

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

DIVISION OF CORPORATION FINANCE

January 15, 2015

<u>Via E-Mail</u> Gordon K. Johnson Chief Financial Officer KemPharm, Inc. 2656 Crosspark Road, Suite 100 Coralville, IA 52241

> Re: KemPharm, Inc. Draft Registration Statement on Form S-1 Submitted December 19, 2014 CIK No. 0001434647

Dear Mr. Johnson:

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 your disclosure throughout the prospectus regarding the Asset Purchase Agreement, dated as of March 21, 2012 and the Agreement to Terminate CLA, dated March 20, 2012. Please revise your disclosure wherever appropriate to discuss the connection between these two agreements and clarify what the Agreement to Terminate CLA ended and why the parties executed it. You should also disclose all material terms of both agreements in the Business section. Further, you should disclose the identities of all of the parties to the Agreement to Terminate throughout the prospectus and in the list of exhibits. In that regard, you should be clear about any material agreements you have entered into with any officer, director, principal shareholder, founder or affiliate. Any such agreement should also be identified in "Related Party Transactions" beginning on page 141 as a related party transaction.

Our Pipeline of NME Prodrug Product Candidates, page 3

2. Please revise your product pipeline table on pages 3 and 92 to substitute the Phase (i.e., Phase I, Phase II, or Phase III) for "Clinical Trials" in the third column (i.e., under the heading "Development Status").

The Offering, page 9

3. Please revise your disclosure on pages 9, 11 and 64 to state the number of warrants to purchase common stock that will be outstanding after completion of the offering.

If the FDA does not conclude that our product candidates are..., page 17

4. Please revise this risk factor to disclose that the acronym "REMS" stands for Risk Evaluation and Mitigation Strategy.

We face substantial competition, which may result in others discovering, page 37

5. Please revise this risk factor to identify competing products for KP511 and KP606 and the names of the competing companies.

We will incur increased costs and demands upon management..., page 60

6. We note your disclosure stating that you anticipate incurring "additional legal, accounting and other expenses in operating as a public company. Please expand this risk factor to include an estimate of the additional legal, accounting and other costs you expect to incur as public company.

Market and Industry Data, page 62

7. We note your disclosure that the "prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties" and that those resources "generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information." A reader may infer from this disclosure that you are not responsible for some of the information in the prospectus. Please revise to exclude such language or state that you are responsible for the referenced information in the prospectus, including estimates and information provided by IMS Health Incorporated.

Research and Development, pages 75 and 76

8. Please disclose the costs incurred for each period presented and, in total, for periods prior to the year ended December 31, 2012 for KP201/APAP. For the remainder of your research and development costs for each period presented, disclose the composition of this cost by project or nature of cost distinguishing between discovery, preclinical and clinical development categories, as applicable. Provide explanation of period to period fluctuations.

Overview, page 88

9. When you discuss your end-of-Phase 2 meeting with the FDA regarding KP201/APAP, please summarize the nature of these discussions, relevant feedback from the FDA and other material information that was communicated between the parties. Please also discuss any other communications you have had with the FDA regarding any of your product candidates, including the communications that formed the basis for your statements that "[b]ased on communications with the FDA, we believe that no additional efficacy trials will be required for KP201/APAP" and "the FDA has confirmed that KP201/APAP is bioequivalent to Norco."

Completed Clinical Trials, page 95

10. In view of the small number of subjects completing each of the five completed studies, please provide additional disclosure wherever you discuss the statistical significance of the results in order to put it in an appropriate context. That disclosure should state that in view of the small number of subjects who completed the study and received either the product or the control, the p-values calculated are relatively unreliable. Please provide the p-values from each completed study and explain what those values measure. Furthermore, because of the small number of subjects who completed the study, the results of future trials that include more subjects are more likely to show differing results. You should also cite the small number of subjects and the resulting unreliability in the bulleted list of risks in the summary and in the risk factors section as a separate risk factor.

Manufacturing, page 106

11. Your disclosure indicates that you contract with your sole source supplier Johnson Mathey Inc. for the manufacture of bulk quantities of KP201 used in KP201/APAP, which is manufactured under contract by a third party. Please revise your disclosure to provide the name of your third party manufacturer of KP201/APAP and to disclose the material terms of your contract with this manufacturer. Also, you should file this agreement as an exhibit.

2013 Summary Compensation Table, page 131

12. We note your summary compensation table covers your 2013 fiscal year. Now that your 2014 fiscal year has ended, please add FY2014 disclosure to the summary compensation table on page 131 and update the rest of the compensation information to include your FY2014 information.

Principal Stockholders, page 147

- 13. We note that James E. Flynn beneficially owns the shares held of record by Deerfield Private Design Fund III indirectly through his involvement with Deerfield Mgmt III, L.P. and Deerfield Management Company, L.P. You state that Mr. Flynn shares beneficial ownership with those entities. However, as a natural person, it appears that Mr. Flynn is actually the sole beneficial owner of those shares. Please revise Footnote 1 to explain how Mr. Flynn exercises beneficial ownership but to also state that he is the sole beneficial owner.
- 14. We note that Jonathan S. Leff, one of your five "independent directors," is a partner and chairman of the Deerfield Institute but beneficially owns no KemPharm, Inc. common stock. Please advise us as to the relationship between the Deerfield Institute and the other Deerfield entities and why Mr. Leff is not reflected in the table as sharing beneficial ownership of the shares held of record by Deerfield Private Design Fund III with Mr. Flynn. Also, if Mr. Leff acts as Deerfield's or Mr. Flynn's representative on the board in accordance with any arrangement or understanding, written or otherwise, please disclose such relationship and the arrangement or understanding in the filing.

2. Summary of Significant Accounting Policies, page F-7

15. Please provide a description of your accounting policy for patent costs, including related legal expenses.

Warrants on Common Stock, page F-20

- 16. On page F-21, you state that the Underwriter Warrants did not meet the criteria for equity classification. Please tell us the terms of the Underwriter Warrants and the accounting guidance you considered in making this determination.
- 17. We may have additional comments on your accounting for equity issuances including stock compensation, underwriter and preferred stock warrant liability, 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.

Deerfield Facility Agreement, page F-37

18. Please tell us whether and, if so, how the effectiveness of the IPO will impact the conversion of the Deerfield Convertible Notes and the exercisability of the Deerfield Warrant into Series D Preferred.

Conversion of 2013 Convertible Notes Into Series D Preferred, page F-38

19. Please tell us whether and, if so, how the effectiveness of the IPO will impact the exercisability of the 2013 Warrants into Series D Preferred.

Other Comments

- 20. Where the following terms first appear, please give the meaning and significance of such terms in plain language that may be understood by a lay reader not acquainted with the relevant industry or scientific field:
 - "bioequivalent";
 - "bioavailability";
 - "statistical significance;
 - "moiety";
 - "prodrugs"; and
 - "new molecular entity."
- 21. Please submit all exhibits as soon as practicable. We may have further comments upon examination of these exhibits.
- 22. 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.
- 23. 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.
- 24. 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 Keira Nakada at (202) 551-3659 or Jim Rosenberg at (202) 551- 3679 if you have questions regarding comments on the financial statements and related matters. Please contact Preston Brewer at (202) 551-3969 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> Brent Siler, Esq. Cooley LLP