

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

December 31, 2013

Via E-Mail
Todd C. Brady, M.D., Ph.D.
President and Chief Executive Officer
Aldexa Therapeutics, Inc.
15 New England Executive Park
Burlington, MA 01803

Re: Aldexa Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted December 4, 2013

CIK No. 0001341235

Dear Dr. Brady:

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.

# <u>Gene</u>ral

- 1. Please submit all exhibits as soon as practicable. We may have further comments upon examination of these exhibits.
- 2. Please confirm that the images included in your draft registration statement are all of the graphic, visual or photographic information you will be including. If you intend to use any additional images, please provide us proofs of such materials. Please note that we may have comments regarding this material.
- 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.

4. We will deliver any comments to your confidential treatment request via separate letter. Please be advised that we will have to grant the confidential treatment request before we can act upon any request for effectiveness of the registration statement you will file.

#### Table of Contents

- 5. Please revise your table of contents to include a reference to your "Industry and Market Data" section on page 118.
- 6. Please note that it is not appropriate to state or imply that you do not have liability for the statements in your registration statement. Your statements that you have not independently verified any third-party information could imply that you are not taking liability for this information. In order to eliminate any inference that you are not liable for all of the information in your registration statement, please delete this statement or include a statement specifically accepting liability for information that appears in your registration statement that was obtained from third party sources. Please also revise your disclosure under "Industry and Market Data" on page 118 to conform to this comment.

#### Prospectus Summary, page 1

#### Overview, page 1

- 7. Please disclose whether the active ingredient or any other essential component of NS2 was developed in house or acquired by means of a license. If the product or intellectual property related to NS2 was acquired or licensed, disclose the terms of the acquisition or the license and file any related agreements as exhibits.
- 8. Please define the term "corticosteroids" to provide a reasonable investor with an understanding of such term.

# <u>Implications of Being an Emerging Growth Company, page 3</u>

9. Please expand your disclosure to indicate (as you have indicated on page 55) that you have irrevocably elected to opt out of the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act and that, as a result, you will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies. In addition, please remove Bullet Point # 3 since you are not taking advantage of the provision listed under that bullet point.

# The Offering, page 4

10. In the introduction to the listing of excluded shares you indicate that the number of shares of your common stock to be outstanding after your offering is based on 47,642,078 shares of common stock outstanding as of September 30, 2013. It appears that this amount includes the anticipated conversion of your Series A and Series B preferred stock as your financial statements indicate that only approximately 3.9 million shares of your common stock were outstanding at that date. Please revise this introductory sentence to clearly indicate that the amount you disclose includes the assumed conversion of your preferred stock.

#### Risk Factors, page 8

# "We will require substantial additional funding...," page 9

11. The information in this risk factor is duplicative of the information contained in the risk factor on page 29 that begins, "If we fail to obtain the capital necessary..." Please eliminate the risk factor on page 9.

#### "If we are not able to test NS2 in SLS or in other diseases...," page 11

12. We note your disclosure that you have filed an IND allowing you to commence a study of NS2 administered as an eye drop in healthy volunteers. It appears that this group of subjects does not relate to any medical condition or pharmaceutical indication. Please expand the risk factor to explain the indication(s) related to the IND you filed and the nature of the additional INDs you will have to file in the future by indication in order to enable you to commence all of the trials you are planning to conduct.

#### "If we fail to attract and retain senior management and key commercial..." page 20

13. Please disclose any difficulties you have experienced attracting or retaining senior management or key personnel in the past.

# "If product liability lawsuits are brought against us...," page 23

14. Please clarify whether you have already obtained product liability coverage and, if so, please state the amount of coverage you have obtained.

#### Use of Proceeds, page 38

15. We note your disclosure that you anticipate you will spend up to \$10 million on clinical trials related to NS2. Please expand this discussion to clarify to which of the planned five clinical trials you expect to apply the \$10 million and the amount you currently anticipate you will apply to each of these trials. Please also disclose whether the application of

Share-based Compensation, page 47

these proceeds will allow you to complete the studies for which you expect to use a portion of the proceeds.

# <u>Capitalization</u> Dilution, page 41

16. Please revise your disclosure of shares excluded from your capitalization and dilution presentations to specifically exclude the options granted in October 2013 consistent with your disclosure in Summary on page 4.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Financial Operations Overview
Critical Accounting Policies and Significant Judgments and Estimates

- 17. Disclosures at page 49 list contemporaneous valuations prepared by independent third-party valuation specialist as of particular dates, including October 23, 2008. Disclosures at page 50 under "June 22, 2012 Grant" states the October 2008 was not contemporaneous. Please revise your disclosures to be consistent that this valuation was or was not contemporaneous.
- 18. Please revise your disclosures to clarify why the fair value of your common stock declined from \$1.39 per share at June 21, 2013 to \$0.88 per share at September 8, 2013 as disclosed in the second footnote to the second table on page 48.
- 19. Please address the following regarding the valuation of your common stock:
  - Once you can reasonably estimate the IPO price, qualitatively and quantitatively discuss in the filing each significant factor contributing to the difference between each valuation and the estimated IPO price.
  - Disclose the intrinsic value of the outstanding vested and unvested options based on the estimated IPO price and the options outstanding as of the most recent practicable date before requesting effectiveness of your registration statement.
  - Continue to update your disclosure for all equity related transactions through the effectiveness date of the registration statement.

#### Business, page 60

#### Overview, page 60

20. We note your disclosure that "Aldexa was formed as a Delaware corporation in 2004." Please expand your disclosure to include the information provided in Note 1 to Financial Statements on page F-8. Specifically, please disclose the fact that you operated as Neuron Systems, Inc. from the date of incorporation until December 20, 2012.

- 21. At first use, please define the following terms to provide a reasonable investor with an understanding of such terms:
  - "catabolizes;"
  - "mucosal lesion;"
  - "compensatory dermal hypertrophy;"
  - "hyperkeratosis;"
  - "NF-kB;"
  - "intra-peritoneal;"
  - "radiation mucositis;"
  - "primary amine;"
  - "substrates;" and
  - "amine-containing stereoisomers."

#### Intellectual Property and Proprietary Rights, page 66

22. We note your discussion of your patent portfolio. Please disclose the jurisdictions, other than the United States, where patents have been issued and where patent applications have been filed or are pending.

# Other Intellectual Property Rights, page 66

- 23. Please expand your disclosure of the License and Supply Agreement to:
  - indicate the maximum amount of potential milestone payments that you may owe to CyDex Pharmaceuticals, Inc. under the terms of the agreement;
  - clarify, if true, that the patents relate to the excipient which is used in the eye drop formulations of NS2;
  - explain the function of the excipient in the formulation and whether the patents relate to composition of matter or method of use or process; and
  - state when the last of these licensed patents expire.

# Competition, page 67

24. Please discuss any products you are aware of that are being developed to specifically target any of the four conditions for which you intend to develop NS2. For each known competing product, please disclose the product, the company developing the product and the stage of development. Please also provide a brief reference to competing targeted products in development on page 19 of the risk factor section under the risk factor that begins, "If our competitors develop treatments for the target indications..."

# Executive Compensation, page 85

25. Please be advised that as an S-1 user you will have to update the Executive Compensation section after January 1, 2014 to include 2013 executive compensation

information. You should retain the 2012 information in the Summary Compensation Table.

Description of Capital Stock
Common Stock
Voting Rights, page 98

26. Please expand your description of your common stock to specify the vote required by security holders to take action, as required by Item 202(a)(1)(v) of Regulation S-K.

#### **Underwriting**

Lock-Up Agreements, page 111

27. When available, please file a form of the lock-up agreement as an exhibit to your registration statement.

#### Financial Statements

Statements of Operations and Comprehensive Income (Loss), page F-4

28. Please limit your pro forma income (loss) per share information to the most recent fiscal year and subsequent interim period.

# General

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 Christine Allen at (202) 551-3652 or Mark Brunhofer at (202) 551-3638 if you have questions regarding comments on the financial statements and related matters. Please contact Christina De Rosa at (202) 551-3577 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>

Keith J. Scherer Of Counsel

Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP

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