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

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

or

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

For the transition period from to

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Commission File Number: 001-36817

AVINGER, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization) **20-8873453** (I.R.S. Employer Identification Number)

400 Chesapeake Drive

Redwood City, California 94063

(Address of principal executive offices and zip code)

(650) 241-7900

(Telephone number, including area code)

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

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

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

Large accelerated filer O

Non-accelerated filer 0

Accelerated filer 0

Smaller reporting company X

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(Do not check if a smaller reporting company)

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

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

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- the outcome of our clinical studies and plans to conduct further clinical studies;
- our plans to modify our current products, or develop new products, to address additional indications;
- the expected timing of submission of a Special 510(k) to FDA for an enhanced version of Pantheris;
- the expected growth in our business and our organization;
- our expectations regarding government and third-party payor coverage and reimbursement;

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

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

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

• our expectations regarding the time during which we will be an emerging growth company under the

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

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

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

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

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

AVINGER, INC.

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

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

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

See accompanying notes.

AVINGER, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

(In thousands, except per share data)

	Three Months Ended			Nine Months Ended			
	Septem 2015	ber 30,	2014	Septemb 2015	oer 30,	2014	
Revenues	\$ 2,721	\$	2,632	\$ 7,856	\$	8,140	