

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

May 23, 2014

Via E-mail
Amarpreet Sawhney, Ph.D.
President and Chief Executive Officer
Ocular Therapeutix, Inc.
36 Crosby Drive, Suite 101

Bedford, MA 01730

**Re:** Ocular Therapeutix, Inc.

Draft Registration Statement on Form S-1 Confidentially Submitted April 29, 2014

File No. 377-00587

Dear Dr. Sawhney:

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.

## General

- 1. We note that you have submitted an application for confidential treatment relating to certain of your exhibits. Please be advised that comments to this application, if any, will be sent under separate cover and that any such comments must be resolved prior to your requesting effectiveness of your registration statement.
- 2. Please confirm that the graphics included in your registration statement are the only graphics you will use in your prospectus. If those are not the only graphics, please provide any additional graphics prior to their use for our review.
- 3. 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. Similarly, please supplementally provide us with any research reports about you that are published or distributed in reliance upon Section 2(a)(3) of the Securities Act of 1933 added by Section 105(a) of the Jumpstart Our Business Startups Act by any broker or dealer that is participating or will participate in your offering.

#### Summary

# Overview of Ocular Therapeutics, page 1

- 4. Please define the terms "hydrogel" and "intravitreal" in this section.
- 5. Please note here that your entire intellectual property portfolio and much of the technology you utilize is licensed from Incept, LLC, a related party.

# Anticipated Benefits of our Punctum Plug Technology, page 3

6. Please state the approximate amount of time it takes for your punctum plugs to dissipate after their active pharmaceutical ingredients have been exhausted.

## Overview of Our Key Product Candidates and Marketed Product, page 4

- 7. Please briefly discuss the therapeutic effects of both dexamethasone and travoprost.
- 8. In your summary discussion of ReSure Sealant please disclose that you had previously initiated and then discontinued commercialization of an earlier version of this product in Europe and that the FDA also requested withdrawal of your initial application for that version.

### Risks Associated with Our Business, page 6

9. Please include a bullet point summarizing the material risk discussed in the risk factor on pages 37-38 and cite the FDA's condition requiring post-approval studies for ReSure Sealant as an example.

### Risk Factors

Risks Related to Our Financial Position and Need for Additional Capital
"Our substantial indebtedness may limit cash flow available to invest in the ongoing needs of our business," page 15

10. Please provide examples of the types of corporate actions the restrictive covenants included in your credit agreement may prevent you from undertaking.

# Risks Related to Our Product Development

"If clinical trials of our punctum plug product candidates or any other product candidate that we develop . . .," page 17

11. Here, and wherever else applicable in your registration statement, please state the reason(s) to your knowledge that the FDA requested you withdraw your application for ReSure Sealant submitted under Section 510(k) of the FDCA.

"If serious adverse or unacceptable side effects are identified during the development of our punctum plug product candidates . . .," page 20

12. Please amend this risk factor to provide examples of the adverse events that have been identified in your clinical trials.

## Risks Related to Manufacturing

"If our sole clinical manufacturing facility is damaged or destroyed or production at this facility is otherwise interrupted . . .," page 22

13. Please amend this risk factor to include the limit of your insurance coverage.

## Risks Related to Commercialization

"Even though ReSure Sealant has received marketing approval from the FDA . . . ," page 23

14. Here, on page 60 of your disclosure, and wherever else applicable in your registration statement, please cite the total revenue generated by ReSale Sealant during the period of commercialization in Europe.

### Special Note Regarding Forward-Looking Statements and Industry Data, page 48

15. Please remove the last sentence of this section. Asserting that you have not independently verified information included in your registration statement can be construed as disclaiming responsibility for such information, which is not appropriate.

## Use of Proceeds, page 50

- 16. Please include separate bullet points identifying the amount of net proceeds you intend to allocate toward expanding your manufacturing capacity and the amount to be allocated on sales and marketing activities, and remove the references to them from your last bullet point.
- 17. Similarly, please include a separate bullet point that identifies the amount of net proceeds you intend to allocate toward preclinical product development and remove the reference to this from your last bullet point.

18. Please include a separate bullet point that discloses the amount of net proceeds, if any, you intend to allocate toward payment of the loans you have borrowed under your credit facility.

Management's Discussion and Analysis of Financial Condition and results of Operations Critical Accounting Policies and Estimate

Determination of the Fair Value of Common Stock, page 67

19. Please tell us the factors contributing to the increase in the common stock fair value of \$0.94 on September 12, 2013 to \$1.45 on November 7, 2013 to \$3.33 on February 12, 2014. In addition, to the extent your estimated IPO price is significantly different from your most recent valuation at March 27, 2014, please tell us the factors contributing to the change in the common stock fair value. Please note that we will defer our evaluation of any stock compensation issues until an estimated IPO price has been determined.

## Options and Restricted Stock Granted, page 69

20. Please provide us a table and narratives that disclose all equity issuances to date or confirm that no additional equity issuances such as options, warrants, preferred stock, common stock, etc. were made subsequent to April 14, 2014.

## Business General

21. In your discussion of clinical trials, please explain more clearly what the p-values and n-values cited represent, where applicable.

### Dexamethasone Punctum Plug (OTX-DP), page 92

22. Where you reference the three severe adverse events experienced by participants in the Phase 2 trial on page 97, please provide the basis for your assertion that they were unrelated to the study treatment.

### Travoprost Punctum Plug (OTX-TP), page 99

23. In your discussion of the pilot studies and clinical study please state the reason(s) to your knowledge why certain of the plugs would not be retained over the entire study period.

# Moxifloxacin Punctum Plug (OTX-MP), page 105

24. In your description of the clinical trial, please further explain your statement that 0% of the plugs being present at the end of the trial indicated that it functioned as designed.

# ReSure Sealant, page 106

25. In your discussion of the pivotal clinical trial, please specify which p-value represents statistical significance.

# Government Regulation General, page 116

26. Please indicate the number of Investigational New Drug Application(s) you have filed with the FDA to date, the product candidate(s) and indication(s) to which they relate and the approximate date(s) when filed.

# Shares eligible for future sale Lock-up Agreements, page 161

27. Please file a copy of the form lock-up agreement as an exhibit to your registration statement or, alternatively, please confirm that it will be filed as an exhibit to your underwriting agreement.

## **Financial Statements**

Notes to Financial Statements

2. Summary of Significant Accounting Policies

Unaudited Pro Forma Information, page F-8

28. Please tell us why you did not reflect the April 2014 financing in the pro forma here as you have in other parts of the filing.

## Inventory Valuation, page F-10

29. Please disclose how much inventories were expensed during the periods presented in preparation for the launch of ReSure Sealant during the first quarter of 2014.

If you intend to respond to these comments with an amended draft registration statement, please submit it and any associated correspondence in accordance with the guidance we provide in the Division's October 11, 2012 announcement on the SEC website at http://www.sec.gov/divisions/corpfin/cfannouncements/drsfilingprocedures101512.htm.

Please keep in mind that we may publicly post filing review correspondence in accordance with our December 1, 2011 policy (http://www.sec.gov/divisions/corpfin/cfannouncements/edgarcorrespondence.htm). If you intend to use Rule 83 (17 CFR 200.83) to request confidential treatment of information in the correspondence you submit on EDGAR, please properly mark that information in each of your confidential submissions to us so we do not repeat or refer to that information in our comment letters to you.

You may contact Keira Nakada at (202) 551-3659 or James Rosenberg at (202) 551-3679 if you have questions regarding comments on the financial statements and related matters. Please contact Scot Foley at (202) 551-3383, John Krug at (202) 551-3862 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Daniel Greenspan for

Jeffrey P. Riedler Assistant Director

cc: David E. Redlick, Esq.
Brian A. Johnson, Esq.
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, Massachusetts 02109