

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Avinger Inc

Form: 8-K

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Corporate Issuer CIK: 1506928

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported):

July 31, 2019

Avinger, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-36817
(Commission File Number)

20-8873453
(IRS Employer Identification No.)

**400 Chesapeake Drive
Redwood City, California 94063**
(Address of principal executive offices, including zip code)

(650) 241-7900
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR § 230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR § 240.12b-2).

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.

Item 2.02 Results of Operations and Financial Condition.

On July 31, 2019, Avinger, Inc. (the "Company") issued a press release regarding its financial results for the quarter ended June 30, 2019. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

This information is intended to be furnished under Item 2.02 of Form 8-K and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

The press release furnished herewith in Exhibit 99.1 contains non-GAAP financial measures. Management believes non-GAAP financial measures assist management and investors in evaluating and comparing period-to-period results and projections in a more meaningful and consistent manner. Reconciliations for these non-GAAP financial measures to the most directly comparable GAAP financial measures are included in the press release.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release of Avinger, Inc. issued on July 31, 2019.

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 hereunto duly authorized.

AVINGER, INC.

Date: July 31, 2019

By: /s/ Mark Weinswig
Mark Weinswig
Chief Financial Officer



Avinger Reports 26% Sequential Revenue Growth in Second Quarter 2019

*Revenue Growth Fuels Strong Operating Metrics
Pantheris SV Limited Launch at Key U.S. Sites in July*

Redwood City, Calif., July 31, 2019 - Avinger, Inc. (Nasdaq: AVGR), a commercial-stage medical device company marketing the first and only intravascular image-guided, catheter-based system for diagnosis and treatment of patients with Peripheral Artery Disease (PAD), today reported results for the quarter ended June 30, 2019.

Second Quarter and Recent Highlights

- Increased revenue 26% from the first quarter 2019, to \$2.3 million, on continued strong growth in Pantheris[®] utilization
- Grew Pantheris revenue 43% in the first half of 2019, to \$2.0 million, compared to the first half of 2018
- Improved gross margin to 31% on increased sales volume, compared with 20% in the first quarter
- Reduced net loss and comprehensive loss 8% from the first quarter, to \$4.7 million
- Improved adjusted EBITDA loss 9% from the first quarter, to \$4.0 million, the lowest level in more than 3 years
- Initiated Pantheris SV (Small Vessel) limited launch and successfully treated first patients at multiple sites in the U.S. in July
- Continued international expansion with the signing of a distribution agreement for Hong Kong and completion of initial Ocelot cases in Australia
- Reported positive clinical outcomes across multiple papers, presentations and clinical conferences, including 5 podium presentations and a live case transmission at CVC 2019
- Further strengthened the balance sheet with \$8.0 million in proceeds received in the first half of 2019 from warrant exercises related to prior underwritten public offerings
- Regained compliance with Nasdaq listing requirements

Jeff Soinski, Avinger's president and CEO, commented, "We are excited to report significantly improved operating results driven by a 26% sequential increase in revenue and an improved gross margin. As we look forward to additional growth opportunities, we have made substantial progress on expanding our sales team with 26 sales professionals actively marketing our platform to centers across the United States, including increased coverage in the Southeast and Southwest sales territories. We expect to further expand our sales footprint and increase the number of active Lumivascular accounts throughout the remainder of the year along with the rollout of our Pantheris SV product."

"We began treating patients in July with our new Pantheris SV platform at multiple key U.S. sites and are excited about the successful outcomes in our first cases. Pantheris SV is a complementary treatment which can be efficiently added to existing centers, enabling our sites to treat a greater share of their atherectomy patients using Avinger's best-in-class technology. We estimate this compelling platform will increase our available atherectomy market by as much as 50% annually, or approximately \$180 million."

Second Quarter 2019 Financial Results

Total revenue was \$2.3 million for the second quarter of 2019, an increase of 26% from the first quarter of 2019, and an increase of 13% compared to the second quarter of 2018, reflecting strong growth in both Pantheris and Ocelot.

Gross margin for the second quarter of 2019 was 31%, compared to 20% for the first quarter of 2019 and -5% for the second quarter of 2018. Operating expenses for the second quarter of 2019 were \$5.4 million, flat compared to the first quarter and a decrease of 3% from the second quarter of 2018.

Net loss and comprehensive loss for the second quarter of 2019 was \$4.7 million, a decrease of 8%, from \$5.1 million in the first quarter of 2019 and a decrease of 20% from \$5.8 million in the second quarter of 2018.

Adjusted EBITDA, as defined under non-GAAP measures in this press release, was a loss of \$4.0 million, an improvement of 9% compared to a loss of \$4.3 million for the first quarter of 2019, and an improvement of 6% compared to a loss of \$4.2 million for the second quarter of 2018.

For more information regarding non-GAAP financial measures discussed in this press release, please see "Non-GAAP Financial Measures" below, as well as the reconciliation of GAAP to non-GAAP measures provided in the tables below.

Balance Sheet

Cash and cash equivalents totaled \$14.8 million as of June 30, 2019, compared with \$16.7 million as of March 31, 2019.

On June 21, 2019, Avinger effected a 1-for-10 reverse stock split in order to regain compliance with the Nasdaq minimum bid price requirement. Avinger received notification that it had regained compliance on July 9, 2019.

As of June 30, 2019, Avinger had approximately 6.4 million shares of common stock, 44,745 shares of Series A preferred stock and 178 shares of Series B preferred stock outstanding. Each share of the Series A preferred stock is convertible into 50 shares of the Company's common stock at a conversion price of \$20.00 per share. Each share of Series B preferred stock is convertible into approximately 250 shares of the Company's common stock at a conversion price of \$4.00.

Conference Call

Avinger will hold a conference call today, July 31, 2019 at 4:30pm ET to discuss its second quarter 2019 financial results.

Individuals interested in listening to the conference call may do so by dialing 844-407-9500 for domestic callers or +1-862-298-0850 for international callers. To listen to a live webcast, please visit <http://www.avinger.com> and select Investor Relations.

A replay of the call will be available beginning July 31, 2019 at approximately 7:30pm PT/ 10:30pm ET through August 7, 2019. To access the replay, dial +1-919-882-2331 and reference Conference ID: 51715. The webcast will also be available on Avinger's website following completion of the call at www.avinger.com.

About Avinger, Inc.

Avinger is a commercial-stage medical device company that designs and develops the first and only image-guided, catheter-based system for the diagnosis and treatment of patients with Peripheral Artery Disease (PAD). PAD is estimated to affect over 12 million people in the U.S. and over 200 million worldwide. Avinger is dedicated to radically changing the way vascular disease is treated through its Lumivascular platform, which currently consists of the Lightbox imaging console, the Ocelot family of chronic total occlusion (CTO) catheters, and the Pantheris® family of atherectomy devices. Avinger is based in Redwood City, California. For more information, please visit www.avinger.com.

Forward-Looking Statements

This news release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These forward-looking statements include statements regarding our future performance, expectations regarding the number of active Lumivascular accounts, the increase of our available atherectomy market, the impact of Pantheris SV on our addressable market, and our anticipated commercial launch and roll-out of Pantheris SV. Such statements are based on current assumptions that involve risks and uncertainties that could cause actual outcomes and results to differ materially. These risks and uncertainties, many of which are beyond our control, include our dependency on a limited number of products; our ability to demonstrate the benefits of our Lumivascular platform; the resource requirements related to Pantheris; the outcome of clinical trial results; potential exposure to third-party product liability, intellectual property and other litigation; lack of long-term data demonstrating the safety and efficacy of our Lumivascular platform products; experiences of high-volume users of our products may lead to better patient outcomes than those of physicians that are less proficient; reliance on third-party vendors; dependency on physician adoption; reliance on key personnel; and requirements to obtain regulatory approval to commercialize our products; as well as the other risks described in the section entitled "Risk Factors" and elsewhere in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 6, 2019. These forward-looking statements speak only as of the date hereof and should not be unduly relied upon. Avinger disclaims any obligation to update these forward-looking statements.

Non-GAAP Financial Measures

Avinger has provided in this press release financial information that has not been prepared in accordance with generally accepted accounting principles in the United States (GAAP). The Company uses these non-GAAP financial measures internally in analyzing its financial results and believes that the use of these non-GAAP financial measures is useful to investors as an additional tool to evaluate ongoing operating results and trends and in comparing the Company's financial results with other companies in its industry, many of which present similar non-GAAP financial measures.

The presentation of these non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable GAAP financial measures, and should be read only in conjunction with the Company's financial statements prepared in accordance with GAAP. A reconciliation of the Company's non-GAAP financial measures to their most directly comparable GAAP measures has been provided in the financial statement tables included in this press release, and investors are encouraged to review these reconciliations.

Adjusted EBITDA. Avinger defines Adjusted EBITDA as net loss and comprehensive loss plus interest expense, net, plus other income, net, plus stock-based compensation expense plus certain inventory charges plus certain depreciation and amortization expense. Investors are cautioned that there are a number of limitations associated with the use of non-GAAP financial measures as analytical tools. Furthermore, these non-GAAP financial measures are not based on any standardized methodology prescribed by GAAP, and the components that Avinger excludes in its calculation of non-GAAP financial measures may differ from the components that its peer companies exclude when they report their non-GAAP results of operations. Avinger compensates for these limitations by providing specific information regarding the GAAP amounts excluded from these non-GAAP financial measures. In the future, the Company may also exclude other non-recurring expenses and other expenses that do not reflect the Company's core business operating results.

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Condensed Statements of Operations and Comprehensive Loss
(in thousands) (unaudited)

	For the Three Months Ended			For the Six Months Ended	
	June 30, 2019	March 31, 2019	June 30, 2018	June 30, 2019	June 30, 2018
Revenue	\$ 2,319	\$ 1,840	\$ 2,058	\$ 4,159	\$ 3,867
Cost of revenue	1,599	1,467	2,169	3,066	3,584
Gross profit (loss)	720	373	(111)	1,093	283
	31%	20%	-5%	26%	7%
Operating expense					
Research and development	1,335	1,414	1,159	2,749	2,936
Selling, general, and administrative	4,091	3,986	4,444	8,077	8,944
Total operating expense	5,426	5,400	5,603	10,826	11,880
Operating income/(loss)	(4,706)	(5,027)	(5,714)	(9,733)	(11,597)
Other income (expense), net:					
Interest expense, net	(274)	(268)	(312)	(542)	(4,951)
Other income, net	329	240	227	569	468
Net loss and comprehensive loss	(4,651)	(5,055)	(5,799)	(9,706)	(16,080)
Accretion of preferred stock dividends	(895)	(895)	(836)	(1,790)	(1,246)
Deemed dividend arising from beneficial conversion feature of convertible preferred stock	-	-	-	-	(5,216)
Net loss attributable to common stockholders	\$ (5,546)	\$ (5,950)	\$ (6,635)	\$ (11,496)	\$ (22,542)
Net loss per share attributable to common stockholders basic and diluted	\$ (0.87)	\$ (1.40)	\$ (0.93)	\$ (2.16)	\$ (51.82)
Weighted average common shares used to compute net loss per share, basic and diluted	6,377	4,248	675	5,319	435

Condensed Balance Sheets
 (in thousands, except per share amounts) (unaudited)

	June 30, 2019	December 31, 2018	March 31, 2019
Assets			
Current assets:			
Cash and cash equivalents	\$ 14,754	\$ 16,410	\$ 16,707
Accounts receivable, net of allowance for doubtful accounts of \$218 and \$260 at June 30, 2019 and December 31, 2018, respectively	1,210	1,154	1,112
Inventories	4,105	3,422	3,955
Prepaid expenses and other current assets	764	635	1,026
Total current assets	20,833	21,621	22,800
Right of use asset	5,596	-	1,313
Property and equipment, net	2,006	2,078	2,140
Other assets	384	-	-
Total assets	\$ 28,819	\$ 23,699	\$ 26,253
Liabilities and stockholders' equity (deficit)			
Current liabilities:			
Accounts payable	\$ 1,086	\$ 1,148	\$ 969
Accrued compensation	1,439	1,197	1,016
Accrued expenses and other current liabilities	776	1,449	906
Leasehold liability	1,063	-	1,313
Borrowings	8,201	7,486	7,837
Preferred stock dividends payable	1,790	2,918	895
Total current liabilities	14,355	14,198	12,936
Leasehold liability	4,533		
Other long-term liabilities	11	41	38
Total liabilities	18,899	14,239	12,974
Stockholders' equity:			
Convertible preferred stock, par value \$0.001	-	-	-
Common stock, par value \$0.001	6	3	6
Additional paid-in capital	348,505	338,342	347,213
Accumulated deficit	(338,591)	(328,885)	(333,940)
Total stockholders' equity	9,920	9,460	13,279
Total liabilities and stockholders' equity	\$ 28,819	\$ 23,699	\$ 26,253

Reconciliation of Adjusted EBITDA to Net loss and comprehensive loss

(in thousands)

(unaudited)

	For the Three Months Ended			For the Six Months Ended	
	June 30, 2019	March 31, 2019	June 30, 2018	June 30, 2019	June 30, 2018
Net loss and comprehensive loss	\$ (4,651)	\$ (5,055)	\$ (5,799)	\$ (9,706)	\$ (16,080)
Add: Interest expense, net	274	268	312	542	4,951
Add: Other income, net	(329)	(240)	(227)	(569)	(468)
Add: Stock-based compensation	516	493	641	1,009	1,260
Add: Certain inventory charges	-	-	607	-	528
Add: Certain depreciation and amortization charges	228	200	241	428	518
Adjusted EBITDA	<u>\$ (3,962)</u>	<u>\$ (4,334)</u>	<u>\$ (4,225)</u>	<u>\$ (8,296)</u>	<u>\$ (9,291)</u>