

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

July 21, 2014

Via E-Mail
Charlie Deignan
Chief Financial Officer
Clearside Biomedical, Inc.
1220 Old Alpharetta Road, Suite 300
Alpharetta, GA 30005

Re: Clearside Biomedical, Inc.

Confidential Draft Registration Statement on Form S-1

Submitted June 24, 2014 CIK No. 0001539029

Dear Mr. Deignan:

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. If our comments are applicable to portions of the filings that we have not cited, please make the appropriate changes elsewhere in the filing in accordance with our comments.
- 2. Please submit all exhibits as soon as practicable. We may have further comments upon examination of these exhibits.
- 3. Please confirm that the graphics included in your registration statement are the only graphic, visual, or photographic information 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.

- 4. 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.
- 5. Your exhibit index indicates that you have submitted or will be submitting a confidential treatment request with respect to portions of certain of your exhibits. Please note that our comments on your request for confidential treatment will be provided under separate cover.

Prospectus Summary

Overview of Clearside Biomedical, page 1

6. Please describe briefly the regulatory approval pathway under Section 505(b)(2) of the FDA the first time you reference it

Risks Associated with Our Business, page 8

7. Please expand the second bullet point to specify that CLS-TA has not yet been dosed in humans and that you have little or no experience with your actual microinjector device in humans.

Risk Factors

"We are very early in our development efforts..." page 19

- 8. Please revise this risk factor to explain why you are not planning to conduct any Phase 1 clinical trials in your CLS-1003 program and to discuss any risks that the FDA may require you to conduct additional safety testing in humans before proceeding with your planned Phase 2 trial.
- 9. Please expand this risk factor to discuss any risks associated with submitting or relying on results from trials conducted outside of the United States without an IND to support your NDA.

"We will incur increased costs and demands..." page 55

10. Please expand this risk factor to include an estimate of the additional legal, accounting and other costs you expect to incur as public company.

Management's Discussion and Analysis of Financial Condition and Results of Operations Research and Development, page 69

11. Please disclose the research and development expenses incurred to date or from the point where you began allocating such costs for each of your significant product candidates.

<u>Critical Accounting Policies and Significant Judgments and Estimates</u> Stock-Based Compensation, page 79

12. Please note we may have additional comments on your accounting for stock compensation or any beneficial conversion features once you have disclosed an estimated offering price. Please supplementally provide us with a quantitative and qualitative analysis explaining the difference between the estimated offering price and the fair value of each equity issuance through the date of effectiveness for the preceding twelve months.

Business, page 85

- 13. Please revise your disclosure to specify when and, if applicable, the indication for which, you submitted any INDs in connection with your clinical trials of CLS-1001 and CLS-1003. If you have conducted clinical trials for which you did not submit a corresponding IND, please tell us why.
- 14. We note your reference in several places, including pages 86, 88, 90, 100 and 101, to discussions with the FDA concerning the timing, design and sufficiency of your anticipated Phase 3 pivotal trial for CLS-1001. Please disclose when such discussions took place and whether these were pursuant to one or more formal meetings.

CLS-1001 Program Targeting Macular Edema Associated with Non-infectious Uveitis, page 96 CLS-1002 Program Targeting Wet Age-Related Macular Degeneration, page 106

- 15. Please expand your disclosure of your preclinical studies in these programs to disclose the number of subjects in each study.
- 16. With respect to the interim efficacy results of your Phase 1/2 trial of CLS-1001 described on pages 94 through 96, if practicable please provide some frame of reference for the observed results by comparing the improvement in IOP, BCVA and retinal thickness to the current standard of care for non-infectious uveitis. Similarly, if it is practicable to do so, please compare the improvement in BCVA observed in the Phase 1 study of CLS-1002, discussed on page 106, to the level of improvement that would be expected for the intravitreal administration of Avastin in patients with wet AMD. If such comparisons are not possible, given the design limitations of these studies, please include a statement noting such limitations.

Our Proprietary SCS Microinjector, page 108

17. As your microinjector is designed to deliver drugs into the suprachoroidal space (SCS) of the eye, please clarify why current standard-of-care intravitreal injection delivery systems could not be used to similarly administer drug to the SCS in lieu of the vitreous area.

Intellectual Property

Patents and Patent Applications, page 114

- 18. Please revise your disclosure:
 - to clarify which of your patents and patent applications you own and which you license from third parties, and from whom, and
 - to identify the "other major markets" in which those patents were issued or applications filed.

License Agreement with Emory and Georgia Tech, page 115

- 19. Please expand your description of your license agreement:
 - to disclose the aggregate amount of the remaining milestone payment(s) you may be required to make; and
 - to clarify when the minimum annual royalty increases to \$100,000.

Management

Non-Management Directors, page 129

20. Please summarize the findings of the Commission concerning the disclosure deficiencies and securities violations described in the Section 21C cease-and-desist order of September 30, 2008 (Release 58690) which resulted in sanctions against Dr. Shaffer.

Part II

Item 16, Exhibits and Financial Statement Schedules, page II-3

- 21. Please file a copy of each of the following agreements as an exhibit to your registration statement or provide your legal analysis as to why you are not required to do so:
 - Your Durham, NC lease; and
 - Your collaboration agreement with Santen.

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 James Peklenk at (202) 551-3661 or Joel Parker at (202) 551-3651 if you have questions regarding comments on the financial statements and related matters. Please contact Amy Reischauer at (202) 551-3793, Daniel Greenspan at (202) 551-3623 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Daniel Greenspan for

Jeffrey P. Riedler Assistant Director

cc: Via E-Mail
Brian F. Leaf
Cooley LLP
11951 Freedom Drive
Reston, VA 20190-5656