

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

February 13, 2020

Jasbir Seehra, Ph.D.
Chief Executive Officer
Keros Therapeutics, Inc.
99 Hayden Avenue, Suite 120, Building E
Lexington, MA 02421

Re: Keros Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted January 21, 2020
CIK No. 0001664710

Dear Dr. Seehra:

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 Submitted on January 21, 2020

#### Our Biological Focus, page 2

1. Please provide context for the strategic goals in the bulleted discussion on page 2 to explain how each of the goals relates to the current offer. If the goals will not be addressed with the proceeds of the offer, please disclose that these goals will not be achievable without additional funding.

#### Our Pipeline, page 3

2. We note the inclusion of ActRII and "Multiple ActRII variants" in the table on page 3. Please expand the table and your disclosure to provide more information about the company's progress with respect to pre-clinical trials for these applications. If you have

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- undertaken IND enabling studies for any of the treatments listed in the table, please describe these studies in the disclosure. Alternatively, please state in the disclosure surrounding the table where you are in the IND process.
- 3. Please balance the pipeline table disclosure by stating the approximate number of patients worldwide who could benefit from each of the therapies in the table or otherwise clarify your estimate of the potential market size for each therapy. In this regard, we note your statements (e.g., page 1) that you are focusing on "novel treatments for patients suffering from hematological and musculoskeletal disorders with high unmet medical need," as well as your statements that the total worldwide number of FOP patients may be approximately 3,500.
- 4. Please add to the table a column for Phase 3.

### Implications of Being an Emerging Growth Company, page 5

5. 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.

## Risk Factors, page 11

- 6. We note that there are references to foreign regulators and foreign markets throughout the Risk Factors and other sections of your prospectus. Please revise to explain what non-US markets, if any, you plan to enter, and what steps you have taken to attain the necessary regulatory and patent approvals.
- 7. We note references throughout the prospectus to risks and benefits associated with orphan drug status. Given the small number of patients who may benefit from certain of the treatments you are developing, please provide more information concerning whether the company currently intends to seek orphan drug status for any of its product candidates.
- 8. We note your disclosure in the Risk Factors and throughout the prospectus regarding the company's having conducted its phase 1 clinical trials in Australia, through its Australian subsidiary, together with the information that foreign trials may not be acceptable to the FDA. Please revise throughout the prospectus to include information about how you will replicate the trials in the US, if necessary to gain FDA approval, and how you will pay for the additional trials.
- 9. We note your disclosure on page 60 and on page 150 that your exclusive forum provision does not apply to actions arising under the Securities Act or the Exchange Act. Please ensure that the exclusive forum provision in the bylaws (as effective on the closing of the offering) states this clearly, or tell us how you will inform investors in future filings that the provision does not apply to any actions arising under the Securities Act or Exchange Act.

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# Management's Discussion and Analysis of Financial Condition and Results of Operations Determination of the Fair Value of Common Stock, page 83

10. Once you have an estimated offering price or range, please explain to us the reasons for any significant differences between the recent valuations of your common stock leading up to your initial public offering and the estimated offering price. Please also explain reasons for significant differences between prices at which you sold preferred stock and valuations of common shares. This information will help facilitate our review of your accounting for equity issuances.

# Consolidated Financial Statements

Note 2. Research and Development Costs, page F-10

11. For all periods presented, please disclose the amount of income earned and costs incurred related to research and development activities of the Novo Nordisk license agreement. Refer to ASC 730-20-50-1.

## General

12. Please provide us mockups of any pages that include any additional pictures or graphics to be presented, including any accompanying captions. Please keep in mind, in scheduling your printing and distribution of the preliminary prospectus, that we may have comments after our review of these materials.

You may contact Christie Wong at 202-551-3684 or Brian Cascio at 202-551-3676 if you have questions regarding comments on the financial statements and related matters. Please contact Julia Griffith at 202-551-3267 or Dietrich King at 202-551-8071 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences