

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

DIVISION OF CORPORATION FINANCE

January 16, 2018

Carl Firth Chief Executive Officer and Chairman ASLAN Pharmaceuticals Limited 83 Clemenceau Avenue #12-03 UE Square Singapore 239920

# Re: ASLAN Pharmaceuticals Limited Draft Registration Statement on Form F-1 Submitted December 20, 2017 CIK No. 0001722926

Dear Dr. Firth:

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.

# Draft Registration Statement on Form F-1 submitted December 20, 2017

# Cover Page

1. Please confirm whether your U.S. IPO price will be substantially the same as the home market trading price. You may use the most recent home market trading price, converted to U.S. dollars at the most recent exchange rate, only if the U.S. IPO price will be largely based on the home market trading price. If you expect that the U.S. IPO price will not be substantially the same as the home market trading price (i.e., the U.S. IPO price will be sold at a substantial discount), please disclose on the cover page of the preliminary prospectus a bona fide price range of the offered securities. If you intend to price the

securities based on the home market price, you may disclose a percentage range based on that price (for example, 10% of the home market price) within which you intend to price the securities. See Item 501(b)(3) of Regulation S-K.

# Prospectus Summary

# Overview, page 1

- 2. Please provide the meaning of any significant scientific or technical terms the first time they are used in order to ensure that lay readers will understand the disclosure. For example, please briefly define "IND," "Herceptin," "grade 3," "grade 4" and "cMET."
- 3. We note your discussion of your use of certain biomarkers to design your clinical trials to focus on patients most likely to respond to your product candidates. Please explain whether this approach will limit the potential market for your products as it appears your product candidates may only be tested on a subset of patients with the disease indications you are targeting.

# Our Product Candidates, page 2

- 4. Please revise the product candidate pipeline charts on pages 2 and 71 for the following:
  - You include "Inflammation" and "Oncology" bars for ASLAN004, but your narrative disclosure starting on page 89 only provides disclosure regarding your market opportunity in severe atopic dermatitis and asthma. Please revise these bars to only include indications you have determined to pursue in clinical studies.
  - We note your disclosure in the footnote that the dotted line section represents the Phase 3 portion of the ongoing trial, which you would progress to if the results from the Phase 2 portion meet the primary endpoint. However, we note the dotted line section only extends halfway through the pivotal trial column. Please revise your chart to clarify whether you will be required to conduct another clinical trial after the Phase 3 portion of the pivotal trial.
  - Please revise the pipeline table to remove the bar for "Modybodies". Because you have not identified a product candidate for these programs, it is premature to include them in a product pipeline table.
- 5. We refer to your disclosure on page 3 that you own global rights to all of your product candidates with two exceptions. However, based on your disclosure on pages 94-97, it appears you license all of your product candidates. Please revise as appropriate.

# Risks Associated With Our Business, page 5

6. Please revise your second bullet point to highlight your disclosure on page 12 that you currently do not generate any revenue from product sales.

- 7. With reference to your disclosure on page 13, please revise your third bullet point to clarify that you will require additional capital beyond this offering prior to completing pivotal studies of, filing for regulatory approval for, or commercializing any of your product candidates.
- 8. Please revise the penultimate bullet point to highlight your disclosures on pages 48-49 and 167-168 that you expect to be classified as a PFIC for the taxable year ending December 31, 2017 and for future taxable years and that you do not intend to provide the information necessary for U.S. holders to make qualified electing fund elections that could mitigate the adverse U.S. federal income tax consequences if you are classified as a PFIC
- 9. With reference to your disclosure on page 41, please add a bullet point disclosing that there is currently a ten percent limit on the daily price movement on the TPEx and that this may materially limit the movement in trading price of any ADSs that are issued in this offering.

### Implications of Being an Emerging Growth Company and a Foreign Private Issuer, page 6

10. 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.

# **Risk Factors**

Our product candidates may cause adverse events or have other properties that could delay..., page 16

11. Please amend this risk factor to note the adverse effects and the serious adverse event identified from the use of *varlitinib* disclosed on page 84.

# Our Asia development platform is unproven and may not result in the competitive advantages..., page 23

12. We note your disclosure that you cannot guarantee that the data collected in Asia can be used for submission to regulators in other jurisdictions. Please expand your disclosure to describe the instances in which the data you collected in Asia was accepted in submissions to regulators in other jurisdictions, the reasons regulators in other jurisdictions may not accept clinical trial data collected in Asia, and any communications you have had with FDA and other regulators regarding your Asia development platform. Please also expand the fourth bullet point on page 6 to provide brief context for your risk factor disclosure indicating that your Asia development platform may not result in the competitive advantages you anticipate.

#### Use of Proceeds, page 53

- 13. Please include the approximate amount of the proceeds that will be allocated to each intended use specified.
- 14. We note your disclosure that you currently do not expect the net proceeds of the offering to be sufficient to cover all of the expenses of the Phase 3 part of your global Phase 2/3 clinical trial for *varlitinib* in gastric cancer. We also note your disclosure on page 13 that you will require additional capital prior to completing pivotal studies of any of your current product candidates. If any material amounts of other funds are necessary to accomplish the specified purposes for which the proceeds are to be obtained, including the completion of the global Phase 2/3 clinical trial for *varlitinib* in gastric cancer, state the amounts and sources of such other funds needed for each such specified purpose. Refer to Item 3.C.1 of Form 20-F.

Management's Discussion and Analysis of Financial Condition and Results of Operations Out-licensing Agreements, page 60

- 15. Please expand your disclosure relating to your out-licensing agreements with BMS and Hyundai to provide the following information:
  - aggregate development, regulatory and commercialization milestone payments;
  - the royalty rate (or range within ten percentage points); and
  - term and termination provisions.

In addition, please file the agreements as exhibits or provide an analysis supporting your determination that you are not required to file them pursuant to Item 601(b)(10) of Regulation S-K.

# <u>Financial Operations Overview</u> <u>Research and Development Expenses, page 61</u>

16. On page 62 you note that you allocate direct costs to product candidates when they enter into clinical development. Tell us where you have disclosed these costs for each of your product candidates that are in clinical development or provide such disclosure for each period presented. For the remainder of projects, tell us the composition of the total R&D expense for each period presented. This can take a variety of forms but is mainly driven by how many projects are managed and how they are reported within the organization. Tell us where you have disclosed expenses by nature as required by paragraph 104 of IAS 1.

# Business Varlitinib (ASLAN001), page 76

- 17. We note your disclosure that you have obtained orphan drug designation from the U.S. FDA for cholangiocarcinoma, which represents approximately 60% of biliary tract cancer cases. Please clarify whether you have an active Investigational New Drug Application ("IND") for *varlitinib* in biliary tract cancer or in cholangiocarcinoma.
- 18. We note your statement that *varlitinib* "has demonstrated an acceptable safety profile and has been well-tolerated" in your clinical trials and that "*varlitinib* and *capecitabine* was safe and well-tolerated." While we will not object to a statement that your drug candidate was well-tolerated, a safety determination is solely within the authority of the FDA or foreign government equivalent regulatory agency. Please delete any disclosure indicating that your drug candidate is safe or has an acceptable safety profile.
- 19. At first use, please provide a brief explanation of the term "p-value" and how it is used to measure statistical significance. Please also explain the relevance of statistical significance to the FDA's evidentiary standards for drug approval. In addition, we refer to the p-value of 0.075 you provide in the first paragraph of page 83. Please disclose whether this result was statistically significant.

# ASLAN004, page 89

20. We note your statement on page 89, "We believe ASLAN004 is the only fully human monoclonal antibody in clinical development that targets the IL-13 receptor 1 subunit." Based on your disclosure in the product pipeline table on pages 2 and 71, it appears ASLAN004 is only in preclinical development. Please advise. In addition, please revise your disclosure to clarify whether you have any plans to conduct clinical trials for the treatment of asthma.

# License and Collaboration Agreements, page 94

21. Please revise your disclosure to provide within a ten percentage range the "mid-double digit share of all licensing revenue" you are required to pay to CSL and the upfront fee you will be required to pay to NTU if you exercise your exclusive option.

# Underwriting

# Determination of Offering Price, page 174

22. We note your disclosure on page 174 that the initial public offering price will be determined through negotiations between you and the representatives. However, we also note your disclosure on page 41 that the TPEx and applicable ROC law requires the offering price of the ADSs is not lower than 90% of the closing price of your ordinary shares on the pricing date or an average of closing prices a certain number of days prior

to the pricing date of the offering. Please revise your disclosure to clarify whether and how the TPEx and ROC requirements will impact pricing.

Notes to Consolidated Financial Statements for the Year Ended December 31, 2016 14. License Agreements Exploit Technologies Pte Ltd (ETPL)/P53 Laboratory, page F-21

23. Please revise your disclosure to provide the aggregate milestone payments to be made under the ETPL agreement.

You may contact Sasha Parikh at 202-551-3627 or Lisa Vanjoske at 202-551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact Irene Paik at 202-551-6553 or Christopher Edwards at 202-551-6761 with any other questions.

Division of Corporation Finance Office of Healthcare & Insurance

cc: Charlie Kim - Cooley LLP