

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

May 15, 2015

Via E-mail
Heidi Henson
Chief Financial Officer
Kura Oncology, Inc.
11119 N. Torrey Pines Road, Suite 125
La Jolla, California 92037

Re: Kura Oncology, Inc.

**Registration Statement on Form S-1** 

Filed April 17, 2015 File No. 333-203503

Dear Ms. Henson:

We have reviewed your 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 amending your registration statement. 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 registration statement, we may have additional comments.

## Prospectus Summary

1. Please include in your Prospectus Summary, under an appropriate subheading, a brief discussion of the most material risks facing your operations.

## Our Product Candidates, page 4

2. We note your disclosure elsewhere in the prospectus that you have not conducted any clinical trials for tipifarnib in either the HRAS or T-Cell lymphoma indications. In a footnote or narrative disclosure to the pipeline chart on this page, you should disclose the identity of the entity that conducted pre-clinical and Phase 1 clinical trials for tipifarnib and when these trials were conducted. Please additionally disclose, if true, that you expect to rely on data from these completed Phase 1 studies in order to file your INDs and launch directly into Phase 2.

#### Business, page 50

3. Please clarify the meaning of any significant scientific or technical terms the first time they are used in the Business section in order to ensure that lay readers will understand the disclosure. For example, please define "protein farnesylation", "kinases" and "RECIST v.1.1" at their first use in this section. Similarly, please revise your prospectus as necessary to explain the meaning of any important scientific terms or concepts that are reasonably likely to be unfamiliar to lay readers.

# Leverage Companion Diagnostics to Realize Positive Clinical Outcomes, page 51

4. We note your statement that you intend to utilize effective companion diagnostics in your clinical trials. We also note your disclosure on page 16, that your development programs may be dependent on the development and commercialization of companion diagnostics. In light of these statements, please expand on the exact role that companion diagnostics will play for your primary product candidates. Specifically, please clarify what role such diagnostics will play in completing successful clinical trials and what stage of clinical trials require the use of such diagnostics.

# Clinical Programs and Pipelines, page53

5. Please revise the pipeline table that appears on pages 4 and 53 so that the arrows indicating tipifarnib's developmental progress do not extend into Phase 2, as your Phase 2 trials have not yet begun.

# <u>Tipifarnib – An Oral Farnesyl Transferase Inhibitor</u> <u>Overview, pages 53-54</u>

- 6. We note your disclosure that tipifarnib's anti-cancer activity has been insufficient to support marketing approval by the FDA. Please disclose:
  - whether an NDA was previously filed with the FDA;
  - when the NDA was filed:
  - the entity which filed the NDA;
  - your relationship to this entity; and
  - the reasons(s) the NDA was not approved.

#### Preclinical Data Supporting Tipifarnib as an Inhibitor of HRAS Function, page 55

7. Please provide a brief explanation of the term "IC50" as a measurement of tipifarnib effectiveness.

# Clinical Development in HRAS Mutant Tumors, page 55

- 8. Please disclose whether you have filed an Investigational New Drug (IND) application for this indication. If no IND was filed, please tell us why.
- 9. We note that you have not conducted Phase 1 clinical trials for this indication and you intend to launch directly into Phase 2. To the extent that you plan to use data from a third party's previously completed Phase 1 clinical trials to advance the product candidate into Phase 2 trials, please revise your disclosure to accurately reflect this information. Specifically, please briefly discuss the Phase 1 trials and their results, identify who conducted the trials and when, and the extent to which relying on a third party's data poses any material risks to product approval.

# Previous Phase II Experience with Tipifarnib in the Treatment of PTCL, page 56

10. Please identify the third party responsible for conducting this Phase 2 clinical trial and indicate the dates during which the trial was conducted.

#### Clinical Development of Peripheral T-cell Lymphoma, page 58

- 11. Please disclose whether you have filed an Investigational New Drug (IND) application for this indication. If no IND was filed, please tell us why.
- 12. We note that you have not conducted Phase 1 clinical trials for this indication and you intend to launch directly into Phase 2. To the extent that you plan to use data from a third party's previously completed Phase 1 clinical trials to advance the product candidate into Phase 2 trials, please revise your disclosure to accurately reflect this information. Specifically, please briefly discuss the Phase 1 trials and their results and identify who conducted the trials and when, and the extent to which relying on a third party's data poses any material risks to product approval.

#### License and Asset Purchase Agreements, page 63

- 13. We note your references to various agreements which appear material to your business, including your license agreements with the University of Michigan and the University of San Francisco. Please amend your disclosure to discuss the material terms of these and any other material agreements. In your description of these agreements you should specifically identify, to the extent material:
  - Each party's rights and obligations;
  - Nature and scope of intellectual property transferred if the agreement involves a license;
  - Duration of agreement and royalty term, if applicable;
  - Termination provisions;

- Investment features or share purchases;
- Payment provisions, which may include the following:
  - o Up-front or execution payments received or paid
  - o Aggregate amounts paid or received to date under agreement
  - o Aggregate future milestone payments to be paid or received
  - o Royalty rates
  - o Profit or revenue-sharing provisions

In addition, please file each agreement as an exhibit to your registration statement as required under Item 601(b)(10) of Regulation S-K.

# Intellectual Property, page 67

- 14. We note your disclosure regarding your patents and patent applications. With respect to the portion of your patent portfolio relevant to each of your significant development programs, please clearly disclose:
  - whether the patents are owned or licensed from third parties;
  - applicable jurisdictions where patents are issued or where patent applications are pending;
  - type of patent protection such as composition of matter, use or process; and
  - expected expiration dates for your patents and patent applications in each of (1) the U.S. and (2) foreign jurisdictions, as a group.

## Certain Relationships and Related Person Transactions, pages 103-108

- 15. Please file the following agreements as exhibits to your registration statement pursuant to Item 601(b)(10) of Regulation S-K:
  - Note purchase agreement with Araxes entered into in October 2014;
  - Note purchase agreement with certain investors entered into in January 2015;
  - Registration rights agreement with the investors in the Private Placement;
  - Service Agreement with Wellspring entered into in October 2014; and
  - Management services agreement with Araxes entered into in October 2014.
- 16. Please describe the services agreement with Wellspring and the management services agreement with Araxes in greater detail. Please disclose the material terms of the agreements including the parties' rights and obligations, payment terms and termination provisions.

Notes to Financial Statements

9. Stockholders' Equity

Restricted Stock Awards, page F-15

- 17. Please present disclosures for employee awards separately from non-employee awards. In addition:
  - Disclose the basis for recognizing \$236,618 of share-based compensation expense;
  - Disclose the amount of and basis for any unrecognized share-based compensation;
     and
  - Disclose the terms of the non-employee awards that require you to re-measure them as they vest, as disclosed in Note 2 under share-based compensation. Separately provide us your analysis with reference to authoritative literature supporting this accounting including your use of the intrinsic value method.

You may contact Rolf Sundwall at (202) 551-3105 or James Rosenberg at (202) 551-3679 if you have questions regarding comments on the financial statements and related matters. Please contact Alla Berenshteyn at (202) 551-4325, Dan 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> James C. Pennington, Esq. Cooley LLP