



DIVISION OF
CORPORATION FINANCE

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

January 5, 2018

George Yeh
President
Taiwan Liposome Company, Ltd.
11F-1, No. 3 Yuanqu Street
Nangang District
Taipei City, Taiwan 11503
Republic of China

Re: Taiwan Liposome Company, Ltd.
Draft Registration Statement on Form F-1
Submitted December 8, 2017
CIK No. 0001722890

Dear Mr. Yeh:

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.

DRS Submitted December 8, 2017

Cover Page

1. We note your statement that the last reported sale price of your ordinary shares on the Taipei Exchange was NT\$ ____ per share, or approximately \$ ____ per share, based on an exchange rate of NT\$ ____ to \$1.00. You may present the most recent home market trading price, converted to U.S. dollars at the most recent exchange rate assuming the U.S. IPO price will be substantially the same as the home market trading price. Based on

your disclosure on page 168 that the initial public offering price has been negotiated by you and the Representatives using many factors, and the restrictions on pricing discussed in your risk factor on page 42, it appears that the U.S. IPO price will not be substantially the same as the home market trading price. Please revise your cover page to provide a bona fide price range as required by Item 501(b)(3) of Regulation S-K. If you intend to price the securities based on the Taipei Exchange trading 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.

Prospectus Summary

Overview, page 1

2. We note your use of the term "significant areas of unmet medical need" here and elsewhere in the document. Such a term might imply that your product is eligible for fast track designation or priority review granted by the FDA for products that treat certain serious unmet medical needs. Please remove your use of this term throughout or otherwise please explain why you believe use of this term is appropriate.
3. We note your statement that you anticipate that your four lead product candidates will be in pivotal clinical trials in 2019. However, we note that for two of these product candidates you have not yet filed INDs. Please supplementally tell us why you believe you will be in pivotal clinical trials for all four product candidates in 2019. Please also balance this disclosure by indicating that you will require additional capital to complete Phase III development of these product candidates. Please make similar disclosure in your Business section.

Pipeline, page 4

4. The table of your pipeline product candidates on pages 4 and 73 should reflect the actual status of your pipeline candidates as of the latest practicable date. The table lists RMS as the indication for TLC178 and indicates that you have already started a Phase I trial for RMS, however we note that you have not filed an IND for TLC178 for pediatric RMS and have not conducted any trials for pediatric RMS. In addition, the table suggests that you are halfway through a Phase II trial for TLC599 when we note that you have just started enrolling patients. Please revise the tables on pages 4 and 73 accordingly. Please ensure that your disclosure clearly states that you have not yet conducted trials for pediatric RMS as your disclosure throughout indicates that the primary target for TLC178 is pediatric RMS.

Risk Factors

We have relied on Taiwan government funding, which could require us to take action..., page 14

5. Please disclose the "certain conditions" upon which you may be required to license your research and development achievements with respect to TLC399 and potentially

TLC178. Please also disclose whether the limitations on use of the relevant R&D outside of Taiwan will impact your ability to market and/or sell related products outside of Taiwan.

We rely completely on third parties to manufacture our preclinical and clinical drug supplies....
page 23

6. Please file your agreement with Hospira Australia Pty Ltd as an exhibit to the registration statement or, in the alternative, tell us why you are not required to file this agreement. See Item 8 of Form F-1 and Item 601(b)(10) of Regulation S-K.

We face substantial political risks associated with doing business in the ROC and the PRC....
page 36

7. Please revise this risk factor to explain the particular risks to you or to investors. We note that certain business transactions and technology agreements between you and any entity in the PRC require the ROC government's approval, and any PRC investor must be a QDII to invest in your business. Please describe whether you have any material transactions or agreements with any PRC entities that are subject to such approval, whether you have obtained this approval, and if you are otherwise materially impacted by these restrictions. Similarly, please disclose whether there are any material risks to you based on the restrictions on PRC investors, including whether any of your current shareholders are PRC investors and whether they meet the proper qualifications for investing.

Use of Proceeds, page 54

8. Please revise to identify the stage of development you expect to achieve for each listed product candidate with the proceeds of the offering. If the anticipated proceeds will not be sufficient to fund all the proposed purposes, please disclose the order of priority of such purposes. To the extent material amounts of other funds are necessary to accomplish the specified purposes, state the amounts and sources of such other funds needed for each specified purpose. Refer to Item 3.C.1 of Form 20-F.

Credit Arrangements, page 65

9. Please file the credit arrangements as exhibits to the registration statement, or tell us why you believe they are not required to be filed. See Item 8 of Form F-1 and Item 601(b)(10) of Regulation S-K.

Business
Overview, page 71

10. Please revise your discussion to disclose the date of filing for each IND submitted for

your lead product candidates, including the sponsor, the relevant product candidate and the indication.

11. We note that many of the trials discussed in this section provide results without providing proper context for such results. For each of the pre-clinical and clinical trials discussed in this section, please disclose the date(s) of the trials and the location; patient information (e.g., number of patients enrolled and treated and the criteria for participation in the study); duration of treatment and dosage information (both amount and frequency); the specific endpoints established by the trial protocol; and actual results observed, including whether statistical significance was demonstrated and the p-values supporting statistical significance.
12. We note your references throughout this section to certain third party studies or claims as compared to your studies. For example, we note on page 76 your statement that a preclinical toxicology study of TA showed proteoglycan loss after just one month, whereas you found no proteoglycan loss. Similarly, on page 79 you state that a recently approved formulation of TA only achieved half of peak pain reduction as compared to TLC599's near peak decreases within a week. These are just examples. Please provide proper context for these and similar claims by providing the specific details and parameters of the study from which this data was drawn, including clinical endpoints, duration of treatment, comparison against placebo or standard treatment, metrics utilized, statistical significance, etc. Without this contextual information, it may be difficult for the reader to draw an accurate and balanced assessment of these favorable results. If you cannot provide this information, please delete the reference.
13. Please clearly disclose the number and type of all treatment-related adverse events and serious adverse events for each clinical trial discussed. For example, we note that your risk factor on page 19 states that in your Phase I clinical trial of TLC399 there were 15 treatment-related adverse events and two subjects that experienced serious adverse events, but your disclosure on page 83 states that to date there have been no unexpected serious adverse reactions or patient withdrawals due to adverse events, and does not indicate that the intraocular pressure events were considered SAEs. Please revise your disclosure throughout accordingly.

TLC599 Preclinical Toxicology Relative to TA, page 76

14. Please explain the significance of the images in Figure 3. It is unclear why some show proteoglycan loss and others do not.

TLC599 Phase I/II Data , page 77

15. We note your statement on page 79 that the change measured in the trial was shown with "statistical significance." Please provide an explanation of the term "statistical significance" and discuss how statistical significance relates to the FDA's evidentiary

standards of efficacy. Please expand your disclosure to provide the results, including p-values, of the component analyses showing statistical significance.

Our Solution: TLC178, page 87

16. We note that the FDA-approved label for vinorelbine states that the safety and effectiveness of vinorelbine in pediatric patients have not been established and showed no meaningful clinical activity in various pediatric cancers. It appears that you are relying on third-party trials relating to the off-label use of vinorelbine in RMS and other sarcomas. Based on your disclosure, it does not appear that vinorelbine has been approved by the FDA for use in RMS and in particular not in pediatric RMS. Please delete the statements in this section and elsewhere as appropriate that vinorelbine has demonstrated efficacy in RMS and other STSs. The safety and efficacy of a product is dependent on the FDA or comparable agencies making this determination. In addition, please provide the dates and specifics of the published trials you reference regarding the use of vinorelbine for RMS. Please also tell us whether the fact that vinorelbine has not been approved for use by the FDA for RMS may impact your ability to use the 505(b)(2) pathway or the approval of an IND for TLC178 in pediatric RMS.
17. Please explain the basis for your statement on page 88 that "with most liposomal chemotherapeutics, the liposomal formation exhibits less toxicity than the free form" and therefore you believe TLC178 will have reduced systemic toxicity as compared to free vinorelbine.

Approved Generic Products, page 92

18. Please expand your disclosure to describe the material terms of your cooperative development agreement and sales agreements with third parties, including milestone amounts, royalty rates and duration of royalty payments, and termination provisions. Please also file these agreements as exhibits to the registration statement, or tell us why you believe you are not required to file such exhibits.

Intellectual Property, page 94

19. For each of your material patents, please disclose (1) the specific product(s) to which such patents or patent applications relate; (2) whether the patents are owned or licensed from third parties, and if so, from whom; (3) the type of patent protection; (4) patent expiration dates and expected expiration dates for patent applications; and (5) the jurisdictions where patents are issued and patent applications are pending.

Employment Agreements with Executive Officers, page 119

20. Please file your employment and service agreements with your executive officers as exhibits to the registration statement.

George Yeh
Taiwan Liposome Company, Ltd.
January 5, 2018
Page 6

Financial Statements

Note (23) Income tax, page F-36

21. Please tell us why income tax calculated based on profit (loss) before tax and statutory tax rate is not NT\$140,038 (NT\$823,753 multiplied by 17%) rather than NT\$535, and then reconciled to NT\$563.

Note 9(2) Commitments, page F-41

22. Please tell us why you do not include the purchase contract commitments of NT\$61,920,000 and research and development commitments of NT\$615,362,000 and royalties in the table of contractual obligations on page 67.

General

23. 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.
24. Please provide us proofs of all graphics, visual, or photographic information you will provide in the printed prospectus prior to its use, for example in a preliminary prospectus. Please note that we may have comments regarding this material.

You may contact Franklin Wyman at 202-551-3660 or Lisa Vanjoske at 202-551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact Jeff Gabor at 202-551-2544 or Erin Jaskot at 202-551-3442 with any other questions.

Division of Corporation Finance
Office of Healthcare & Insurance

cc: Charlie Kim