

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

April 29, 2015

Via E-Mail
Kamil Ali-Jackson
Chief Legal Officer
Aclaris Therapeutics, Inc.
101 Lindenwood Drive, Suite 400
Malyern, PA 19355

**Re:** Aclaris Therapeutics, Inc.

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

Submitted April 2, 2015 CIK No. 0001557746

Dear Ms. Ali-Jackson:

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.

## Our Business, page 1

1. Please revise your disclosure to clarify the distinction and import between the terms "clinically relevant" and "statistically significant" where these terms first appear. For example, we note you state on page 1 "[i]n these trials, following one or two applications of A-101, we observed clinically relevant and statistically significant improvements in clearing SK lesions on the face, trunk and extremities of the body."

# Strategy, page 2

2. Where appropriate in your list of key strategic components, please revise to clarify, if true, that you currently do not have any collaboration or licensing agreements and have not acquired any additional drug candidates.

# We will incur increased costs and demands upon management as a result..., page 47

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

## Industry and Market Data, page 48

4. You state that "[i]ndustry publications and third-party research, surveys and studies...do not guarantee the accuracy or completeness of such information." Please revise your disclosure to remove this statement as it could be understood to implicitly disclaim your liability for information contained in your registration statement or, alternatively, specifically state that you are responsible for the referenced information.

# Use of Proceeds, page 49

- 5. Please revise your disclosure that you expect the offering proceeds to allow you to complete your "planned clinical trials" of A-101 to specify, if true, that the proceeds will allow you to complete all three of your planned Phase 3 clinical trials and to seek regulatory approval of A-101 for the treatment of SK.
- 6. Please revise this section to disclose to what stage of development you anticipate reaching as a result of your allocation of proceeds for the research and development of A-101 for the treatment of common warts and A-102 for the treatment of SK and common warts.

#### Stock Based Compensation, page 60

- 7. Please revise your disclosures to include a discussion of the assumptions used in the probability-weighted expected return method used in the valuation of the common stock shares at each valuation date.
- 8. We may have additional comments on your accounting for equity issuances including stock compensation and beneficial conversion features. Once you have an estimated offering price, please provide us an analysis explaining the reasons for the differences between recent valuations of your common stock leading up to the IPO and the estimated offering price.

# A-101 Mechanism of Action, page 72

9. We note your graphic and pre- and post-treatment photos on page 73 that illustrate this mechanism of action for A-101 and its results in a patient who responded to treatment with A-101. In the absence of sufficient information accompanying the pre- and post-treatment photographs, potential investors may be unable to put such pictures in their

proper context. For example, it is unclear whether the examples shown on the pages are fair representations of the observed outcomes of your trials. Nor is it clear how the "before" and "after" photographs depicted compare to photographs of the larger spectrum of patients. The photographs raise a host of questions, including:

- What criteria was used to select this patient from among the larger patient population;
- How does the patient depicted in the photographs relate to the other patients and overall results; and
- How do the pictures shown compare to the pictures of other patients in the trials.

Accordingly, please remove these photographs from your registration statement.

# Clinical Development, page 74

10. Please expand the discussion concerning the three Phase 2 clinical trials to disclose the number of subjects receiving each of the product concentrations administered and the control, respectively.

#### Clinical Development, page 74

11. We note you submitted an IND for A-101 in September 2013 and propose to have a post-Phase II meeting with the FDA later this year. We also note that based on discussions with the FDA you believe your drug candidates and applicator will be reviewed and approved as a single product. Please expand your disclosure to include a summary of the dates and substance of your material discussions and other communications with the FDA pertaining to your candidates.

## <u>Investigator-Sponsored trial, page 82</u>

- 12. We note your disclosure on page 82 regarding a trial conducted by a physician-investigator using an A-101 topical solution in subjects with common warts. Please provide additional information about this trial including:
  - The indication(s) listed on the IND application;
  - The date of the IND submission to the FDA;
  - The name of the investigator;
  - The demographic characteristics of the persons who were studied and how they were recruited; and
  - The location(s) of the trial.

# Manufacturing, page 83

13. Please briefly discuss each party's ability to terminate your supply agreement with PeroxyChem LLC.

14. The long-term supply or service agreements for the clinical and commercial supply of the pen-type applicator and final finished packaged drug product appear to be material. Please provide expanded disclosure describing the material terms of these agreements and file the agreements as exhibits. Alternatively, please provide an analysis as to why you are not substantially dependent upon the agreements.

#### Notes to Financial Statements

- 3. Fair Value of Financial Assets and Liabilities, page F-13
  - 15. Please provide us analyses under ASC 320-10-50-1B and ASC 820-10-50-2B supporting your presentation of marketable securities by "major security types" and "classes." In this regard, please tell us why you did not further disaggregate your corporate debt securities.
  - 16. You disclose that "in determining the fair value of its marketable securities valued using Level 2 inputs, the Company primarily relied on quoted prices in markets that are not active for identical or similar securities." Please provide us, for each "class" (see comment 1 above), the valuation technique(s) and inputs used in your fair value measurement. Refer to ASC 820-10-50-2bbb.

# Other Comments

- 17. Please submit all exhibits as soon as practicable. We may have further comments upon examination of these exhibits.
- 18. 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.
- 19. 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.
- 20. Your exhibit index indicates that you have submitted 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.

You may contact Staff Accountant Christine Torney at (202) 551-3652 or Senior Assistant Chief Accountant Jim Rosenberg at (202) 551-3679 if you have questions regarding comments on the financial statements and related matters. Please contact Staff Attorney Preston Brewer at (202) 551-3969, Senior Staff Attorney John Krug at (202) 551-3862 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Jeffrey P. Riedler

Jeffrey P. Riedler Assistant Director

cc: <u>Via E-Mail</u> Brian F. Leaf, Esq. Cooley LLP