



DIVISION OF
CORPORATION FINANCE

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

December 13, 2018

Reza Zadno
President and Chief Executive Officer
Avedro, Inc.
201 Jones Road
Waltham, MA 02451

Re: Avedro, Inc.
Draft Registration Statement on Form S-1
Submitted on November 15, 2018
CIK No. 0001343304

Dear Dr. Zadno:

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.

Draft Registration Statement on Form S-1 submitted November 15, 2018

Overview, page 1

1. Please revise your disclosure at the bottom of page 2 to indicate the number of Mosaic Systems that you have sold to date.
2. Please revise to explain briefly the terms "refractive" and "CE mark" at first use.
3. Please revise the table on page 3 to clarify the status/plans for each of the applications where no text is presented.

Our Avedro Corneal Remodeling Program, page 4

4. We note your disclosure at the top of page 5 highlighting, "High procedure success rate

with durable results.” Please tell us the basis for this claim. In this regard, your cover graphic suggests that the basis is the Phase III clinical trial data for treatment of progressive keratoconus and corneal ectasia using your current KXL system; however, your disclosure on page 110 suggests that the claim is based on an independent study of patients who received a “substantially similar” treatment to the one that you provide for keratoconus. In addition, please revise to clearly identify the relevant “procedure” and explain the meaning of the term “durable.” Also, provide us a copy of the 2015 independent retrospective study.

Risks Associated with Our Business, page 7

5. Please revise to highlight the going concern opinion for the fiscal year ended December 31, 2017 and your disclosure on page 94 concerning the sufficiency of cash to fund your operations for the next twelve months.

Implications of Being an Emerging Growth Company , page 8

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.

Our products are currently regulated in some territories as medical devices..., page 56

7. With respect to regulation in the United States, please tell us whether this risk factor is more relevant to specific procedure/formulation combinations in your pipeline.

Use of Proceeds, page 78

8. Please revise to explain briefly the types of U.S. Commercialization activities that you intend to fund with the offering proceeds.
9. Please revise to disclose separately the amount of proceeds intended for development of your latest-generation KXL system and the amount intended for development of the Mosaic system. With reference to your table on page 3, revise your discussion on page 78 to clarify whether the offering proceeds will be used exclusively for the ongoing Phase 3 KXL trial and for the planned Phase 2a Mosaic trial or whether the proceeds are intended for any of the other VibeX development work highlighted in the page 3 table. Also, briefly discuss whether the proceeds that you intend to allocate toward each clinical trial is intended to allow you to reach conclusion of that development stage or, alternatively, indicate the amounts and sources of other funds needed for you to do so. Refer to Instruction 3 to Item 504 of Regulation S-K.

Critical Accounting Policies and Estimates
Stock Based Compensation, page 101

10. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features.

Business, page 103

11. We note your disclosure on page 105 concerning your plans to cross-sell your device systems to the same target customers. In light of your disclosure on page 104 concerning the versatility of the Mosaic system and the overlap in the applications identified in your table on page 3, please tell us whether the Mosaic system, if and when approved, and/or the “latest generation” KXL system, if and when approved, would serve as replacements for the installed base of current generation KXL systems in the US market. With respect to your international installed base and with reference to your disclosure on page 119, please tell us whether the 18 Mosaic systems you have sold to date have been to customers who also own one of your KXL systems.

The Mosaic System, page 118

12. We note that you plan on conducting a Phase 2a clinical trial outside the United States to evaluate the safety and efficacy of the PiXL procedure using the Mosaic system and its associated drug formulation for the treatment of presbyopia. Please revise your disclosure to include a description of any Phase 1 or other clinical trials you have conducted with this drug and device combination and to summarize the data resulting from these studies.

Sales and Marketing, page 129

13. Please revise to discuss briefly the degree of training required to operate your various systems. Also, tell us whether the claim highlighted on page 5 concerning the ease of use and minimal learning curve applies to your latest generation KXL system and your Mosaic system.

Competition, page 133

14. We note your statement on page 134 asserting that you have a leading market presence in the corneal ectatic disorder market outside the United States. Please disclose the basis for this statement. Please also expand your disclosures concerning the Corneal Ectatic Disorders Market and the Vision Correction Market sections to discuss the available treatment options outside the United States and the competitive landscape of these markets. Also revise your disclosure on page 5, as applicable, to clarify that your

leadership position outside the United States relates to the corneal ectatic disorder market.

Patents, page 135

15. Please revise your disclosure regarding your patent portfolio to separate by product candidate or procedure and drug formulation the number of issued patents you have, whether the patents are licensed or owned, the type of patent, jurisdiction and expiration date.

Intellectual Property Agreements, page 138

16. Your disclosure on page 139 indicates that royalties under the Amended CalTech Agreement are payable on a product-by-product basis until expiration of the last-to-expire claim of a licensed patent that covers such product. Please revise to disclose the relevant expiration date for the last-to-expire patent.

Regulation in the European Union, page 160

17. We note your disclosure that you underwent a conformity assessment procedure that included an evaluation of clinical data supporting the safety and performance of your product during normal conditions of use. Where appropriate, please provide a summary of the clinical data supporting the safety and performance of your products which resulted in the issuance of the EC Certificates of Conformity.

General

18. We refer to your top cover graphic appearing under the heading "High Procedure Success With Durable Results" and refer you to Compliance Disclosure Interpretation, Securities Act Forms, Question 101.02 concerning use of graphic presentations in a prospectus. We note that this graphic, as well as the associated footnote disclosure, prominently presents complex testing results without adequate context and employs complex terminology that may be unfamiliar to investors. Accordingly, please revise to remove this cover graphic from the prospectus.
19. Please revise the second cover graphic under the heading "Innovative Devices" to highlight that the Mosaic System is not FDA approved. With reference to your table on page 3, please also tell us why you believe it is appropriate to present separate graphical images of the riboflavin formulations given that you are not commercially selling any formulations in the US on a stand-alone basis and given that two of the three formulations are not FDA approved for use with your KXL device.
20. You disclose on pages 26-27 that you sell your products into Iran pursuant to general licenses issued by the Treasury Department's Office of Foreign Assets Control. You disclose on pages 7, 128 and 130 that you have sold your products into more than 80 countries, and on page F-9 you list revenue from Asia and the Middle East.

Iran and Syria, in the Middle East, and North Korea, in Asia, are designated by the State Department as state sponsors of terrorism and are subject to U.S. economic sanctions and export controls. Sudan, located in Africa but included in some references to the Middle East, also is designated as a state sponsor of terrorism and is subject to US export controls. Please describe to us the nature and extent of your past, current, and anticipated contacts with Iran, Syria, North Korea and/or Sudan, including contacts with their governments, whether through distributors or other direct or indirect arrangements. In this regard, we note that your website provides for persons from each of those countries to contact you with comments or questions, and to request news and updates via email, including information about upcoming events and seminars.

21. Please also discuss the materiality of your contacts with the countries referenced in the comment above, in quantitative terms and in terms of qualitative factors that a reasonable investor would deem important in making an investment decision. Tell us the approximate dollar amounts of revenues, assets and liabilities associated with those countries for the last two fiscal years and the subsequent interim period. Address for us the potential impact of the investor sentiment evidenced by divestment and similar initiatives that have been directed toward companies that have operations associated with U.S.-designated state sponsors of terrorism.

You may contact Christine Torney at (202) 551-3652 or Angela Connell, Accounting Branch Chief, at (202) 551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Irene Paik at (202) 551-6553 or Joseph McCann at (202) 551-6262 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Healthcare & Insurance

cc: Marc Recht - Cooley LLP