



DIVISION OF
CORPORATION FINANCE

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

July 19, 2024

Fu-Feng Kuo
Chief Executive Officer
Jyong Biotech Ltd.
23F-3, No. 95, Section 1, Xintai 5th Road
Xizhi District, New Taipei City
Taiwan, 221

Re: Jyong Biotech Ltd.
Amendment No. 2 to Registration Statement on Form F-1
Filed June 21, 2024
File No. 333-277725

Dear Fu-Feng Kuo:

We have reviewed your amended registration statement and have the following comments.

Please respond to this letter by amending your registration statement and providing the requested information. If you do not believe a comment applies to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing any amendment to your registration statement and the information you provide in response to this letter, we may have additional comments. Unless we note otherwise, any references to prior comments are to comments in our May 31, 2024 letter.

Amendment No. 2 to Registration Statement on Form F-1

Prospectus Summary

Overview, page 1

1. Please revise the discussion of your current plans to develop MCS-2 (API-2) to clarify the FDA's concerns communicated on pages 1-2 of its February 23, 2024 correspondence, which you provided in response to our May 31, 2024 request. The communication indicates that your proposed plan to conduct one phase 1 study and one phase 3 efficacy study using your product containing API-2 faces significant challenges. Please update your Summary to briefly describe the FDA's concerns and provide a more fulsome discussion of these concerns in the Business section.
2. We note your response to prior comment 1 and reissue in part. Please revise your disclosure throughout your filing to remove language indicating that the comparability is

an inevitable conclusion, such as "[O]nce the US FDA is convinced about the comparability of API-1 and API-2...." You may discuss what happens if you are able to demonstrate comparability, but you must indicate that to date you have not been able to do so and what your path forward is if you are unable to demonstrate comparability. Please also state if you have had discussions with the Taiwan regulator about the substitution of API-2 for API-1 in MCS-2. If you have not, or if the Taiwan regulator also requires comparability studies, it is not appropriate to indicate that you have completed Phase 1 studies for PCP (API-1).

3. In response to prior comment 1 you state that you are preparing CMC information for API-2, are planning to establish comparability between API-1 and API-2, and once the FDA is convinced about the comparability you will then initiate the MCS-2 Phase III and Phase I PK study. Please revise your disclosure to state that you currently do not have an API-2 supplier and that you cannot proceed until you identify a supplier of API-2. Please also include such disclosure throughout your prospectus where you discuss PCP, including but not limited to pages 6, 109, and 124. Additionally include a risk factor discussion addressing the potential consequences if the FDA does not agree that API-1 is comparable to API-2.
4. In response to prior comment 4 you state that you plan to demonstrate that API-1 and API-2 are comparable to be able to rely on all prior trials. You also state that due to a failed MCS-2-US-a study you will conduct an additional Phase III pivotal study in the US using API-2. Please clarify, if accurate, that you must first conduct API-1 and API-2 comparability studies and if the FDA accepts such results and determines that API-1 and API-2 are comparable, only then will you be able to conduct the additional Phase III pivotal study using API-2. Further, you also state that your plans will be discussed at the CMC meeting. Clarify, as you do on page 2, that you received a denial notice from the FDA on May 23, 2024 for a CMC meeting.
5. We note your response to comment 5 and 6. Your pipeline table should provide one line for each product candidate being developed to address a single indication. The purpose of the pipeline table is not to depict the alternative ways you may develop the same product candidate. Currently, your table depicts three lines depicting MCS-2 being developed to address BPH/LUTS. Please revise your table to remove two of the lines depicting MCS-2 for BPH/LUTS as they are not additional candidates, they are alternative ways that you may attempt to develop MCS-2 for BPH/LUTS. The line item that should be depicted in the table is the one that depicts the method of development you are actively pursuing with the FDA.

If you are able to rely on trials performed using API-1, it is not appropriate to include a separate line item in your table indicating that you have a separate product candidate for MCS-2 (API-1). If the FDA determines that API-1 and API-2 are sufficiently comparable to rely on the clinical trials performed using API-1, then you may reflect the completion of the successful trials using API-1 in your pipeline table for the line item depicting the development of MCS-2 (API-2). Until the FDA has made that comparability determination, such results relating to API-1 relate to a development pathway that you are not currently able to pursue due to the fact that API-1 is currently not available. Similarly, if the new Phase III study using API-2 is successful and you are able to demonstrate to the

FDA that API-1 and API-2 are sufficiently comparable, then you will be able to rely on the MCS-2-TWN-a study in the pipeline table if you have been able to re-analyze the data from the study to successfully demonstrate to the FDA that it is reliable.

We also note your table indicates you are developing PCP (API-1) for Prostate Cancer in Taiwan. Please explain how you are pursuing this using API-1 given that API-1 is not currently available. Alternatively, remove it from your pipeline table.

6. We note your response to prior comment 8 and reissue our comment. Please refer to page 2 of 7 from the FDA correspondence dated 26, 2023 you provided in response to our request on May 31, 2024, which states:

"Because of the heterogeneous nature of a botanical drug and uncertainty about its active constituents a critical issue for botanical drugs is ensuring that the therapeutic effect for drug batches is consistent. In general, therapeutic consistency can be supported by a 'totality of the evidence' approach, including botanical raw material control, quality control, by chemical test(s), manufacturing control, a biological assay (if needed) and clinical data. Seemingly minor changes in the API source and/or manufacturing process may result in a meaningful difference in the clinical effects and raise concerns about the applicability of earlier pharmacological, nonclinical and clinical data."

See also pages 2-3 of 10 which states, "any changes (e.g. changes in the agricultural sites, agricultural and collection practices and/or processing/manufacturing methods) should be assessed carefully to determine if the BDS and the botanical drug product (BDP) batches produced after such a proposed change would be sufficiently similar pharmacologically and/or therapeutically to batches prior to such a change."

Please note the potential impact of these "seemingly minor changes" apply to changes in suppliers of the active pharmaceutical ingredient as well as the change in the active pharmaceutical ingredient provided by the supplier of API-1 prior to its relocation and following its relocation. Therefore, in order to produce MCS-2 using API-1 following a relocation, you would have to demonstrate comparability again. Please revise your disclosure to clarify that if you intend to develop MCS-2 using API-1 if it becomes available, you will have to demonstrate comparability again. If you are unable to demonstrate comparability, you will have to perform more clinical trials.

7. Please provide us with a copy of the FDA meeting minutes from your January 20, 2013 CMC meeting in which the FDA staff encouraged you to select multiple vendors for the botanical raw material and advised you to identify more raw material vendors to avoid any potential supply shortages in the early stages. The June 26, 2023 FDA correspondence you provided indicates that "minor changes in the API source and/or manufacturing process may result in a meaningful difference in the clinical effects and raise concerns about the applicability of earlier pharmacological, nonclinical and clinical data" which appears inconsistent with this advice.

Risk Factors, page 17

8. Please include a risk factor addressing the possibility that the FDA does not agree that API-1 and API-2 are sufficiently comparable. The discussion should address the FDA's concerns related to changes in agricultural sites, agricultural and collection practices,

processing and manufacturing methods, etc. and the consequences if the FDA determines that API-1 and API-2 are not sufficiently comparable.

9. Please include an additional risk factor discussing the FDA's stated concerns about your proposed plan to conduct only one phase 1 study and one phase 3 efficacy study. The discussion should identify the FDA's concerns you will have to address in order to successfully develop MCS-2 (API-2), given your current plan and the potential consequences, if you are unable to demonstrate to the FDA that your proposal is sufficient to demonstrate safety and efficacy.

Leverage differentiated approaches to advance our development..., page 112

10. In response to prior comment 14 you state you plan to complete all source data verification, database lock and statistical analysis, and draft the clinical study report. Such steps appear necessary for you to advance your product candidate. You also state on page 1 that you do not plan to discuss PCP with the TFDA until after you have conducted comparability studies. Please clarify if this process is dependent on first selecting an API-2 supplier and conducting successful comparability studies or if you will be verifying and analyzing the data at the same time you are performing comparability studies. Please clarify that if the comparability studies are not successful, the PCP clinical trials will have to be performed again using PCP (API-2).

Our Drug Candidates

Phase II Clinical Studies, page 118

11. In response to prior comment 15 we note the additional disclosure provided under Clinical Data and Phase I Clinical Studies. Please also include disclosure under Phase II and Phase III Clinical Studies, on pages 118 and 119 respectively, to state that if your comparability studies are not accepted by the FDA you will need to conduct additional Phase II and Phase III studies to continue your clinical development.

Phase III Clinical Studies, page 119

12. We note your response to prior comment 16 and reissue in part. Please clarify here, as you do on page 123, that the remaining data you are referring to is the data from the two Phase III studies conducted in Taiwan and the one Phase III US open label extension study. Also include a discussion here and on page 123 that the U.S. FDA has expressed concerns regarding the reproducibility of some of the reported efficacy results for Study MCS-2-TWN-a as you do on page 1.
13. We note your response to prior comment 17. Specifically, that you will not need to reproduce the Phase III study in US (MCS-2-US-a) if the US FDA has approved the comparability of API-1 and API-2 and the results of an additional Phase III study (MCS-2-US-b) using API-2. Provide the basis for your determination that the FDA will rely on results of trials that failed to demonstrate a difference between the treatment groups for the primary efficacy endpoint in the intent-to-treat population. Please also include additional disclosure stating that if the FDA does not approve your comparability studies you will need to reproduce MCS-2 (API-1) Phase III study in the US because it failed to show a difference between treatment groups for the primary efficacy endpoint in the intent-to-treat population.

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14. We note that in response to prior comment 18 you removed the US-a + TWN-a/ITT results from Table 1 and 2. However, we note that your disclosure still contains statements such as "[a]ccording to the results of phase III clinical trials after pooling US-a and TWN-a..." Given your disclosure throughout your prospectus that the FDA determined your Phase III clinical trial in the U.S. failed to show a difference between the treatment groups for the primary efficacy endpoint in the intent- to-treat population, pooling the results masks the different outcomes from the two trials. Please amend to separately present the results of each of the Phase III trials completed throughout your filing.

Please contact Mary Mast at 202-551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Doris Stacey Gama at 202-551-3188 or Suzanne Hayes at 202-551-3675 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Ross Carmel, Esq.