

# SECURITIES & EXCHANGE COMMISSION EDGAR FILING

**Avinger Inc**

**Form: 10-Q**

**Date Filed: 2020-11-10**

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, 2020

or

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

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:	Trading Symbol(s):	Name of each exchange on which registered:
Common Stock, par value \$0.001 per share	AVGR	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 6, 2020, the number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 84,922,079.

## 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 current clinical studies and any additional clinical studies we initiate;
  - our plans to modify our current products, or develop new products, to address additional indications;
  - our ability to obtain additional financing through future equity or debt financings;
  - the expected timing of 510(k) clearances by the FDA for enhanced versions of Pantheris, Ocelot and Lightbox;
  - the expected timing of 510(k) submission to the FDA, and associated marketing clearances by the FDA, for additional versions of Pantheris, Ocelot and Lightbox;
  - 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 and Ocelot to qualify for reimbursement codes used by other atherectomy products;
  - our ability to continue as a going concern;
  - our ability to remain in compliance with the listing requirements of the Nasdaq Capital Market;
  - 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;
  - the effects of the COVID-19 pandemic on our business and results of operations;
  - 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;
  - developments and projections relating to our competitors or our industry; and
  - our expectations of qualitative and quantitative effects of COVID-19 to the extent discussed, as well as any expectations of recovery from or forward looking short-term or long-term implications thereof.
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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, our Quarterly Report on Form 10-Q filed with the SEC on May 13, 2020, our Quarterly Report on Form 10-Q filed with the SEC on July 31, 2020, and our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 5, 2020. 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.

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**AVINGER, INC.**  
**AS OF AND FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2020**

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"Avinger," "Pantheris," "Lumivascular," and "Tigereye" 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 <sup>TM</sup> symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and trade names.

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PART I. FINANCIAL INFORMATION

ITEM 1. UNAUDITED FINANCIAL STATEMENTS

AVINGER, INC.  
CONDENSED BALANCE SHEETS  
(unaudited)

(In thousands, except share and per share data)

	September 30, 2020	December 31, 2019
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 25,326	\$ 10,943
Accounts receivable, net of allowance for doubtful accounts of \$19 at both September 30, 2020 and December 31, 2019	1,341	1,458
Inventories	3,994	3,912
Prepaid expenses and other current assets	524	311
Total current assets	<u>31,185</u>	<u>16,624</u>
Right of use asset	4,269	4,856
Property and equipment, net	942	1,661
Other assets	550	684
Total assets	<u>\$ 36,946</u>	<u>\$ 23,825</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 632	\$ 663
Accrued compensation	1,455	1,782
Series A preferred stock dividends payable	2,900	—
Accrued expenses and other current liabilities	683	654
Leasehold liability, current portion	787	722
Borrowings, current portion	11,632	8,967
Total current liabilities	<u>18,089</u>	<u>12,788</u>
Leasehold liability, long-term portion	3,483	4,135
Borrowings, long-term portion	911	—
Other long-term liabilities	9	7
Total liabilities	<u>22,492</u>	<u>16,930</u>
Commitments and contingencies (Note 6)		
<b>Stockholders' equity:</b>		
Convertible preferred stock issuable in series, par value of \$0.001;		
Shares authorized: 5,000,000 at September 30, 2020 and December 31, 2019;		
Shares issued and outstanding: 48,503 at September 30, 2020 and December 31, 2019; aggregate liquidation preference of \$48,503 at September 30, 2020 and December 31, 2019		
	—	—
Common stock, par value of \$0.001;		
Shares authorized: 100,000,000 at September 30, 2020 and December 31, 2019;		
Shares issued and outstanding: 84,921,079 and 10,364,663 at September 30, 2020 and December 31, 2019, respectively		
	85	10
Additional paid-in capital	377,080	355,220
Accumulated deficit	(362,711)	(348,335)
Total stockholders' equity	<u>14,454</u>	<u>6,895</u>
Total liabilities and stockholders' equity	<u>\$ 36,946</u>	<u>\$ 23,825</u>

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,	
	2020	2019	2020	2019
Revenues	\$ 2,302	\$ 2,410	\$ 6,029	\$ 6,569
Cost of revenues	1,525	1,563	4,392	4,629
Gross profit	<u>777</u>	<u>847</u>	<u>1,637</u>	<u>1,940</u>
Operating expenses:				
Research and development	1,417	1,371	4,308	4,120
Selling, general and administrative	3,461	4,091	10,501	12,168
Total operating expenses	<u>4,878</u>	<u>5,462</u>	<u>14,809</u>	<u>16,288</u>
Loss from operations	(4,101)	(4,615)	(13,172)	(14,348)
Interest income	1	70	33	242
Interest expense	(433)	(377)	(1,245)	(1,091)
Other income, net	8	299	8	868
Net loss and comprehensive loss	(4,525)	(4,623)	(14,376)	(14,329)
Accretion of preferred stock dividends	(967)	(895)	(2,901)	(2,685)
Net loss attributable to common stockholders	<u>\$ (5,492)</u>	<u>\$ (5,518)</u>	<u>\$ (17,277)</u>	<u>\$ (17,014)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.08)</u>	<u>\$ (0.70)</u>	<u>\$ (0.46)</u>	<u>\$ (2.75)</u>
Weighted average common shares used to compute net loss per share, basic and diluted	<u>69,459</u>	<u>7,900</u>	<u>37,246</u>	<u>6,189</u>

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, 2020	48,503	\$ —	51,339,024	\$ 51	\$ 365,684	\$ (358,186)	\$ 7,549
Issuance of common stock in public offerings, net of commissions and issuance costs	—	—	33,221,725	33	11,979	—	12,012
Vesting of restricted stock units	—	—	360,330	1	—	—	1
Employee stock-based compensation	—	—	—	—	384	—	384
Accretion of Series A preferred stock dividends	—	—	—	—	(967)	—	(967)
Net and comprehensive loss	—	—	—	—	—	(4,525)	(4,525)
Balance at September 30, 2020	48,503	\$ —	84,921,079	\$ 85	\$ 377,080	\$ (362,711)	\$ 14,454

	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 and vesting of restricted stock units	—	—	107,303	—	18	—	18
Employee stock-based compensation	—	—	—	—	523	—	523
Issuance of common stock in 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

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, 2019	48,503	\$ —	10,364,663	\$ 10	\$ 355,220	\$ (348,335)	\$ 6,895
Issuance of common stock in public offerings, net of commissions and issuance costs	—	—	74,140,297	74	23,574	—	23,648
Issuance of common stock under officers and directors purchase plan and vesting of restricted stock units	—	—	416,119	1	27	—	28
Employee stock-based compensation	—	—	—	—	1,160	—	1,160
Accretion of Series A preferred stock dividends	—	—	—	—	(2,901)	—	(2,901)
Net and comprehensive loss	—	—	—	—	—	(14,376)	(14,376)
Balance at September 30, 2020	48,503	\$ —	84,921,079	\$ 85	\$ 377,080	\$ (362,711)	\$ 14,454

	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
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)	—	—
Exercises of warrants for common stock	—	—	1,998,079	2	7,991	—	7,993
Issuance of common stock in public offering, net of commissions and issuance costs	—	—	3,813,559	4	3,807	—	3,811
Issuance of common stock under officers and directors purchase plan and vesting of restricted stock units	—	—	115,091	—	54	—	54
Employee stock-based compensation	—	—	—	—	1,532	—	1,532
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

See accompanying notes.

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

	Nine Months Ended September 30,	
	2020	2019
<b>Cash flows from operating activities</b>		
Net loss	\$ (14,376)	\$ (14,329)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	676	654
Amortization of debt issuance costs and debt discount	126	129
Stock-based compensation	1,160	1,532
Noncash interest expense	1,119	962
Change in right of use asset	129	(357)
Provision for excess and obsolete inventories	390	80
Other non-cash (gains) losses, net	(52)	—
Changes in operating assets and liabilities:		
Accounts receivable	142	(147)
Inventories	(464)	(1,149)
Prepaid expenses and other current assets	(197)	(59)
Other assets	5	(16)
Accounts payable	(31)	(229)
Accrued compensation	(327)	(8)
Accrued expenses and other current liabilities	29	(768)
Other long-term liabilities	—	(32)
Net cash used in operating activities	(11,671)	(13,737)
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	—	(88)
Proceeds from sale of property and equipment	40	18
Net cash provided by (used in) investing activities	40	(70)
<b>Cash flows from financing activities</b>		
Proceeds from borrowings	2,330	—
Proceeds from the issuance of common stock related to warrant exercises	—	7,993
Proceeds from the issuance of common stock in public offerings, net	23,648	3,811
Proceeds from the issuance of common stock under officers and directors purchase plan	36	54
Net cash provided by financing activities	26,014	11,858
Net change in cash and cash equivalents	14,383	(1,949)
Cash and cash equivalents, beginning of period	10,943	16,410
Cash and cash equivalents, end of period	\$ 25,326	\$ 14,461
<b>Supplemental disclosure of cash flow information</b>		
Noncash investing and financing activities:		
Accretion of Series A preferred stock dividends	\$ 2,901	\$ 2,685
Issuance of Series A preferred stock to pay dividends	\$ —	\$ 2,918
Reclassification of right of use asset to prepaid rent	\$ (129)	\$ 358
Increase to right of use asset and leasehold liability arising from lease amendment	\$ —	4,680
Transfers between inventory and property and equipment	\$ (7)	\$ 380

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 Kittykat, as well as its Lumivascular platform products, Ocelot, Ocelot PIXL, Ocelot MVRX and Ocelaris (“Tigereye”), all of which are designed to allow physicians to penetrate a total blockage in an artery, known as a chronic total occlusion (“CTO”). The Company also has image-guided atherectomy systems under its suite of Lumivascular products, Pantheris and Pantheris SV, which are designed to allow physicians to precisely remove arterial plaque in PAD patients. 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, 2020, the Company had an accumulated deficit of \$362.7 million. The Company expects to incur losses for the foreseeable future. The Company believes that its cash and cash equivalents of \$25.3 million at September 30, 2020 and expected revenues and funds from operations will be sufficient to allow the Company to fund its current operations through at least the fourth quarter of 2021. Even though we received net proceeds of approximately \$8 million from the issuance of common stock upon the exercise of warrants during April and May of 2019, net proceeds of \$3.8 million from the sales of our common stock in our August 2019 offering, \$3.9 million from the sale of our common stock in our January 2020 offering, \$2.3 million of loan proceeds in April 2020 pursuant to the Paycheck Protection Program (“PPP”) under the Coronavirus Aid, Relief and Economic Security (“CARES”) Act, \$3.0 million from the sale of our common stock in April and May 2020, \$5.5 million from the sale of our common stock in June and July 2020 and \$11.3 million from the sale of our common stock in August and September 2020, 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. In addition, the COVID-19 pandemic and responses thereto have resulted in reduced consumer and investor confidence, instability in the credit and financial markets, volatile corporate profits, restrictions on elective medical procedures, and reduced business and consumer spending, which could increase the cost of capital and/or limit the availability of capital to the Company. During the second quarter of 2020 we took certain actions to manage available cash and other resources to mitigate the effects of COVID-19 on our business, which included reduction of discretionary costs, reduction of base salaries for all of our non-manufacturing employees by 20% and reduction of hours worked by our manufacturing workers by 20%. While salaries and hours worked largely returned to prior levels in July 2020, we will continue to employ certain actions to manage our resources in the foreseeable future. There can be no assurance that such strategies will be successful in mitigating the negative impacts of the COVID-19 pandemic on our business. These conditions raise substantial doubt about the Company’s ability to continue as a going concern.

If the Company is unable to raise additional capital in sufficient amounts or on terms acceptable to it, the Company may have to significantly reduce its operations or delay, scale back or discontinue the development of one or more of its products. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. The Company's ultimate success will largely depend on its continued development of innovative medical technologies, its ability to successfully commercialize its products and its ability to raise significant additional funding.

Additionally, due to the substantial doubt about the Company's ability to continue operating as a going concern and the material adverse change clause in the Loan Agreement with CRG Partners III L.P. and certain of its affiliated funds (collectively "CRG"), the entire amount of borrowings at September 30, 2020 and December 31, 2019 has been classified as current in these financial statements. CRG has not invoked the material adverse change clause.

## **Public Offerings**

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.

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.

On January 31, 2020, we completed a public offering of 6,428,572 shares of common stock at an offering price of \$0.70 per share. As a result, we received net proceeds of approximately \$3.9 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses. Due to anti-dilution provisions, the conversion price of the outstanding shares of Series B preferred stock, which was issued in our February 2018 offering, was reduced to \$0.70 per share.

On April 30, 2020, we completed a public offering of 12,600,000 shares of common stock at an offering price of \$0.25 per share. On May 6, 2020 we issued an additional 1,890,000 shares of common stock at the same offering price pursuant to the exercise in full of the underwriter's over-allotment option in connection with the aforementioned offering. As a result, we received aggregate net proceeds of approximately \$3.0 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses. Due to anti-dilution provisions, the conversion price of the outstanding shares of Series B preferred stock, which was issued in our February 2018 offering, was reduced to \$0.25 per share.

On June 26, 2020, we completed a public offering of 20,000,000 shares of common stock at an offering price of \$0.27 per share. On July 9, 2020 we issued an additional 3,000,000 shares of common stock at the same offering price pursuant to the exercise in full of the underwriter's over-allotment option in connection with the aforementioned offering resulting in \$0.7 million of additional net proceeds. As a result, we received aggregate net proceeds of approximately \$5.5 million including the overallotment option and after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses.

On August 6, 2020, under the Shelf Registration Statement, we completed a public offering of 15,789,474 shares of common stock at an offering price of \$0.38 per share. On August 11, 2020 we issued an additional 2,368,421 shares of common stock at the same offering price pursuant to the exercise in full of the underwriter's over-allotment option in connection with the aforementioned offering. As a result, we received aggregate net proceeds of approximately \$6.2 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses.

On August 25, 2020, under the Shelf Registration Statement, we completed a public offering of 11,063,830 shares of common stock at an offering price of \$0.47 per share. On September 1, 2020 we issued an additional 1,000,000 shares of common stock at the same offering price pursuant to the exercise in full of the underwriter's over-allotment option in connection with the aforementioned offering. As a result, we received aggregate net proceeds of approximately \$5.1 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses.

## **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 ("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, 2020 are not necessarily indicative of results to be expected for the year ending December 31, 2020, or for any other interim period or for any future year. The December 31, 2019 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, 2019, which was filed with the SEC on March 5, 2020. 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, 2019.

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 a 1-for-10 reverse stock split of the Company's common stock. The reverse stock split became effective on June 21, 2019. The par values of the common stock and convertible preferred stock were not adjusted as a result of the reverse stock splits. 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 split.

### **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, 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, 2020 and December 31, 2019. 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, based on quoted market prices. As of September 30, 2020 and December 31, 2019, the Company's cash equivalents are entirely comprised of investments in money market funds. Any related unrealized gains and losses are recorded in other comprehensive income (loss) and included as a separate component of stockholders' equity. There were no unrealized gains and losses as of September 30, 2020 and December 31, 2019. 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, 2020 and December 31, 2019.

The Company's accounts receivable are due from a variety of healthcare organizations in the United States and select international markets. At September 30, 2020 and December 31, 2019, no customer represented 10% or more of the Company's accounts receivable. For the three and nine months ended September 30, 2020 and 2019, there were no customers that represented 10% or more of revenues. Disruption of sales orders or a deterioration of financial condition of its customers would have a negative impact on the Company's financial position and results of operations.

The Company manufactures its commercial products in-house, including the Pantheris and Ocelot family of catheters. Certain of the Company's product components and sub-assemblies continue to be manufactured by sole suppliers, including internally. 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 and maintenance. 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 typically 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”) 842, *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.

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 control of the product 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 and evaluation agreements, product warranty costs, product written-off due to excess or obsolescence, and certain direct costs such as shipping costs.

### Product Warranty Costs

The Company typically offers a one-year warranty 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Beginning balance	\$ 221	\$ 215	\$ 215	\$ 272
Warranty provision	13	34	124	70
Usage/Release	(35)	(35)	(140)	(128)
Ending balance	\$ 199	\$ 214	\$ 199	\$ 214

## 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 stockholder 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, 2020 and 2019, there were no shares subject to repurchase. Since the Company was in a loss position for both 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 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net loss attributable to common stockholders	\$ (5,492)	\$ (5,518)	\$ (17,277)	\$ (17,014)
Weighted average common stock outstanding, basic and diluted	69,459	7,900	37,246	6,189
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.08)	\$ (0.70)	\$ (0.46)	\$ (2.75)

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 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Common stock warrants equivalents	2,753,999	2,757,741	2,753,999	3,346,568
Common stock options	6,903	7,444	7,100	7,596
Convertible preferred stock	48,503	44,923	48,503	45,046
Unvested restricted stock units	749,512	371,651	820,743	316,575
	<u>3,558,917</u>	<u>3,181,759</u>	<u>3,630,345</u>	<u>3,715,785</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, which are comprised of property and equipment, are based in the United States. For the three months ended September 30, 2020 and 2019, 94% and 96%, respectively, of the Company's revenues were in the United States. For both the nine months ended September 30, 2020 and 2019, 94% of the Company's revenues were in the United States based on the shipping location of the external customer.

## Recent Accounting Pronouncements

### *Recently adopted accounting standards*

In June 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-13, *Financial Instruments – Credit Losses*, which changes the methodology to be used to measure credit losses for certain financial instruments and financial assets, including trade receivables. The new methodology requires the recognition of an allowance that reflects the current estimate of credit losses expected to be incurred over the life of the financial asset. The new standard became effective for the Company in the first quarter of 2020. The adoption of this standard did not have a material impact on the Company's condensed financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which among other things, eliminates certain exceptions in the current rules regarding the approach for intraperiod tax allocations and the methodology for calculating income taxes in an interim period, and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The standard becomes effective for the Company in the first quarter of 2021 and early adoption is permitted. This new standard is not expected to have a material impact on the Company's condensed financial statements.

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which among other things, simplifies the accounting models for the allocation of proceeds attributable to the issuance of a convertible debt instrument. As a result, after adopting the ASU's guidance, entities will not separately present in equity an embedded conversion feature in such debt. Instead, they will account for a convertible debt instrument wholly as debt, and for convertible preferred stock wholly as preferred stock (i.e., as a single unit of account), unless (i) a convertible instrument contains features that require bifurcation as a derivative under ASC 815 or (ii) a convertible debt instrument was issued at a substantial premium. The standard becomes effective for the Company in the first quarter of 2022 and early adoption is permitted. This new standard is not expected to have a material impact on the Company's condensed 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, 2020 and December 31, 2019, cash equivalents were all categorized as Level 1 and consisted of money market funds. As of September 30, 2020 and December 31, 2019, there were no financial assets and liabilities categorized as Level 2 or Level 3. There were no transfers between fair value hierarchy levels during the three months ended September 30, 2020.

### 4. Inventories

Inventories consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Raw materials	\$ 1,403	\$ 1,426
Work-in-process	765	596
Finished products	1,826	1,890
Total inventories	<u>\$ 3,994</u>	<u>\$ 3,912</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 million in principal amount from CRG on or before March 29, 2017. The Company borrowed \$30 million on September 22, 2015. The Company borrowed an additional \$10 million on June 15, 2016 under the Loan Agreement.

On February 14, 2018, the Company and CRG further amended the Loan Agreement concurrent with the conversion of \$38 million of the principal amount of the senior secured term loan (plus \$3.8 million in back-end fees and prepayment premium applicable thereto) into a newly authorized Series A convertible preferred stock (see below).

On March 2, 2020, the Company entered into Amendment No. 3 to the Loan Agreement to, among other things:

- extend the period that the Company can make interest payments in payment in kind ("PIK") to June 30, 2021;
- lower the Minimum Revenue Covenants to \$10 million for 2020, \$12 million for 2021, and \$15 million for 2022;
- insert certain terms to clarify that all fees, including the prepayment premium, are due if the obligations are accelerated; and
- insert a new provision to make clear that to the extent the Company divides its assets/liabilities into divisions, such assets/liabilities will be treated as transferred to a third party.

On May 12, 2020, the Company entered into Amendment No. 4 to the Loan Agreement to, among other things:

- grant to the Company the right to optionally prepay in whole or in part the outstanding principal amount of the Loans for the Redemption Price, subject to certain conditions; and
- waive the Company's requirement to comply with the Minimum Revenue Covenant for 2020.

Under the amended Loan Agreement, no cash payments for either principal or interest are due until the third quarter of 2021. The accrued interest will be 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 \$1.4 million with total principal payments of \$2.7 million in 2021, \$5.5 million in 2022 and \$2.7 million in 2023. The maturity date of the Loan is June 30, 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 seven and half years 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 15.0% of the amounts borrowed plus any payment-in-kind (PIK) is 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 amended Loan Agreement included a covenant that the Company maintain a minimum of \$3.5 million of cash and certain cash equivalents, and the Company has 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.

As of September 30, 2020, the Company was in compliance with all applicable covenants under the Loan Agreement.

As of September 30, 2020, principal, final facility fee and PIK payments due under the Loan Agreement are as follows (in thousands):

**Year Ending December 31,**

2020 (remaining three months of the year)	\$	—
2021		3,400
2022		6,266
2023		4,518
		<u>14,184</u>
Less: Amount of PIK additions and final facility fee to be accreted subsequent to September 30, 2020		(3,520)
Less: Amount representing debt financing costs		(461)
Borrowings, as of September 30, 2020	\$	<u>10,203</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, 2020 and December 31, 2019, the balance of the aggregate debt discount was approximately \$461,000 and \$588,000, respectively. The Company's interest expense associated with the amortization of debt discount was approximately \$42,000 during both the three months ended September 30, 2020 and 2019. The Company's interest expense associated with the amortization of debt discount was approximately \$127,000 during both the nine months ended September 30, 2020 and 2019. For the three months ended September 30, 2020 and 2019, the Company incurred interest expense of approximately \$427,000 and \$377,000, respectively. For the nine months ended September 30, 2020 and 2019, the Company incurred interest expense of approximately \$1.2 million and \$1.1 million, respectively.

Due to the material adverse change clause in the Loan Agreement with CRG, the entire amount of borrowings at September 30, 2020 and December 31, 2019 is classified as current in these financial statements. CRG has not invoked the material adverse change clause.

*Paycheck Protection Program*

On April 23, 2020, we received loan proceeds of \$2.3 million (the "PPP Loan") pursuant to the PPP under the CARES Act.

The Loan, which was in the form of a promissory note, dated April 20, 2020 (the "Promissory Note"), between the Company and Silicon Valley Bank as the lender, matures on April 20, 2022 and bears interest at a fixed rate of 1% per annum, payable monthly commencing six months from the date of the Loan. The Company may voluntarily prepay the borrowings in full with no associated penalty or premium.

Under the terms of the PPP, the principal may be forgiven if the Loan proceeds are used for qualifying expenses as described in the CARES Act, such as payroll costs, benefits mortgage interest, rent, and utilities. No assurance can be provided that the Company will obtain forgiveness of the Loan in whole or in part. In addition, details of the PPP continue to evolve regarding which companies are qualified to receive loans pursuant to the PPP and on what terms, and the Company may be required to repay some or all of the Loan due to these changes or different interpretations of the PPP requirements.

The Promissory Note evidencing the PPP Loan contains customary representations, warranties, and covenants for this type of transaction, including customary events of default relating to, among other things, payment defaults and breaches of representations and warranties or other provisions of the Promissory Note. The occurrence of an event of default may result in, among other things, the Company becoming obligated to repay all amounts outstanding.

On June 5, 2020, the President of the United States signed the Paycheck Protection Program Flexibility Act (the "PPPFA") into law. The PPPFA gives borrowers of a PPP loan more flexibility and time to spend the loan proceeds and allows the funds to be used on broader categories of expenses while still qualifying for loan forgiveness. We expect to apply for forgiveness of the PPP loan in the fourth quarter of 2020. While we believe that we have complied with the requirements to obtain forgiveness, there can be no assurance that any or all of the PPP loan amount will be forgiven. We also continue to evaluate and may still pursue additional programs under the CARES Act, but there is no guarantee that we will meet any eligibility requirements to participate in such programs or, even if we are able to participate, that such programs will provide meaningful benefit to our business.

As of September 30, 2020, principal and interest payments due under the PPP Loan are as follows (in thousands):

**Year Ending December 31,**

2020 (remaining three months of the year)	\$	264
2021		1,575
2022		521
		2,360
Less: Amount of interest to be accreted subsequent to September 30, 2020		(20)
Borrowings, as of September 30, 2020	\$	2,340

For the three and nine months ended September 30, 2020, the Company incurred interest expense of approximately \$6,000 related to the PPP Loan.

## 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.

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 expired on November 15, 2019 (which was 15 days prior to the expiration of the facility lease). The sublessee paid a base rent of \$82,410 per month. In addition to the base rent, the sublessee paid 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 are obligated to pay approximately \$5.8 million in base rent payments through November 2024, beginning on December 1, 2019. This amendment did 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 lease do provide an implicit rate.

For the three months ended September 30, 2020, our operating lease expense, excluding variable maintenance fees and other expenses paid by the Company on a monthly basis, was approximately \$105,000, which totaled approximately \$314,000 for each of the three month periods ended September 30, 2020 and 2019. Rent expense for the nine months ended September 30, 2020 and 2019 was approximately \$942,000 and \$1.1 million, respectively. Operating right-of-use asset amortization for the three months ended September 30, 2020 and 2019 was approximately \$242,000 and \$225,000, respectively. Operating right-of-use asset amortization for the nine months ended September 30, 2020 and 2019 was approximately \$718,000 and \$444,000, respectively. Due to payments being made in excess of operating lease expense recognized, the Company recorded approximately \$331,000 as prepaid rent included in other assets on the condensed balance sheet as of September 30, 2020.

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, 2020 (in thousands):

<b>Year Ending December 31,</b>	
2020 (remaining three months of the year)	\$ 274
2021	1,123
2022	1,162
2023	1,203
2024	1,138
	4,900
Less: Imputed interest	(630)
Leasehold liability as of September 30, 2020	\$ 4,270

### **Purchase Obligations**

Purchase obligations consist of agreements to purchase goods and services entered into in the ordinary course of business. The Company had non-cancelable commitments to suppliers for purchases totaling approximately \$1.1 million as of September 30, 2020.

### **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.

## **7. Stockholders' Equity**

### **Convertible Preferred Stock**

As of September 30, 2020, 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 48,503 shares were issued and outstanding.

#### *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 and December 2019, 2,945 and 3,580 additional shares, respectively, were issued to CRG as payment of dividends accrued through December 31, 2019. As of September 30, 2020, 48,325 shares of Series A preferred stock were outstanding. The Series A preferred stock accrued additional dividends of approximately \$967,000 and \$895,000 during the quarters ended September 30, 2020 and 2019, respectively and approximately \$2.9 million and \$2.7 million during the nine months ended September 30, 2020 and 2019, 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. During the year ended December 31, 2019, 1,523 of these shares converted into 380,750 shares of common stock. As of September 30, 2020 and December 31, 2019, 178 shares of Series B preferred stock remained outstanding which are currently convertible at \$0.25 per share.

### 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. During the nine months ended September 30, 2019, 2,170 shares of Series C preferred stock, which then constituted all the remaining Series C shares, were converted into 542,500 shares of common stock, leaving no shares of Series C preferred stock outstanding.

### Common Stock

As of September 30, 2020, 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 84,921,079 shares were issued and outstanding.

### Common Stock Warrants

As of September 30, 2020, we had outstanding warrants to purchase common stock as follows:

	<b>Total Outstanding and Exercisable</b>	<b>Underlying Shares of Common Stock</b>	<b>Exercise Price per Share</b>	<b>Expiration Date</b>
Series 1 Warrants issued in February 2018 financing	8,979,000	897,900	\$ 20.00	February 2025
Series 2 Warrants issued in February 2018 financing	8,709,500	870,950	\$ 20.00	February 2025
Warrants issued in July 2018 financing	1,083,091	108,309	\$ 15.80	July 2021
Warrants issued in November 2018 financing	8,768,395	876,840	\$ 4.00	November 2023
<b>Total</b>	<b>27,539,986</b>	<b>2,753,999</b>		

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, all of which 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 \$20.00 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, 2020, 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, 2020, 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. During the year ended December 31, 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, 2020 and December 31, 2019, warrants to purchase an aggregate of 876,840 shares of common stock were outstanding.

As of September 30, 2020 and December 31, 2019, warrants to purchase an aggregate of 2,753,999 shares of common stock were outstanding.

## **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, 2020, 202,544 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 (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Intrinsic Value (in thousands)
Balance at December 31, 2019	7,401	\$ 1,309.47	6.81	\$ —
Granted	—	\$ —		
Exercised	—	\$ —		
Expired	(549)	\$ 2,138.72		
Forfeited	(26)	\$ 820.00		
Balance at September 30, 2020	<u>6,826</u>	\$ 1,241.89	6.05	\$ —
Exercisable at September 30, 2020	<u>6,781</u>	\$ 1,244.72	6.05	\$ —
Vested and expected to vest at September 30, 2020	<u>6,826</u>	\$ 1,241.89	6.05	\$ —

There were no options granted or exercised during the nine months ended September 30, 2020 or 2019. As of September 30, 2020, there was approximately \$11,000 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 0.4 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 months ended September 30, 2020 and 2019.

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, 2019	908,504	\$ 4.09	1.81
Awarded	47,500	\$ 0.58	—
Released	(363,085)	\$ 4.58	—
Forfeited	(152,727)	\$ 3.04	—
Awards outstanding at September 30, 2020	<u>440,192</u>	\$ 3.67	1.20

As of September 30, 2020, there was approximately \$1.5 million of remaining unamortized stock-based compensation expense associated with RSUs, which will be expensed over a weighted average remaining service period of approximately 1.2 years. The 440,192 outstanding non-vested and expected to vest RSUs have an aggregate fair value of approximately \$0.1 million. The Company used the closing market price of \$0.32 per share at September 30, 2020, to determine the aggregate fair value for the RSUs outstanding at that date. For the nine months ended September 30, 2020 and 2019, the fair value of RSUs vested was approximately \$134,000 and \$110,000, respectively.

#### 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. 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 and March 10, 2020, the Board of Directors approved an additional 40,000 and 125,000 shares, respectively, to be made available under the ODPP. Common stock issued under the ODPP during the nine months ended September 30, 2020 totaled 53,034 shares. As of September 30, 2020, there were 92,170 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, 2020 and 2019, is as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2020	2019	2020	2019
Cost of revenues	\$ 36	\$ 40	\$ 97	\$ 128
Research and development expenses	116	122	354	339
Selling, general and administrative expenses	232	361	709	1,065
	<u>\$ 384</u>	<u>\$ 523</u>	<u>\$ 1,160</u>	<u>\$ 1,532</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 sections of this Quarterly Report on Form 10-Q, our Quarterly Report on Form 10-Q filed with the SEC on May 13, 2020, our Quarterly Report on Form 10-Q filed with the SEC on July 31, 2020, and our Annual Report on Form 10-K filed with the SEC on March 5, 2020 titled "Risk Factors."*

### Overview

We are a commercial-stage medical device company that designs, manufactures, and sells image-guided, catheter-based systems that are used by physicians to treat patients with peripheral artery disease, or PAD. Patients with PAD have a build-up of plaque in the arteries that supply blood to areas away from the heart, particularly the pelvis and legs. Our mission is to significantly improve the treatment of vascular disease through the introduction of products based on our Lumivasular 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. We are located in Redwood City, California. 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 CE Marking for our original Ocelot product in September 2011 and received U.S. Food and Drug Administration, or FDA, 510(k) clearance in November 2012. We received 510(k) clearance from the 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 version of Pantheris targeting smaller vessels, and commenced sales in July 2019. The Pantheris SV has a smaller diameter and longer length that we believe will optimize it for its targeted use.

In September of 2020, we received 510(k) clearance of Ocelaris ("Tigereye"), a next generation CTO crossing system utilizing Avinger's proprietary image-guided technology platform. Tigereye is a product line extension of Avinger's Ocelot family of image-guided CTO crossing catheters. Its design elements include an upgrade of the image capture rate to provide high definition, real-time intravascular imaging similar to the company's Pantheris image-guided atherectomy system and a user-controlled deflectable tip designed to assist in steerability within the lumen. Tigereye also features a new distal tip configuration with faster rotational speeds designed to penetrate challenging lesions. The Tigereye catheter has a working length of 140 cm and 5 French sheath compatibility for treatment of lesions in the peripheral vessels both above and below the knee. The product became available in the fourth quarter of 2020 for first cases in the U.S.

Current treatments for PAD, including bypass surgery, can be costly and may result in complications, high levels of post-surgery pain, and lengthy hospital stays and recovery times. Minimally invasive, or endovascular, treatments for PAD include stenting, angioplasty, and atherectomy, which is the use of a catheter-based device for the removal of plaque. These treatments all have limitations in their safety or efficacy profiles and frequently result in recurrence of the disease, also known as restenosis. We believe one of the main contributing factors to high restenosis rates for PAD patients treated with endovascular technologies is the amount of vascular injury that occurs during an intervention. Specifically, these treatments often disrupt the membrane between the outermost layers of the artery, which is referred to as the external elastic lamina, or EEL.

We believe our Lumivasular platform is the only technology that offers real-time visualization of the inside of the artery during PAD treatment through the use of optical coherence tomography, or OCT, a high resolution, light-based, radiation-free imaging technology. Our Lumivasular platform provides physicians with real-time OCT images from the inside of an artery, and we believe Ocelot and Pantheris are the first products to offer intravascular visualization during CTO crossing and atherectomy, respectively. We believe this approach will significantly improve patient outcomes by providing physicians with a clearer picture of the artery using radiation-free image guidance during treatment, enabling them to better differentiate between plaque and healthy arterial structures. Our Lumivasular platform is designed to improve patient safety by enabling physicians to direct treatment towards the plaque, while avoiding damage to healthy portions of the artery.

During the first quarter of 2015, we completed enrollment of patients in VISION, a clinical trial designed to support our August 2015 510(k) submission to 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 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.

During the fourth quarter of 2017, we began enrolling patients in INSIGHT, a clinical trial designed to support a submission to 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 continue development efforts on the next generation of the Lightbox imaging console, the L300, which is being designed to provide enhanced imaging capabilities in a much smaller form factor and be available to users at a lower cost. We anticipate filing a 510(k) submission for the L300 in the first quarter of 2021.

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.

We have assembled a team with extensive medical device development and commercialization experience in both start-up and large, multi-national medical device companies. We assemble all of our products at our manufacturing facility but certain critical processes, such as coating and sterilization, are performed by outside vendors. We expect our current manufacturing facility in California, will be sufficient through at least 2020. We generated revenues of \$7.9 million in 2018, and \$9.1 million in 2019. The growth experienced in 2019 was largely due to our next generation Pantheris and the launch of Pantheris SV.

## **Recent Developments**

### *COVID-19 Update*

As a result of the effects of the COVID-19 pandemic, experienced a significant decline in sales in the second quarter of 2020, particularly as individuals, as well as hospitals and other medical providers, deferred elective procedures in response to COVID-19. During the quarter ended September 30, 2020, we experienced a rebound of sales as practitioners began to once again perform elective procedures. While certain jurisdictions easing are restrictions on performing elective procedures, we cannot be certain that other jurisdictions in the United States will do so in the near future. Furthermore, some jurisdictions have experienced and continue to experience a resurgence in COVID-19 cases, which has prompted certain hospitals and other medical providers in such areas to again defer elective procedures or further prolong or reinstate existing restrictions on such procedures. If other jurisdictions experience a resurgence in COVID-19 cases, they may also prolong restrictions on elective procedures. This situation has created a significant amount of volatility in the medical industry which makes future developments and results difficult to predict. Consequently, it is unclear whether the reduction in sales was temporary and whether such sales may be recoverable in the future. If such lost sales are not fully recoverable in the future, our business and results of operations will be significantly adversely affected. In addition to the effects on sales, we have also experienced delays in site initiation and patient enrollment for one of our clinical studies. If we are unable to successfully complete these or other clinical studies, our business and results of operations could be harmed.

We have undertaken and continue to evaluate further action to manage our available cash and other resources to help mitigate the effects of COVID-19 on our business, including by adjusting production to match demand for our products and reducing discretionary costs. During the second quarter of 2020 we took certain actions to manage available cash and other resources to mitigate the effects of COVID-19 on our business, which included reduction of discretionary costs, reduction of base salaries for all of our non-manufacturing employees by 20% and reduction of hours worked by our manufacturing workers by 20%. While some measures, including salaries and hours worked, have returned to prior levels, we will continue to employ certain actions to manage our resources in the foreseeable future, such as managing discretionary costs. In addition, there can be no assurance that such strategies will be successful in effectively managing our resources and mitigating the negative impact of the COVID-19 on our business and operating results. In addition, the COVID-19 pandemic and responses thereto have resulted in reduced consumer and investor confidence, instability in the credit and financial markets, volatile corporate profits, and reduced business and consumer spending, which could increase the cost of capital and/or limit the availability of capital to the Company.

On March 27, 2020, the President of the United States signed the Coronavirus Aid Relief, and Economic Security (CARES) Act into law. The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. We are evaluating the applicability of the CARES Act to the Company, and the potential impacts on our business.

We applied for and, on April 23, 2020, received loan proceeds of \$2.3 million (the "Loan") pursuant to the Paycheck Protection Program ("PPP") under the CARES Act, (see Financing and Equity below for more details).

On June 5, 2020, the President of the United States signed the Paycheck Protection Program Flexibility Act (PPPFA) into law. The PPPFA gives borrowers of a PPP loan more flexibility and time to spend the loan proceeds and allows the funds to be used on broader categories of expenses while still qualifying for loan forgiveness. We are evaluating forgiveness requirements pursuant to the PPPFA but can provide no guarantee that we will meet any of the requirements of forgiveness. We also continue to evaluate and may still pursue additional programs under the CARES Act, but there is no guarantee that we will meet any eligibility requirements to participate in such programs or, even if we are able to participate, that such programs will provide meaningful benefit to our business.

#### *Nasdaq Delisting Notice*

On March 10, 2020, we received a letter from the Listing Qualifications Department of The NASDAQ Stock Market, LLC ("Nasdaq") notifying us that the Company was not in compliance with Nasdaq Listing Rule 5550(a)(2), as the minimum bid price for our common stock was less than \$1 for the previous 30 consecutive business days. We initially had a period of 180 calendar days, or until September 8, 2020, to regain compliance with the rule referred to in this paragraph. On April 20, 2020, we received a subsequent written notice from Nasdaq indicating that Nasdaq filed an immediately effective rule change with SEC on April 16, 2020, pursuant which the compliance periods for bid price and market value of publicly held shares requirements were tolled through June 30, 2020. As a result, we have until November 20, 2020, to regain compliance with Nasdaq's minimum bid price requirement.

To regain compliance, the bid price of our common stock must close at \$1 or more for a minimum of ten consecutive business days. The notice has no present impact on the listing of our securities on Nasdaq. In the event that we do not regain compliance with the Nasdaq Listing Rules prior to the expiration of the compliance period, we will receive written notification that its securities are subject to delisting. At that time, we may appeal the delisting determination to a hearings panel pursuant to the procedures set forth in the applicable Nasdaq Listing Rules. We intend to actively monitor the bid price of our common stock and will consider available options to resolve the deficiency and regain compliance with the Nasdaq Listing Rules, including conducting a reverse stock split.

#### **Financing and Equity**

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 this document have been retroactively adjusted for all periods presented to give effect to the reverse stock splits.

During the three and nine months ended September 30, 2020 our net loss and comprehensive net loss was \$4.5 million and \$14.4 million, respectively. We have not been profitable since inception, and as of September 30, 2020, accumulated deficit was \$362.7 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 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. 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.

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 March 2, 2020, we entered into Amendment No. 3 to the Term Loan Agreement (the "Amendment No. 3 Loan Agreement") with CRG. Under its terms, the Amendment No. 3 Loan Agreement, among other things: (1) extended the period during which the Company may elect to pay its entire interest payments in PIK interest payments through June 30, 2021; and (2) reduced the minimum revenue covenants to \$10 million for 2020, \$12 million for 2021, and \$15 million for 2022. On May 12, 202, we entered into Amendment No. 4 to the Term Loan Agreement (the "Amendment No. 4 Loan Agreement") with CRG which, among other things, waived the Company's requirement to comply with the minimum revenue covenant for 2020.

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. 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.

On January 31, 2020, we completed a public offering of 6,428,572 shares of common stock at an offering price of \$0.70 per share. As a result, we received net proceeds of approximately \$3.9 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses. Due to anti-dilution provisions, the conversion price of the outstanding shares of Series B preferred stock, which was issued in our February 2018 offering, was reduced to \$0.70 per share.

On April 23, 2020, we received loan proceeds of \$2.3 million pursuant to the Paycheck Protection Program under the CARES Act. The Loan, which was in the form of a promissory note, dated April 20, 2020, between the Company and Silicon Valley Bank as the lender, matures on April 20, 2022 and bears interest at a fixed rate of 1% per annum, payable monthly commencing in six months. Under the terms of the PPP and the PPPFA, the principal may be forgiven if the Loan proceeds are used for qualifying expenses as described in the CARES Act, such as payroll costs, benefits mortgage interest, rent, and utilities. No assurance can be provided that the Company will obtain forgiveness of the Loan in whole or in part. The Company may be required to repay some or all of the Loan due to changes or different interpretations of the PPP requirements that continue to evolve.

The Promissory Note evidencing the PPP Loan contains customary representations, warranties, and covenants for this type of transaction, including customary events of default relating to, among other things, payment defaults and breaches of representations and warranties or other provisions of the Promissory Note. The occurrence of an event of default may result in, among other things, the Company becoming obligated to repay all amounts outstanding. We continue to evaluate and may still apply for additional programs under the CARES Act, there is no guarantee that we will meet any eligibility requirements to participate in such programs or, even if we are able to participate, that such programs will provide meaningful benefit to our business.

On April 30, 2020, we completed a public offering of 12,600,000 shares of common stock at an offering price of \$0.25 per share. On May 6, 2020 we issued an additional 1,890,000 shares of common stock at the same offering price pursuant to the exercise in full of the underwriter's over-allotment option in connection with the aforementioned offering. As a result, we received aggregate net proceeds of approximately \$3.0 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses. Due to anti-dilution provisions, the conversion price of the outstanding shares of Series B preferred stock, which was issued in our February 2018 offering, was reduced to \$0.25 per share.

On June 26, 2020, we completed a public offering of 20,000,000 shares of common stock at an offering price of \$0.27 per share. On July 9, 2020 we issued an additional 3,000,000 shares of common stock at the same offering price pursuant to the exercise in full of the underwriter's over-allotment option in connection with the aforementioned offering resulting in \$0.7 million of additional net proceeds. As a result, we received aggregate net proceeds of approximately \$5.5 million including the over-allotment option and after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses.

On August 6, 2020, under the Shelf Registration Statement, we completed a public offering of 15,789,474 shares of common stock at an offering price of \$0.38 per share. On August 11, 2020 we issued an additional 2,368,421 shares of common stock at the same offering price pursuant to the exercise in full of the underwriter's over-allotment option in connection with the aforementioned offering. As a result, we received aggregate net proceeds of approximately \$6.2 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses.

On August 25, 2020, under the Shelf Registration Statement, we completed a public offering of 11,063,830 shares of common stock at an offering price of \$0.47 per share. On September 1, 2020 we issued an additional 1,000,000 shares of common stock at the same offering price pursuant to the exercise in full of the underwriter's over-allotment option in connection with the aforementioned offering. As a result, we received aggregate net proceeds of approximately \$5.1 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses.

### **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 three months ended September 30, 2020, 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 5, 2020.

## **Components of Our Results of Operations**

### ***Revenues***

All of our revenues are currently derived from sales of our Lightbox console, as well as related services, and sales of our various PAD catheters in the United States and select international markets. No single customer accounted for more than 10% of our revenues during the three and nine months ended September 30, 2020 and 2019.

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, during the first quarter, our results can be harmed by adverse weather and by resetting of annual patient healthcare insurance plan deductibles, both of which may cause patients to delay elective procedures. In the third quarter, the number of elective procedures nationwide is historically lower than other quarters throughout the year, which we believe is primarily attributable to the summer vacations of physicians and their patients.

### ***Cost of Revenues and Gross Margin***

Cost of revenues consists primarily of costs related to manufacturing overhead, materials and direct labor. We expense all warranty costs and inventory provisions as cost of revenues. We periodically write down inventory for estimated excess, obsolete and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes and overall market conditions. A significant portion of our cost of revenues currently consists of manufacturing overhead costs. These overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. We expect overhead costs as a percentage of revenues to become less significant as our production volume increases. 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 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 fluctuate compared to the prior year as we navigate through and attempt to mitigate the effects of COVID-19.

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

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

### Other Income (Expense), net

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

### Results of Operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(in thousands, except percentages)			
Revenues	\$ 2,302	\$ 2,410	\$ 6,029	\$ 6,569
Cost of revenues	1,525	1,563	4,392	4,629
Gross profit	777	847	1,637	1,940
Gross margin	34%	35%	27%	30%
Operating expenses:				
Research and development	1,417	1,371	4,308	4,120
Selling, general and administrative	3,461	4,091	10,501	12,168
Total operating expenses	4,878	5,462	14,809	16,288
Loss from operations	(4,101)	(4,615)	(13,172)	(14,348)
Interest expense, net	(432)	(307)	(1,212)	(849)
Other income, net	8	299	8	868
Net loss and comprehensive loss	<u>\$ (4,525)</u>	<u>\$ (4,623)</u>	<u>\$ (14,376)</u>	<u>\$ (14,329)</u>

### Comparison of Three Months Ended September 30, 2020 and 2019

#### Revenues.

For the three months ended September 30, 2020, revenue decreased by approximately \$0.1 million or 5% compared to the three months ended September 30, 2019. The decrease is primarily the result of the continuing deferral of elective procedures by hospitals and other medical providers in response to the COVID-19 pandemic; specifically, in jurisdictions that have yet to ease restrictions associated with elective procedures. We expect that sales will continue to be volatile as such restrictions are prolonged or other jurisdictions adopt or reinstate such restrictions.

#### Cost of Revenues and Gross Margin.

For the three months ended September 30, 2020, cost of revenues remained flat compared to the three months ended September 30, 2019. Stock-based compensation expense within cost of revenues totaled \$36,000 and \$40,000 for the three months ended September 30, 2020 and 2019, respectively.

Gross margin for the three months ended September 30, 2020 decreased to 34%, compared to 35% in the three months ended September 30, 2019. The decrease in gross margin was primarily a result of the decline in revenues due to COVID-19 and customer mix.

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

R&D expense for the three months ended September 30, 2020 remained relatively flat compared to the three months ended September 30, 2019. Compensation expense decreased compared to the prior year period which was largely offset by higher project spending for next generation products including the L300 imaging console. Stock-based compensation expense within R&D totaled approximately \$0.1 million during both the three months ended September 30, 2020 and 2019.

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

SG&A expense for the three months ended September 30, 2020 decreased by approximately \$0.6 million or 15%, compared to the three months ended September 30, 2019, primarily due to a decrease in compensation costs resulting from expense reduction measures, lower third-party expenses and decreased variable compensation resulting from the decline in sales prompted by COVID-19. Stock-based compensation expense within SG&A totaled approximately \$0.2 million and \$0.4 million during the three months ended September 30, 2020 and 2019, respectively.

*Interest Expense, Net.*

Interest expense, net for the three months ended September 30, 2020 increased by \$0.1 million or 41%, compared to the three months ended September 30, 2019 primarily due to the higher CRG loan balance from interest being compounded and lower interest income as compared to the prior year period due to a decline in money market interest rates during the period.

*Other Income, Net.*

Other income, net primarily consists of gains and losses resulting from the remeasurement of foreign exchange transactions and other miscellaneous income and expenses. During the three months ended September 30, 2019, this also consisted of sublease income. Our subleasing arrangement of a portion of the Company's facilities was concluded during 2019. Consequently, the three months ended September 30, 2020 consisted of only net gains due to remeasurement of foreign exchange transactions resulting in a decrease of approximately \$0.3 million or 97%.

**Comparison of Nine Months Ended September 30, 2020 and 2019**

*Revenues.*

For the nine months ended September 30, 2020, revenue decreased by \$0.5 million or 8% compared to the nine months ended September 30, 2019. The decrease reflects the effects of COVID-19 prompting hospitals and other medical providers to defer elective procedures. This decline was partially offset by increases in revenue from sales of Pantheris SV product, which was released commercially in July 2019.

*Cost of Revenues and Gross Margin.*

For the nine months ended September 30, 2020, cost of revenues decreased by \$0.2 million or 5% compared to the nine months ended September 30, 2019. This decrease was primarily attributable to the decrease in revenues for the same period. Stock-based compensation expense within cost of revenues totaled \$0.1 million for both the nine months ended September 30, 2020 and 2019.

Gross margin for the nine months ended September 30, 2020 decreased to 27%, compared to 30% in the nine months ended September 30, 2019. The decrease in gross margin was primarily a result of the decline in revenues due to COVID-19, higher excess and obsolete charges on inventory and an unfavorable customer mix shift.

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

R&D expense for the nine months ended September 30, 2020 increased by \$0.2 million or 5%, compared to the nine months ended September 30, 2019 primarily due to a higher project spending for next generation products including the L300 imaging console, largely offset by decreases in compensation expense. Stock-based compensation expense within R&D totaled approximately \$0.4 million and \$0.3 million during the nine months ended September 30, 2020 and 2019.

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

SG&A expense for the nine months ended September 30, 2020 decreased by \$1.7 million or 14%, compared to the nine months ended September 30, 2019, primarily due to a decrease in compensation costs resulting from expense reduction measures and decreased variable compensation. Stock-based compensation expense within SG&A totaled approximately \$0.7 million and \$1.1 million during the nine months ended September 30, 2020 and 2019, respectively.

*Interest Expense, Net.*

Interest expense, net for the nine months ended September 30, 2020 increased by \$0.4 million or 43%, compared to the nine months ended September 30, 2019 primarily due to the higher CRG loan balance from interest being compounded and lower interest income as compared to the prior year period, due to the decline in the money market interest rates during the period.

*Other Income, Net.*

During the nine months ended September 30, 2019, other income, net consisted of sublease income. Our subleasing arrangement of a portion of the Company's facilities was concluded during 2019. Consequently, the nine months ended September 30, 2020 consisted of only net gains and losses due to remeasurement of foreign exchange transactions resulting in a decrease of approximately \$0.9 million or 99%.

## Liquidity and Capital Resources

As of September 30, 2020, we had cash and cash equivalents of \$25.3 million and an accumulated deficit of \$362.7 million, compared to cash and cash equivalents of \$10.9 million and an accumulated deficit of \$348.3 million as of December 31, 2019. The Company expects to incur losses for the foreseeable future. The Company believes that its cash and cash equivalents of \$25.3 million at September 30, 2020 and expected revenues, debt and financing activities and funds from operations will be sufficient to allow the Company to fund its current operations through at least the fourth quarter of 2021. 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.

In addition, the COVID-19 pandemic and responses thereto have resulted in reduced consumer and investor confidence, instability in the credit and financial markets, volatile corporate profits, restrictions on elective medical procedures, and reduced business and consumer spending, which could increase the cost of capital and/or limit the availability of capital to the Company. While we have taken certain actions to manage our available cash and other resources to mitigate the effects of COVID-19 on our business, there can be no assurance that such strategies will be successful in mitigating the negative impacts of the COVID-19 pandemic on our liquidity and capital resources.

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 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. 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. Due to anti-dilution provisions, the conversion price of the outstanding shares of Series B preferred stock, which was issued in our February 2018 offering, was reduced to \$1.18 per share.

During the year ended December 31, 2019, we received proceeds of approximately \$8.0 million from the issuance of 1,998,079 shares of common stock related to warrant exercises associated with the Series C preferred stock.

On January 31, 2020, we completed a public offering of 6,428,572 shares of common stock at an offering price of \$0.70 per share. As a result, we received net proceeds of approximately \$3.9 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses. Due to anti-dilution provisions, the conversion price of the outstanding shares of Series B preferred stock, which was issued in our February 2018 offering, was reduced to \$0.70 per share.

On March 2, 2020, the Company and CRG further amended the Loan Agreement to change the date upon which cash payments for interest will commence from the first quarter of 2020 to the third quarter of 2021. No cash payments for principal will be made until the final two years of the loan, which matures in June 2023. On May 12, 2020, the Company and CRG entered into another amendment to waive the Company’s requirement to comply with the minimum required revenue covenant for 2020 and granted to Company the ability to optionally prepay in whole or in part the outstanding principal amount of the Loans for the Redemption Price.

On April 23, 2020, we received loan proceeds of \$2.3 million pursuant to the Paycheck Protection Program under the CARES Act. The Loan, which was in the form of a promissory note, dated April 20, 2020, between the Company and Silicon Valley Bank as the lender, matures on April 20, 2022 and bears interest at a fixed rate of 1% per annum, payable monthly commencing in six months. Under the terms of the PPP, the principal may be forgiven if the Loan proceeds are used for qualifying expenses as described in the CARES Act and the PPPFA, such as payroll costs, benefits mortgage interest, rent, and utilities. No assurance can be provided that the Company will obtain forgiveness of the Loan in whole or in part. In addition, details of the PPP continue to evolve regarding which companies are qualified to receive loans pursuant to the PPP and on what terms, and the Company may be required to repay some or all of the Loan due to these changes or different interpretations of the PPP requirements.

The Promissory Note evidencing the PPP Loan contains customary representations, warranties, and covenants for this type of transaction, including customary events of default relating to, among other things, payment defaults and breaches of representations and warranties or other provisions of the Promissory Note. The occurrence of an event of default may result in, among other things, the Company becoming obligated to repay all amounts outstanding. We continue to evaluate and may still apply for additional programs under the CARES Act, there is no guarantee that we will meet any eligibility requirements to participate in such programs or, even if we are able to participate, that such programs will provide meaningful benefit to our business.

On April 30, 2020, we completed a public offering of 12,600,000 shares of common stock at an offering price of \$0.25 per share. On May 6, 2020 we issued an additional 1,890,000 shares of common stock at the same offering price pursuant to the exercise in full of the underwriter's over-allotment option in connection with the aforementioned offering. As a result, we received aggregate net proceeds of approximately \$3.0 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses. Due to anti-dilution provisions, the conversion price of the outstanding shares of Series B preferred stock, which was issued in our February 2018 offering, was reduced to \$0.25 per share.

On June 26, 2020, we completed a public offering of 20,000,000 shares of common stock at an offering price of \$0.27 per share. On July 9, 2020 we issued an additional 3,000,000 shares of common stock at the same offering price pursuant to the exercise in full of the underwriter's over-allotment option in connection with the aforementioned offering resulting in \$0.7 million of additional net proceeds. As a result, we received aggregate net proceeds of approximately \$5.5 million including the over-allotment option and after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses.

On August 6, 2020, under the Shelf Registration Statement, we completed a public offering of 15,789,474 shares of common stock at an offering price of \$0.38 per share. On August 11, 2020 we issued an additional 2,368,421 shares of common stock at the same offering price pursuant to the exercise in full of the underwriter's over-allotment option in connection with the aforementioned offering. As a result, we received aggregate net proceeds of approximately \$6.2 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses.

On August 25, 2020, under the Shelf Registration Statement, we completed a public offering of 11,063,830 shares of common stock at an offering price of \$0.47 per share. On September 1, 2020 we issued an additional 1,000,000 shares of common stock at the same offering price pursuant to the exercise in full of the underwriter's over-allotment option in connection with the aforementioned offering. As a result, we received aggregate net proceeds of approximately \$5.1 million after underwriting discounts, commissions, legal and accounting fees, and other ancillary expenses.

## Cash Flows

	Nine Months Ended September 30,	
	2020	2019
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	\$ (11,671)	\$ (13,737)
Investing activities	40	(70)
Financing activities	26,014	11,858
Net increase (decrease) in cash and cash equivalents	<u>\$ 14,383</u>	<u>\$ (1,949)</u>

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

Net cash used in operating activities for the nine months ended September 30, 2020 was \$11.7 million, consisting primarily of a net loss of \$14.4 million and an increase in net operating assets of approximately \$0.8 million, partially offset by non-cash charges of \$3.5 million. Non-cash charges largely related to stock-based compensation of \$1.2 million, non-cash interest expense of \$1.1 million, depreciation of \$0.7 million and provisions for excess and obsolete inventory of \$0.4 million. The increase in net operating assets was primarily due to the increase in prepaid expenses and inventory and a decrease in accrued compensation; partially offset by a decrease in accounts payable.

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 \$2.4 million, offset by non-cash charges of \$3.0 million. The increase in net operating assets was due to fluctuations in inventories, prepaid expenses, accounts payable and accrued expenses and other current liabilities, due to timing of payments and reduction of leasehold liability. The non-cash charges primarily consisted of depreciation and amortization of \$0.7 million, stock-based compensation of \$1.5 million and non-cash interest expense of \$1.0 million; partially offset by an increase in the right of use asset of \$0.4 million.

### **Net Cash Provided by (Used in) Investing Activities**

Net cash provided by investing activities during the nine months ended September 30, 2020 was \$40,000 resulting from the proceeds from the sale of property and equipment.

Net cash used in investing activities during 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 Provided by Financing Activities**

Net cash provided by financing activities in the nine months ended September 30, 2020 of \$26.0 million primarily relates to proceeds from the issuance of common stock in our public offerings, net of various issuance costs and proceeds of \$2.3 million from borrowings pursuant to the PPP under the CARES Act.

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.

### **Off-Balance Sheet Arrangements**

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

### **Contractual Obligations**

Our principal obligations consist of the operating lease for our facilities, our Loan Agreement with CRG, our PPP Loan and non-cancelable purchase commitments. The following table sets out our contractual obligations as of September 30, 2020. Due by period (in thousands):

	Payments Due by Period				Total
	Less Than 1 Year	1 - 3 Years	4-5 Years	More Than 5 Years	
Operating lease obligations	\$ 1,113	\$ 2,345	\$ 1,442	\$ —	\$ 4,900
CRG Loan	1,722	12,462	—	—	14,184
PPP Loan	1,447	914	—	—	2,361
Noncancelable purchase commitments	984	91	5	—	1,080
	<u>\$ 5,266</u>	<u>\$ 15,812</u>	<u>\$ 1,447</u>	<u>\$ —</u>	<u>\$ 22,525</u>

The total CRG Loan amount, shown as borrowings on the balance sheet as of September 30, 2020, is \$9.8 million. The contractual obligation in the table above of \$14.2 million under the CRG Loan includes future interest to be accrued but not paid in cash as well as a \$1.6 million back-end fee to be paid in June 2023 upon maturity of the CRG Loan which is being accreted. For more information, see Part I, Item 1 "Unaudited Financial Statements, Footnote 5. Borrowings."

The total PPP Loan amount, shown as borrowings on the balance sheet as of September 30, 2020, is \$2.34 million. The contractual obligation in the table above of \$2.36 million under the PPP Loan includes future interest to be accrued. For more information, see Part I, Item 1 “Unaudited Financial Statements, Footnote 5. Borrowings.”

Under the terms of the PPP, the principal may be forgiven if the Loan proceeds are used for qualifying expenses as described in the CARES Act and the PPPFA, such as payroll costs, benefits mortgage interest, rent, and utilities. No assurance can be provided that the Company will obtain forgiveness of the Loan in whole or in part.

### 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, 2020 and December 31, 2019, 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. There were no customers that represented more than 10% of our accounts receivable as of September 30, 2020 and December 31, 2019.

#### *Foreign Currency Risk*

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

### ITEM 4. CONTROLS AND PROCEDURES

#### **Evaluation of Disclosure Controls and Procedures**

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

As required by Rule 13a-15(b) under the Exchange Act, our management, under the supervision and with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2020. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of September 30, 2020, 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 three months ended September 30, 2020 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 5, 2020.

### Risks Related to Our Business

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

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

The results of short-term clinical experience of our Lumivascular platform products, including Pantheris, do not necessarily predict long-term clinical benefit. Restenosis rates typically increase over time. We believe that physicians will compare the rates of long-term restenosis and reintervention for procedures using our Lumivascular platform products against alternative procedures, such as angioplasty, stenting, bypass surgery and other atherectomy procedures. If the long-term rates of restenosis and reintervention do not meet physicians' expectations, our Lumivascular platform products may not become widely adopted and physicians may consider alternative treatments for their patients. Another significant factor that physicians will consider is acute safety data on complications that occur during the use of our Lumivascular platform products. If the results obtained from any post-market studies that we conduct or post-clearance surveillance indicate that the use of our Lumivascular platform products are not as safe or effective as other treatment options or as current short-term data would suggest, adoption of our product may suffer and our business would be harmed. In addition, we are responsible for the costs associated with conducting studies to obtain safety and efficacy data. If we are unable to obtain sufficient financing, whether through our operations or from third parties, we will not be able to conduct the studies necessary to obtain long-term data regarding the safety and efficacy of our products.

Even if we believe the data collected from clinical studies or clinical experience indicate positive results, each physician's actual experience with our products will vary. Physicians who are technically proficient participate in our clinical trials and are high-volume users of our Lumivascular platform products. Consequently, the results of our clinical trials and their experiences using our products may lead to better patient outcomes than those of physicians that are less proficient, perform fewer procedures or who use our products infrequently.

***The ongoing COVID-19 pandemic and responses thereto have adversely affected and we expect will continue to adversely affect our supply chain, workforce, approval process, and business operations.***

In December 2019, a novel strain of coronavirus, SARS-CoV-2, was reported to have surfaced in Wuhan, China. Since then, SARS-CoV-2, and the resulting disease COVID-19 has spread to multiple countries, including the United States and all of the primary markets where we conduct business. On March 10, 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, and the U.S. government-imposed restrictions on travel between the United States and Europe for a 30-day period. Further, on March 13, 2020, the President of the United States declared the COVID-19 pandemic a national emergency, invoking powers under the Stafford Act, the legislation that directs federal emergency disaster response. Almost all U.S. states and many local jurisdictions have issued, and others in the future may issue, "shelter-in-place" orders, quarantines, executive orders and similar government orders, restrictions, and recommendations for their residents to control the spread of COVID-19. Such orders, restrictions and recommendations, and the perception that additional orders, restrictions or recommendations could occur, have resulted in widespread closures of businesses not deemed "essential," work stoppages, slowdowns and delays, work-from-home policies, travel restrictions and cancellation of events, as well as record declines in stock prices, among other effects. We continue to monitor our operations and government mandates and may elect or be required to temporarily close our offices to protect our employees, and limit our access to customers and limit customer use of our products as they are required to prioritize resources to address the public healthcare needs arising from the COVID-19 pandemic. The disruptions to our activities and operations will negatively impact our business, some of our operating results and may negatively impact our financial condition. There is a risk that government actions will not be effective at containing COVID-19, and that government actions, including the orders and restrictions described above, that are intended to contain the spread of COVID-19 will have a devastating negative impact on the world economy at large, in which case the risks to our sales, operating results and financial condition described herein would be elevated significantly.

The duration of COVID-19's impact on our business may be difficult to assess or predict. The widespread pandemic has resulted, and may continue to result for an extended period, in significant disruption of global financial markets, reducing our ability to access capital, which would negatively affect our liquidity. Further, quarantines or government reaction or shutdowns for could disrupt our supply chain. Travel and import restrictions may also disrupt our ability to manufacture or distribute our devices. Any import or export or other cargo restrictions related to our products or the raw materials used to manufacture our products would restrict our ability to manufacture and ship products and harm our business, financial condition and results of operations. Our key personnel and other employees could also be affected by COVID-19, potentially reducing their availability, and an outbreak such as COVID-19 or the procedures we take to mitigate its effect on our workforce could reduce the efficiency of our operations or prove insufficient. We may delay or reduce certain capital spending and related projects until the travel and logistical impacts related to COVID-19 are lifted, which will delay the completion of such projects.

In addition, the conduct of clinical trials required to obtain clearance of additional indications and studies gathering post-market data for some of our products previously cleared by the FDA have been, and we expect may continue to be, affected by the COVID-19 pandemic. Specifically, site initiation and patient enrollment have been delayed for one of our clinical studies, and we are experiencing delays in completing the INSIGHT clinical study with the current restrictions on clinical work. As hospital resources are prioritized for the COVID-19 outbreak and quarantines impede patient movement or interrupt healthcare services, these and other clinical studies may continue to be disrupted. If we are unable to successfully complete these or other clinical studies, and thus obtain regulatory approvals and efficacy data sought, our business and operating results may be harmed.

While certain jurisdictions have begun easing restrictions on performing elective procedures, we cannot be certain that other jurisdictions will do so, or that, once hospitals do begin easing restrictions on elective procedures, patients will begin requesting such procedures. Furthermore, some jurisdictions have experienced and continue to experience a resurgence in COVID-19 cases, which has prompted certain hospitals and other medical providers in such areas to again defer elective procedures or further prolong or reinstate restrictions on such procedures. If other jurisdictions experience a resurgence in COVID-19 cases, they may also prolong or reinstate restrictions on elective procedures.

The global outbreak of COVID-19 continues to rapidly evolve. The ultimate impact of the COVID-19 outbreak is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business or the global economy as a whole. However, these effects have harmed our business, financial condition, and results of operations in the near term and could have a continuing material impact on our operations, sales, and ability to continue as a going concern.

***Customer demand for and our ability to sell and market our products have been and we expect will continue to be adversely affected by the COVID-19 pandemic and responses thereto.***

Restrictions on the ability to travel, social distancing policies, orders and restrictions, including those described above, and recommendations and fears of COVID-19 spreading within medical centers has caused both patients and providers to delay or cancel procedures that use our devices. We are unable to accurately predict when these policies, orders and restrictions will be relaxed or lifted, and there can be no assurances that patients or providers will restart procedures that use our devices upon termination of these policies, orders and restrictions, particularly if there remains any continued community outbreak of COVID-19.

A prolonged economic contraction or recession may also result in employer layoffs of their employees in markets where we conduct business, which could result in lower procedure demand. In particular, as certain of the procedures that use our products have limited reimbursement and require patients to pay for the procedures in whole or in part, a reduction in employment would reduce utilization and sales of our products. We have already experienced reduced sales as a result of the effects of the COVID-19 pandemic. While we experienced a rebound in sales during the third quarter of 2020 as practitioners and hospitals began to once again perform elective procedures, it is unclear whether our sales will continue to increase and whether sales lost earlier in the year may be recoverable in the future. If our sales decline, or if such lost sales are not recoverable in the future, our business and results of operations will be significantly adversely affected.

Our sales and marketing personnel often rely on in-person and onsite access to healthcare providers which is currently restricted as hospitals reduce access to essential personnel only. These restrictions have harmed our sales and marketing efforts, and continued restrictions would have a negative impact on our sales and results of operations. An increase of COVID-19-related hospital admissions may overload hospitals with unexpected patients, thereby delaying further procedures that use our devices but that are deemed elective by the hospital. In addition, we made temporary salary and work hour reductions, though we have reverted salaries and hours to prior levels, we and may, in the future, take further actions including reinstating reductions to salary and work hours, furloughs, restructuring or layoffs which may negatively impact our workforce and our business.

The global outbreak of COVID-19 continues to evolve rapidly. The ultimate impact of the COVID-19 outbreak is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business or the global economy as a whole. However, these effects have harmed our business, financial condition, and results of operations in the near term and could have a continuing material impact on our operations, sales, and ability to continue as a going concern.

***We may not be eligible to participate in the relief programs provided under the recently adopted Coronavirus Aid Relief, and Economic Security (CARES) Act and even if we are eligible we may not realize any material benefits from participating in such programs.***

On March 27, 2020, the President of the United States signed the Coronavirus Aid Relief, and Economic Security (CARES) Act into law. The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. We are evaluating the applicability of the CARES Act to the Company, and the potential impacts on our business. We applied for, and received, a loan (the "PPP Loan") in the principal amount of \$2.3 million under the Paycheck Protection Program (the "PPP") of the CARES Act. The PPP Loan bears interest at a fixed rate of 1% annually and matures on April 20, 2022. Under the terms of the PPP, the principal may be forgiven if the Loan proceeds are used for qualifying expenses as described in the CARES Act, such as payroll costs, benefits, rent, and utilities. In addition, on June 5, 2020, the President of the United States signed the Paycheck Protection Program Flexibility Act (the "PPPFA") into law. The PPPFA gives borrowers of a PPP loan more flexibility and time to spend the loan proceeds and allows the funds to be used on broader categories of expenses while still qualifying for loan forgiveness. We are evaluating forgiveness requirements pursuant to the PPP and PPPFA but can provide no guarantee that we will meet any of the requirements of forgiveness. However, no assurance can be provided that the Company will obtain forgiveness of the PPP Loan in whole or in part. While we may determine to apply for additional programs available under the CARES Act, there is no guarantee that we will meet any eligibility requirements to participate in such programs or, even if we are able to participate, that such programs will provide meaningful benefit to our business.

***We may not be entitled to forgiveness of our recently received PPP Loan, and our application for the PPP Loan could in the future be determined to have been impermissible or could result in damage to our reputation.***

On April 23, 2020 we received proceeds of \$2.3 million from a loan under the Paycheck Protection Program of the CARES Act, a portion of which may be forgiven, which we intend to use to retain current employees, maintain payroll and make lease and utility payments. The PPP Loan matures on April 20, 2022 and bears annual interest at a rate of 1.0%. Commencing on the date that is the later of (i) the date that is the 10th month after the end of the Company's PPP Loan covered period (as described below) and (ii) assuming the Company has applied for PPP Loan forgiveness within the period described in clause (i), the date on which SBA remits the loan forgiveness amount on the Company's PPP Loan to the PPP lender (or notifies such lender that no loan forgiveness is allowed), we are required to pay the lender equal monthly payments of principal and interest as required to fully amortize by April 20, 2022 any principal amount outstanding on the PPP Loan as of October 21, 2020. On June 5, 2020, the President of the United States signed the PPPFA into law. The PPPFA gives borrowers of a PPP loan more flexibility and time to spend the loan proceeds and allows the funds to be used on broader categories of expenses while still qualifying for loan forgiveness. A portion of the PPP Loan may be forgiven by the SBA upon our application and upon documentation of expenditures in accordance with the SBA requirements. Under the CARES Act and the PPPFA, loan forgiveness is available for the sum of documented payroll costs, covered rent payments, covered mortgage interest and covered utilities during the twenty-four week period or, if elected by the Company, the eight week period beginning on the date of the loan is advanced. Not more than 40% of the forgiven amount may be for non-payroll costs. The amount of the PPP Loan eligible to be forgiven may be limited due to declines in headcount, whether voluntary or involuntary, or if salaries and wages for employees with salaries of \$100,000 or less annually are reduced by more than 25% as compared to the period of January 1, 2020 through March 31, 2020. We will be required to repay any portion of the outstanding principal that is not forgiven, along with accrued interest, in accordance with the amortization schedule described above, and we cannot provide any assurance that we will be eligible for loan forgiveness, that we will ultimately apply for forgiveness, or that any amount of the PPP Loan will ultimately be forgiven by the SBA. Furthermore, on April 28, 2020, the Secretary of the U.S. Department of the Treasury stated that the SBA will perform a full review of any PPP loan over \$2.0 million before forgiving the loan.

In order to apply for the PPP Loan, we were required to certify, among other things, that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. We made this certification in good faith after analyzing, among other things, our financial situation and access to alternative forms of capital, and believe that we satisfied all eligibility criteria for the PPP Loan, and that our receipt of the PPP Loan is consistent with the broad objectives of the Paycheck Protection Program of the CARES Act. The certification described above does not contain any objective criteria and is subject to interpretation. On April 23, 2020, the SBA issued guidance stating that it is unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith. The lack of clarity regarding loan eligibility under the Paycheck Protection Program has resulted in significant media coverage and controversy with respect to public companies applying for and receiving loans. If, despite our good-faith belief that given our Company's circumstances we satisfied all eligible requirements for the PPP Loan, we are later determined to have violated any of the laws or governmental regulations that apply to us in connection with the PPP Loan, such as the False Claims Act, or it is otherwise determined that we were ineligible to receive the PPP Loan, we may be subject to penalties, including significant civil, criminal and administrative penalties and could be required to repay the PPP Loan in its entirety. In addition, receipt of a PPP Loan may result in adverse publicity and damage to reputation, and a review or audit by the SBA or other government entity or claims under the False Claims Act could consume significant financial and management resources. Any of these events could have a material adverse effect on our business, results of operations and financial condition.

## Risks Related to Our Common Stock

### ***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.

On March 10, 2020, we received a letter from Nasdaq's Listing Qualifications Department notifying us that the Company was not in compliance with Nasdaq Listing Rule 5550(a)(2), as the minimum bid price for the Company's listed securities was less than \$1 for the previous 30 consecutive business days. The Company initially had a period of 180 calendar days, or until September 8, 2020, to regain compliance with the rule referred to in this paragraph. On April 20, 2020, we received a subsequent written notice from Nasdaq indicating that Nasdaq filed an immediately effective rule change with SEC on April 16, 2020, pursuant which the compliance periods for bid price and market value of publicly held shares requirements were tolled through June 30, 2020. As a result, the Company now has until November 20, 2020 to regain compliance with Nasdaq's minimum bid price requirement referred to in this paragraph. To regain compliance, the bid price of the Company's common stock must close at \$1 or more for a minimum of ten consecutive business days. The notice has no present impact on the listing of the Company's securities on Nasdaq.

In the event that the Company does not regain compliance with the Nasdaq Listing Rules prior to the expiration of the compliance period, it will receive written notification that its securities are subject to delisting. At that time, the Company may appeal the delisting determination to a hearings panel pursuant to the procedures set forth in the applicable Nasdaq Listing Rules. The Company intends to actively monitor its bid price and will consider available options to resolve the deficiency and regain compliance with the Nasdaq Listing Rules, including conducting a reverse stock split.

The Company intends to present a proposal to its stockholders at the Company's next annual meeting to be held on December 10, 2020 to effect a reverse stock split at a ratio not less than 1-for-5 and not greater than 1-for-20. There is no guarantee that, if approved, a reverse stock split would result in the Company meeting the minimum bid price. Further, because the meeting to obtain stockholder approval will not be held until after November 20, 2020, Nasdaq may determine to delist our securities.

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.

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

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees to us or to our stockholders, (iii) any action asserting a claim arising pursuant to the Delaware General Corporation Law or our certificate of incorporation or bylaws (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws, or (v) any action asserting a claim governed by the internal affairs doctrine. This exclusive forum provision would not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers or employees. If a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

**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:

<b>Exhibit Number</b>	<b>Exhibit Title</b>
31.1	<a href="#"><u>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.</u></a>
31.2	<a href="#"><u>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.</u></a>
32.1*	<a href="#"><u>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.</u></a>
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 10, 2020

/s/ JEFFERY M. SOINSKI

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

Date: November 10, 2020

/s/ MARK WEINSWIG

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Mark Weinswig  
*Chief Financial Officer*  
*(Principal Financial and Accounting 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, 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 10, 2020

/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 10, 2020

/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, 2020, 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 the 10<sup>th</sup> day of November, 2020.

**IN WITNESS WHEREOF**, the undersigned have set their hands hereto as of the 10<sup>th</sup> day of November, 2020.

/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.