also registered for resale 870 shares of common stock held by CRG, which may be sold freely in the public market.

Our directors and employees may sell our stock through 10b5-1 trading plans or in the market during open windows under our insider trading policy without such plans in place. Sales of our common stock by our directors and employees could be perceived negatively by investors or cause downward pressure on our common stock and cause a reduction in the price of our common stock as a result. We have also registered shares of our common stock that we may issue under our employee equity incentive plans. These shares will be able to be sold freely in the public market upon issuance.

Nasdaq may delist our securities from its exchange, which could harm our business and limit our stockholders' liquidity.

Our common stock is currently listed on the Nasdaq Capital Market, which has qualitative and quantitative listing criteria. However, we cannot assure you that our common stock will continue to be listed on Nasdaq in the future. In order to continue listing our common stock on Nasdaq, we must maintain certain financial, distribution and stock price levels. Generally, we must maintain a minimum amount in stockholders' equity and a minimum number of holders of our common stock.

The continued listing requirements in Nasdaq Marketplace Rule 5550(a)(2) requires issuers to maintain a minimum bid price of at least \$1.00 per share. The trading price of our common stock has closed below \$1.00 each trading day since September 25, 2019. As of the date hereof, we have not received any notice from Nasdaq that we are not in compliance with Nasdaq Marketplace Rule 5550(a)(2). If we fail to comply with Rule 5550(a)(2), Nasdaq may delist our common stock from trading on its exchange.

If Nasdaq delists our common stock from trading on its exchange and we are not able to list our securities on another national securities exchange, we expect our securities could be quoted on an over-the-counter market. If this were to occur, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as "covered securities." If our common stock continues to be listed on NASDAQ, our common stock will be a covered security. Although the states are preempted from regulating the sale of our securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case.

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

Series A preferred stock has a liquidation preference that gets paid prior to any payment on our common stock (including shares issuable upon the exercise of our outstanding warrants) and Series B preferred stock. As a result, if we were to dissolve, liquidate, merge with another company or sell our assets, the holders of our Series A preferred stock would have the right to receive up to approximately \$41,800,000, plus any unpaid dividends from any such transaction before any amount is paid to the holders of our Series B preferred stock, Series C preferred stock or common stock or pursuant to the redemption rights in the warrants for fundamental transactions. The payment of the liquidation preferences could result in common stockholders, Series B preferred stockholders, Series C preferred stockholders and warrant holders not receiving any consideration if we were to liquidate, dissolve or wind up, either voluntarily or involuntarily. In January 2019, we paid Series A preferred stock dividends of \$2.9 million through the issuance of a 2,945 shares of Series A preferred stock.

The existence of the liquidation preferences may reduce the value of our common stock, make it harder for us to sell shares of common stock in offerings in the future, or prevent or delay a change of control.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The following exhibits are being filed herewith:

Exhibit Number	Exhibit Title
10.1	Amended and Restated Officer and Director Share Purchase Plan
31.1	Certification of the Principal 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 Principal 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

* The certifications filed as Exhibits 32.1 are not deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the Company under the Securities Exchange Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof irrespective of any general incorporation by reference language contained in any such filing, except to the extent that the registrant specifically incorporates it by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Avinger, Inc.
(Registrant)

Date: November 5, 2019

/s/ JEFFERY M. SOINSKI

Jeffrey M. Soinski
Chief Executive Officer
(Principal Executive Officer)

Date: November 5, 2019

/s/ MARK WEINSWIG

Mark Weinswig
Chief Financial Officer
(Principal Financial and Accounting Officer)

AVINGER, INC.

Amended and Restated Officer and Director Share Purchase Plan

August 28, 2019

1. Purpose. The purpose of the Plan is to provide a convenient method by which Eligible Individuals of the Company may purchase fully vested Company common stock at fair market value. This Plan is effective as of August 22, 2018.

2. Definitions.

2.1 "1934 Act" means the Securities Exchange Act of 1934, as amended. Reference to a specific section of the 1934 Act or regulation thereunder shall include such section or regulation, any valid regulation promulgated under such section, and any comparable provision of any future legislation or regulation amending, supplementing or superseding such section or regulation.

2.2 "Board" means the Board of Directors of the Company.

2.3 "Committee" means the Compensation Committee of the Board.

2.4 "Company" means Avinger, Inc.

2.5 "Director" means a nonemployee member of the Board.

2.6 "Eligible Individual" means an Officer or Director who has been designated by the Committee as eligible to participate in the Plan.

2.7 "Fair Market Value" means (a) if the shares are traded on The Nasdaq Capital Market, the "market price" as defined under the rules of The Nasdaq Capital Market or (b) if the shares are not traded on The Nasdaq Capital Market, the closing sales price for a Share (or the closing bid, if no sales were reported) on the relevant date, or if there were no sales on such date, the last quoted per Share selling price for Shares on the nearest day before the relevant date, as quoted on the established stock exchange or national market system where the Shares are listed on the day of determination, as reported in The Wall Street Journal or such other source as the Committee deems reliable.

2.8 "Fees" means the cash retainer fees and meeting fees payable to a Director biannually as a result of his or her service on the Board and its committees during the applicable biannual payment period.

2.9 "Officer" means a person who is an "Executive Officer" of the Company within the meaning of Nasdaq Listing Rule 5605(a) or its successor provision. As of the date of the adoption of this Plan, the term "Executive Officer" for purposes of Nasdaq Listing Rule 5605(a) means the Company's president, principal financial officer, principal accounting officer (or, if there is no such accounting officer, the controller), any vice-president in charge of a principal business unit, division or function (such as sales, administration or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company, including officers of the Company's parent or subsidiaries if they perform such policy-making functions for the Company.

2.10 "Participant" means an Eligible Individual who elects to participate in the Plan in accordance with Section 5.1.

2.11 "Plan" means this Officer and Director Share Purchase Plan, as it may be amended from time to time.

2.12 "Share" means a share of the Company's common stock.

2.13 "Trading Day" means a day on which national stock exchanges and The Nasdaq Capital Market are open for trading. A Trading Day begins at the time trading begins on such day.

2.14 "Trading Window" means the period commencing at the opening of market on the third Trading Day following the date of public disclosure of the financial results for a particular fiscal quarter or fiscal year of the Company and continuing until the close of market on the fifteenth Trading Day prior to the close of the fiscal quarter, provided that during this period no circumstances exist that otherwise closes the Trading Window.

3. Administration.

3.1 The Plan will be interpreted and administered by the Committee, whose actions and interpretations will be final and binding.

3.2 The Committee, in its sole discretion, will have the power, subject to, and within the limitations of, the express provisions of the Plan:

3.2.1 To interpret and determine the meaning, validity and parameters of the terms and provisions of the Plan and to determine any question arising under, or in connection with, the administration, operation or validity of the Plan;

3.2.2 To determine the form and manner for Participants to make elections under the Plan and to approve forms of election to be used in conjunction with the Plan;

3.2.3 To determine the time or times when Eligible Individuals may elect to participate in the Plan or otherwise change such elections;

3.2.4 To select the Officers and Directors who will be eligible to participate in the Plan from time to time;

3.2.5 To make any and all determinations as it may deem necessary or appropriate for the administration of the Plan, including the number of Shares to be issued in exchange for a Participant's aggregate deductions;

3.2.6 To establish, amend and revoke rules and procedures relating to the Plan (for example, but not by way of limitation, with respect to Eligible Individual elections to participate in the Plan and the delivery of Shares) as it may deem necessary or appropriate for the administration of the Plan;

3.2.7 To employ such brokers, counsel, agents and advisers, and to obtain such broker, legal, clerical and other services, as it may deem necessary or appropriate in carrying out the provisions of the Plan; and

3.2.8 To delegate all or any part of its authority and powers under the Plan to one or more officers or employees of the Company, including with respect to the day-to-day administration of the Plan.

4. Shares Subject to the Plan.

4.1 Subject to adjustment as provided in Section 4.2, the total number of Shares available for issuance under the Plan shall equal sixty thousand (60,000). Shares granted under the Plan may be either authorized but unissued Shares or treasury Shares.

4.2 In the event that any dividend or other distribution (whether in the form of cash, Shares, other securities, or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of Shares or other securities of the Company, or other change in the corporate structure of the Company affecting the Shares, then the Committee shall, in such manner as it may deem equitable, adjust the number and class of Shares which may be delivered under the Plan. Notwithstanding the preceding, the number of Shares available for issuance under the Plan always shall be a whole number.

5. Election to Purchase Shares.

5.1 Elections.

(i) Each Eligible Individual's decision to participate in the Plan shall be entirely voluntary. An Eligible Individual may become a Participant in the Plan by enrolling or re-enrolling in the Plan during a Trading Window, provided that the Participant does not otherwise possess material non-public information concerning the Company (within the meaning of the 1934 Act) at the time of his or her election. In order to enroll, an Eligible Individual must complete, sign and submit to the Company an election form, in such form as the Committee will determine in its sole discretion.

(ii) On his or her election form, each Eligible Individual must authorize payroll deductions or, in the case of Directors, deductions from Fees for the purposes of purchasing fully vested Shares. Any deductions for this Plan will occur after normal and appropriate withholding for all Federal, State and other applicable taxes and obligations and after voluntary withholdings for participation in other Company benefit plans. With respect to Officers, the payroll deductions may not reduce the individual's compensation below an amount equal to two (2) times the federal or applicable state minimum wage, whichever is higher, required to be paid each pay period. Payroll deductions for a Participant who is an Officer will commence with the first full payroll period immediately following the date the Participant submits a properly completed election form to the Company. Deductions from Fees for a Participant who is a Director will commence on the first day on which the foregone Fees would have been paid to the Director and will apply only to Fees earned and paid after the date the Participant submits a properly completed election form to the Company.

5.2 Duration of Elections. An Eligible Individual's election form will remain in effect unless amended or terminated as provided in Section 5.3.

5.3 Amendment or Termination of Elections.

(i) A Participant may terminate his or her participation in the Plan at any time by providing notice of termination to the Company in a manner and pursuant to such procedures as the Committee may determine from time to time. A Participant's election to terminate participation shall be effective as soon as administratively practicable following the Company's receipt of the Participant's notice of termination, provided that the Participant has certified that his or her decision to terminate participation is made in good faith and in full compliance with both the letter and spirit of all federal and state securities laws.

(ii) A Participant may increase or decrease the rate of his or her payroll deductions or Fee deductions, as applicable, by submitting a new election form to the Company at any time during a Trading Window, provided that the Participant does not otherwise possess material non-public information concerning the Company (within the meaning of the 1934 Act) at the time of his or her new election. Notwithstanding the foregoing, a Participant may not decrease the rate of his or her deductions below \$500 with respect to each Officer payroll date or \$500 with respect to each Director Fee payment date, as applicable. Provided that a Participant has properly submitted a completed election form, the change in payroll or Fee deduction rate will be effective as soon as administratively practicable following the date the Company receives the Participant's new election form and will apply only to compensation or Fees earned after such date.

6. Purchase and Delivery of Shares.

6.1 On, or as soon as administratively practicable following, each payroll date or, in the case of Directors, each date on which Fees would otherwise be paid, each Participant's aggregate deductions for the applicable period will be converted into fully vested Shares based on the Fair Market Value of a Share on such date. No fractional Shares will be purchased. Any payroll or Fee deductions which are not sufficient to purchase a full Share will be paid to the Participant in cash.

6.2 Shares paid out to a Participant under the Plan will be delivered electronically to the Participant's broker as indicated in the Participant's election form or, if not specified, to the Participant's broker(s) of record as listed in the Company's records at the time of delivery.

7. Amendment or Termination of the Plan. The Committee may, at any time and for any reason, amend or terminate the Plan without regard to whether the amendment or termination may adversely affect any Participant. Without limiting the generality of the foregoing, such amendment or termination may be effective immediately notwithstanding that (i) elections have been made and are then in effect and (ii) deductions have been withheld but not yet applied to the purchase of Shares, in which case such deductions will be paid to the Participant in cash as soon as administratively practicable. No amendment or modification will require the consent of any Participants.

8. No Guarantee of Future Service. Neither the establishment or maintenance of the Plan, the purchase of Shares, nor any action of the Company or the Committee, will be held or construed to confer upon any Officer or Director any right to be continued as an employee or Director of the Company, as applicable, nor, upon dismissal, any right or interest in any specific assets of the Company other than as provided in the Plan. The Company expressly reserves the right to discharge any Officer at any time, with or without cause.

9. Tax Reporting. The participant will be responsible for reporting and paying any and all federal, state, or any other tax liabilities that arise from selling or otherwise disposing of the Shares. At any time, the Company may, but will not be obligated to, withhold from the Participant's compensation the amount necessary for the Company to meet applicable withholding obligations, including any withholding required to make available to the Company any tax deductions or benefits attributable to the issuance, sale or disposition of Shares by the Participant.

10. Choice of Law. All questions concerning the construction, validity, and interpretation of the Plan will be governed by the law of the State of California, exclusive of the conflict of laws provisions thereof.

11. Severability. In the event any provision of the Plan shall be held illegal or invalid for any reason, the illegality or invalidity shall not affect the remaining parts of the Plan, and the Plan shall be construed and enforced as if the illegal or invalid provision had not been included.

12. Requirements of Law. The Company shall not be required to issue any certificate or certificates for Shares hereunder prior to fulfillment of all the following conditions: (a) the admission of such Shares to listing on all stock exchanges on which such class of stock is then listed; (b) the completion of any registration or other qualification of such Shares under any U.S. state or federal law or under the rulings or regulations of the Securities and Exchange Commission or any other governmental regulatory body, which the Committee shall, in its absolute discretion, deem necessary or advisable; and (c) the obtaining of any approval or other clearance from any U.S. state or federal governmental agency, which the Committee shall, in its absolute discretion, determine to be necessary or advisable.

13. Headings. The headings in the Plan are for convenience only and will not be deemed to constitute a part hereof nor to affect the meaning hereof.

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

I, Jeffrey Soinski, hereby certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Avinger, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 5, 2019

/s/ Jeffrey M. Soinski

Jeffrey M. Soinski

Chief Executive Officer

(Principal Executive Officer)

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

I, Mark Weinswig, hereby certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Avinger, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 5, 2019

/s/ Mark Weinswig
Mark Weinswig
Chief Financial Officer
(Principal Financial and Accounting Officer)

**CERTIFICATIONS OF 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**

In connection with the Quarterly Report of Avinger, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2019, as filed with the Securities and Exchange Commission (the "Report"), Jeffrey Soinski, as Chief Executive Officer of the Company, and Mark Weinswig, Chief Financial Officer of the Company, each hereby certifies, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350), to his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of November 5, 2019.

/s/ Jeffrey M. Soinski

Jeffrey M. Soinski

Chief Executive Officer

(Principal Executive Officer)

/s/ Mark Weinswig

Mark Weinswig

Chief Financial Officer

(Principal Financial and Accounting Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.