

CORPORATION FINANCE

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

Mail Stop 4546

June 28, 2017

Dr. Samantha Du Chief Executive Officer Zai Lab Limited 4560 Jinke Rd Bldg.1, Fourth Floor Pudong Shanghai, China 201210

Re: Zai Lab Limited

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

Submitted May 31, 2017 CIK No. 0001704292

Dear Dr. Du:

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. 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.
- 2. We note that you intend to request confidential treatment for several exhibits. We will send comments on your application for confidential treatment under separate cover.

## Prospectus summary, page 1 Our innovative pipeline, page 2

- 3. The table of your pipeline product candidates on page 2, 94 and 96 should reflect the actual, and not the anticipated, status of your pipeline candidates as of the latest practicable date. For example, the table currently suggests that ZL-2306 is currently in Phase 3 trials for breast cancer and ovarian cancer, but the footnotes to the table suggest that Phase 3 trials have not been initiated.
- 4. Please revise the pipeline table to remove the internal discovery programs. Because you have not identified a product candidate for these programs, it is premature to include them in a product pipeline table.
- 5. Please revise the column reflecting the commercial rights to more clearly indicate where you have commercialization rights.
- 6. Please remove the column reflecting the partner clinical stage since that information does not correlate to the status of your pipeline products within the regulatory framework in China.
- 7. Please explain the relevance of the statement that your planned Phase III studies for niraparib are expected to be similar in design to Tesaro's clinical studies of niraparib.
- 8. We note your statement that you expect to commercialize niraparib for the treatment of ovarian cancer in Hong Kong and Macau during the second half of 2018 after being approved by the FDA and EMA. It is not appropriate to assume your product candidate will obtain regulatory approval. Please revise to clarify whether it currently has EMA approval. If it does not, please clarify that you hope to commercialize the product candidate in these jurisdictions, if you are able to obtain regulatory approval.

## Industry, page 4

9. In your discussion of the CFDA regulatory outlook, please balance the disclosure to reflect that the implementation of CFDA reform is uncertain and the impact this may have on your strategy.

## Risks associated with our business, page 6

10. In the first bullet point, please quantify your losses for the most recent fiscal year.

## The offering, page 9

11. Please disclose what percentage of your total share capital will be held by the public immediately after the offering.

## Risk factors, page 12

Reimbursement may not be available for our drug candidates in China..., page 28

12. We note your statement that niraparib is unlikely to be included on National Drug Reimbursement List. Please tell us why niraparib is not expected to be included and the criteria you must satisfy for inclusion on the NDRL.

## Uncertainties with respect to the PRC legal system..., page 38

13. Please explain how the proposed Foreign Investment Law as currently proposed would impact your corporate structure, corporate governance practice and business operations.

## The depositary for our ADSs will give us a discretionary proxy, page 59

14. Please reconcile the inclusion of this risk with your disclosure under "Voting Rights" on page 199 that the depositary will vote or attempt to vote only as ADS holders instruct and will not itself exercise any voting discretion.

## Use of Proceeds, page 65

15. Please clarify whether your current expectations are to complete the niraparib Phase III studies, the omadacycline Phase III studies and the ZL-2301 Phase II/III studies with the proceeds from this offering.

## Capitalization, page 67

- 16. Please tell us why the preferred shares and warrant liabilities are not included in your Total Capitalization amount in the table.
- 17. Please tell us why it is appropriate to include the exercise of warrants to purchase preferred shares in the pro forma. Please explain how these exercises are factually supportable and directly attributable to your offering.
- 18. It appears that your pro forms should reflect total shareholders' equity and a positive total capitalization rather than deficits. Please revise accordingly.

Management's discussion and analysis of financial condition and results of operations
Critical accounting policies and significant judgments and estimates
Share-based compensation, page 74

19. You disclose the use the binomial option pricing model in determining the estimated fair value of options granted. However, please expand your policy to explain how you estimated the fair value of the underlying ordinary shares and include the following:

- The methods that management used to determine the fair value of the Company's shares and the nature of the material assumptions involved,
- The extent to which the estimates are considered highly complex and subjective, and
- The estimates will not be necessary to determine the fair value of new awards once the ADSs begin trading.
- 20. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the ordinary shares underlying your equity issuances and the reasons for any differences between the recent valuations of your ordinary shares leading up to the IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features.

## Results of Operations

# Research and development expenses, page 77

21. Please revise your disclosure to include the amount of external research and development expense for niraparib incurred during the year ended December 31, 2015. Please disclose that no other program individually represents a significant amount of these expenses in 2015 or 2016; otherwise disclose the program(s) and amounts incurred.

## Liquidity and capital resources, page 79

22. Please disclose the impact on your liquidity and on your ability to pay dividends related to the restrictions from receiving funds from your PRC subsidiary as discussed in Note 13 to the consolidated financial statements. Include in your disclosure, the amount of funds currently restricted from being received from the subsidiary.

#### JOBS Act exemptions and foreign private issuer status, page 85

23. You disclose that you have elected not to take advantage of the extended transition period for complying with new or revised accounting standards. Please expand your disclosure to include a statement that the election is irrevocable.

## Business, page 92

24. We note that you expect to complete the construction of your large molecule facility in the first half of 2018. Please disclose the estimated costs to complete this facility and how you intend to finance the construction.

# Overview of our licensing agreements, page 125

25. For each of the license agreements described in this section, please disclose the aggregate milestone payments that are payable under the agreement.

Management, page 170 Other key employees and advisors, page 172

26. Please explain the role of your scientific advisory board and clarify, here or in the appropriate section of your filing, how members of the board are compensated.

You may contact Vanessa Robertson at (202) 551-3649 or Jim Rosenberg at (202) 551-3679 if you have questions regarding comments on the financial statements and related matters. Please contact Chris Edwards at (202) 551-6761 or Suzanne Hayes at (202) 551-3675 with any other questions.

Sincerely,

/s/ Suzanne Hayes

Suzanne Hayes Assistant Director Office of Healthcare and Insurance

Cc: Patrick O'Brien, Esq. Ropes & Gray, LLP