

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

DIVISION OF CORPORATION FINANCE

May 29, 2014

<u>Via E-Mail</u> Jodie P. Morrison President and Chief Executive Officer Tokai Pharmaceuticals, Inc. One Broadway, 14th floor Cambridge, MA 02142

> Re: Tokai Pharmaceuticals, Inc. Confidential Draft Registration Statement on Form S-1 Submitted May 2, 2014 CIK No. 0001404281

Dear Ms. Morrison:

We have reviewed your confidential 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 confidential 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 confidential 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.

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- 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. We note that you have submitted a request for confidential treatment of portions of certain of your exhibits. We will provide any comments on your confidential treatment request and the related disclosure in a separate comment letter.
- 6. Please amend your filing to include updated financial statements meeting the requirements of Regulation S-X, as well as any financial information required by Rule 8-04 and 8-05 of Regulation S-X.

# **Risk Factors**

## "If serious adverse or unforeseen side effects are identified ..." page 16

7. Please expand this risk factor to disclose the nature and amount of any serious treatment-related side effects reported in your clinical trials to date and whether you have experienced interruptions or delays as a result of such adverse events.

## "We will incur increased costs as a result of operating as a public company..." page 39

8. Please expand this risk factor to include an estimate of the annual costs you expect to incur as public company.

## Use of Proceeds, page 44

9. Please revise your disclosure to identify the financial advisor to which you will pay a portion of the proceeds and briefly describe the services rendered. In the Business section, please describe any ongoing material terms of your agreement with such advisor. In addition, please file a copy of your agreement with this advisor as an exhibit to your registration statement pursuant to Item 601 of Regulation S-K.

## Business, page 68

- 10. In this section and in the Prospectus Summary, please briefly disclose the significance of fast track FDA review.
- 11. Please revise your disclosure to specify when, and the indication for which, you submitted any INDs in connection with your clinical trials of galeterone. If you have

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conducted clinical trials for which you did not submit a corresponding IND, please tell us why.

<u>Galeterone Clinical Development</u> <u>ARMOR2 Trial</u> Clinical Trial Presented at ASCO GU, page 76

12. In addition the interim efficacy data provided, please advise us and disclose, if applicable, whether there were any interim data available for the other patient populations you identify on page 75.

## Reformulation of Galeterone, page 78

13. Please expand your disclosure to explain what you mean by a "spray dried dispersion formulation" and how it is administered.

# Intellectual Property Galeterone Patent Portfolio, page 85

14. Please explain what a provisional patent application is and disclose the foreign jurisdictions associated with your patents and patent applications.

## License Agreement with University of Maryland, page 87

15. Please disclose the expiration date of the license with UMB or, if applicable, state that it is perpetual unless terminated in accordance with its terms.

## Employment Agreements, Severance and Change in Control Agreements, page 109

16. Please disclose the material terms of each of the employment agreements with Mr. McBride and Dr. Ferrante and file these agreements pursuant to Item 601(b)(10) of Regulation S-K.

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

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confidential submissions to us so we do not repeat or refer to that information in our comment letters to you.

You may contact Jim Peklenk at (202) 551-3661 or Andrew Mew at (202) 551-3377 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: <u>Via E-Mail</u> Stuart M. Falber Wilmer Cutler Pickering Hale and Dorr LLP 60 State Street Boston, MA 02109