

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

Mail Stop 4720

October 20, 2015

Via E-mail
Mark Iwicki
Chief Executive Officer
Kala Pharmaceuticals, Inc.
100 Beaver Street, Suite 201
Waltham, MA 02453

Re: Kala Pharmaceuticals, Inc.

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

Submitted September 21, 2015

CIK No. 0001479419

Dear Mr. Iwicki:

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.

# Prospectus Summary, page 1

#### Overview, page 1

1. Please provide a brief explanation of the Section 505(b)(2) pathway to FDA approval and how it differs from Section 505(b)(1) approval.

## Our Product Candidates, page 2

2. Please revise your pipeline table to delete the reference to KPI-285. Since you have not yet selected an indication for the product candidate, it is premature to include it in a product pipeline table. Please make conforming changes to the pipeline table on page 82.

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3. Please revise your discussion of KPI-121 0.25% for Meibomian Gland Disease to disclose the primary endpoints for the Phase 2 trial and that the product candidate did not meet one of its primary endpoints.

## Risks Associated with Our Business, page 4

4. Please expand the disclosure in your first bullet point to disclose the fact that the report of your independent registered public accounting firm states that there is substantial doubt regarding your ability to continue as a going concern.

# Risk Factors, page 10

"If serious adverse or unacceptable side effects...," page 20

5. Please disclose whether any patients in clinical studies of KPI-121 0.25% or KPI-121 1.0% initiated to date have experienced serious adverse events related to the administration of KPI-121 0.25% or KPI-121 1.0%.

# Use of Proceeds, page 54

6. For each product candidate that you intend to develop with the proceeds from this offering, please state the anticipated stage of development that you expect to reach using the proceeds of the offering.

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

Stock-based compensation and common stock valuation, page 71

7. 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.

# Business, page 81

### Overview, page 81

8. Please disclose all investigational new drug applications ("INDs") that you have submitted to the FDA as well as the indication(s) and sponsor(s) for any active INDs related to your product candidates.

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# Our MPP Technology MPP Technology, page 86

9. We note your statement below the graphic on page 87 that the graphic "is not intended to provide an actual representation of the proportion of nanoparticles that reach the eye surface or the way in which our MPP drug nanoparticles interact with the ocular surface." If the graphic is not an accurate depiction of how your product candidate works, please delete the graphic from the prospectus.

## Intellectual Property, page 103

10. Please revise this section to indicate which of your material patents or patent applications are owned by you, licensed by you or co-owned with another party. If licensed or co-owned, please indicate the licensor or co-owner.

<u>License Agreements</u>
The John Hopkins University
Financial Terms, page 105

11. We note your statement that you must "pay a percentage, ranging from low single digits to low double digits, of certain consideration that [you] or [your] affiliates receive from sublicensing rights under the licensed JHU intellectual property..." Please revise your description of royalty rates to provide a range that does not exceed ten percent (e.g. between twenty and thirty percent).

# <u>Transactions with Related Persons</u> <u>Series B-1 Preferred Stock Financing, page 142</u>

12. Please disclose the consideration received from the sale of your Series B-1 preferred stock.

#### General

- 13. 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.
- 14. 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.

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You may contact Mark Brunhofer at (202) 551-3638 or James Rosenberg at (202) 551-3679 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) 551-3675 with any other questions.

Sincerely,

/s/ Suzanne Hayes

Suzanne Hayes Assistant Director Office of Healthcare and Insurance

cc: Via E-mail

Lia Der Marderosian, Esq. Wilmer Cutler Pickering Hale and Dorr LLP 60 State Street Boston, Massachusetts 02109