

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

December 3, 2014

Via E-mail
John B. Simpson, Ph.D., M.D.
Chief Executive Officer
Avinger, Inc.
400 Chesapeake Drive
Redwood City, CA 94063

Re: Avinger, Inc.

**Draft Registration Statement on Form S-1** 

Submitted November 6, 2014

CIK No. 0001506928

Dear Dr. Simpson:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

#### Graphics

1. Regarding the proposed artwork that counsel provided to us, please remove references to the Pantheris trial or revise your graphics to contain prominent disclosure that enrollment in that trial is not complete and that is intended to support a submission for FDA approval in the second half of 2015.

## Prospectus Summary, page 1

2. Please reconcile your disclosure here and throughout your prospectus that you are selling your current products, and intend to sell Pantheris upon approval, into select European markets with the disclosure in your risk factor on page 24 that you do not currently intend to devote significant resources to market your products internationally and that you intend to focus your resources and efforts on the United States market. Likewise, explain

why the market data referencing the global prevalence of PAD is relevant to your investors. Please also revise similar disclosure in your prospectus as appropriate, including on page 69.

## Market Overview, page 2

- 3. Please clarify if the market data from Sage Group in the second sentence is an estimate of the number of people or if this is the number of diagnosed patients with PAD.
- 4. We note from your disclosures on pages 73 and 74 of your prospectus that 500,000 PAD angioplasty procedures, 370,000 PAD stent procedures and 80,000 PAD atherectomy procedures in the pelvis and legs were performed in the United States in 2013. From those numbers, it appears that there is a current preference for balloon and stent procedures over atherectomy procedures. If you intend an atherectomy procedure using Pantheris to replace balloon and stent procedures, please clarify in an appropriate location in your prospectus what management believes it will take to convince the medical community to use Pantheris to perform an atherectomy procedure versus using balloon or stent procedures. Include risk factor disclosure as appropriate.
- 5. Please disclose in an appropriate location in your prospectus if Pantheris would be used in conjunction with your existing products or if it would replace the use of your existing products. Include risk factor disclosure if appropriate.

## Company, page 6

6. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

## Use of Proceeds, page 44

7. If true, please revise your disclosure to indicate that the convertible promissory notes could be redeemed at 125% of outstanding principal and accrued and unpaid interest if redeemed prior to maturity. Please also revise to clarify the amounts you currently intend to devote to each stated use, such as the amounts for payment of interest and principal on your credit facility.

## Dilution, page 48

8. Please disclose how the numbers and percentages in the table on page 49 would change assuming the exercise or conversion of the securities referenced in the first three bullet points below that table.

# Management's Discussion and Analysis of Financial Condition and Results of Operations

#### Overview, page 53

9. We see that you effected a reduction in force during the third and fourth quarters of 2013. Please help us understand the materiality of the reduction in force and tell us your consideration of providing the disclosures specified in FASB ASC 420-10-50 and SAB Topic 5P.

# Contractual Obligations, page 60

10. It appears that there may have been significant changes in your contractual obligations since the date of the information in this table. We note for example your disclosure on page 115 regarding the conversion of almost \$7.8 million of notes in September 2014. Please tell us what consideration you have given to highlighting any changes that may impact the values noted in the table.

## Convertible Promissory Notes, page 60

11. From your disclosure it appears that the holders of the notes may elect to convert their notes upon the closing of your offering. If known, please disclose if the note holders have indicated any intent to hold or convert their notes at the closing of your offering.

## Critical Accounting Policies and Estimates

# Common Stock Valuation, page 64

12. Please tell us the estimated IPO price range. To the extent there is a significant difference between the estimated grant-date fair value of your common stock during the past twelve months and the estimated IPO price, please discuss for us each significant factor contributing to the difference.

## Business, page 69

## Improved efficacy through reduced risk or restenosis, page 74

13. Please clarify whether the Mountain Sinai Hospital study utilized your products. If not, please clarify that your products may not achieve similar results.

#### Expanded patient population, page 75

14. Please disclose the basis for your disclosure that your platform increases CTO crossing success rates.

# Lumivascular platform designed for ease of adoption, page 75

15. Please disclose here and page 3 the "certain characteristics and features" noted on page 14 that may prevent widespread market adoption of your lumivascular platform.

## Competition, page 83

16. With a view toward disclosure, please tell us which of your competitors have "previously attempted to combine intravascular imaging with atherectomy." Also tell us why, if known to you and as implied by your disclosure, those competitors no longer offer such products.

## Intellectual property, page 84

17. Please disclose the expiration dates of your patents. Refer to Regulation S-K Item 101(c)(iv)

## Management, page 95

18. We note from your disclosure on page F-38 that Dr. Simpson is the president and managing officer of JBS Consulting and from your disclosure on page F-39 that Mr. Simpson is the chief executive officer of Recreation. If Dr. Simpson and Mr. Simpson still hold those positions please make the appropriate disclosures in your Management section. Include any appropriate disclosure and risk factors about potential conflicts of interests and the diversion of attention that may experience due to their roles at other businesses.

#### Director Compensation, page 103

19. Please disclose the number of shares underlying the options granted in 2014 and the number described in the first sentence of the second paragraph of this section.

## Certain Relationships and Related Party Transactions, page 115

- 20. We note your references to \$120,000 in this section. In light of your disclosure that you qualify as a "smaller reporting company," please revise your disclosure as appropriate to comply with Regulation S-K Item 404(d)(1).
- 21. Please revise to clarify the duration of each of the agreements referenced on page 115.
- 22. Please also clarify how Black Diamond Ventures is affiliated with you, as indicated by the table on page 116, given that such entity does not appear in the table on page 120 or in the biographies of your officers and directors. In this regard, please note that the information you disclose pursuant to Regulation S-K Item 403 should be as of the most

recent practicable date, not merely the date as of which you disclosed financial information, such as June 30, 2014. Please revise.

# 2013 Bridge Loan, page 116

23. Please reconcile the aggregate principal amount disclosed here with the amount disclosed on page II-2.

#### Financial Statements

## Note 2. Summary of Significant Accounting Policies

## Revenue Recognition, page F-12 and F-13

- 24. We note that for your Lightbox lease agreements, you allocate revenue to the lease as the contingent disposable products are delivered. Please help us better understand the arrangements by responding to the following:
  - Please describe the key terms of the lease agreements and pricing mechanism for the disposable sales, including minimum lease periods for Lightbox or minimum purchase quantity for disposable products, if any.
  - Describe your consideration why the lease agreements for Lightbox qualify as leases under FASB ASC 840-10-15-6 (a)-(c), as we also note that collectability of the minimum lease payments is not reasonably predictable given the contingent future catheter sales.
  - Describe how you determine the best estimate of selling price for your leases and whether such allocation results in any deferred revenue.

#### **Exhibits**

25. Please file as exhibits to your filing the employment letters described under "Executive Officer Employment Letters" and the change in control severance agreements described on page 106. Please also file as exhibits the lock-up agreements mentioned on page 135 and the Note and Warrant Purchase Agreement referenced on page F-25.

You may contact Li Xiao at (202) 551-4391 or Gary Todd, Senior Accountant, at (202) 551-3605 if you have questions regarding comments on the financial statements and related matters. Please contact Tim Buchmiller at (202) 551-3635 or Geoff Kruczek, Senior Attorney, at (202) 551-3641 with any other questions.

Sincerely,

/s/ Geoff Kruczek for

Amanda Ravitz
Assistant Director

cc (via e-mail): Philip H. Oettinger, Esq.

Wilson Sonsini Goodrich & Rosati

**Professional Corporation**