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

DIVISION OF
CORPORATION FINANCE

October 24, 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. 5 to Registration Statement on Form F-1
Filed October 5, 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 August 30, 2024 letter.

Amendment No. 5 to Registration Statement on Form F-1

Prospectus Summary
Summary, page 1

1. We note that in response to prior comments 2, 7, 9 and 10 you state that if you are unable to establish comparability between API-1 and API-2 you "might" be required to repeat the MCS-2 and PCP clinical trials using API-2. Please clarify if there is another alternative to move forward with MCS-2 and PCP development other than demonstrating comparability of API-1 and API-2 or repeating the MCS-2 and PCP clinical trials using API-2. If you are referring to no longer pursuing product development please state so. Please make these revisions throughout your registration statement.

2. We note your response to prior comment 3 stating that PCP using API-1 is in the source data verification process, that you are working with the FDA to establish comparability of API-1 and API-2, and that you will discuss the statistical results of PCP using API-2 with Taiwan regulators and proceed to Phase III if the FDA accepts such results and determines that API-1 and API-2 are comparable. Please clarify, if true, that to date you have not had any discussions with the TFDA regarding the unavailability of API-1 and plan to have such discussions once, and if, you are able to prove comparability of API-1 and API-2. Additionally, clarify the basis for your belief that the TFDA will accept the U.S. FDA conclusion regarding comparability.

3. We note your responses to prior comment 5 and 12 and reissue those comments. You continue to state that the "source for API-1 may again become available in the future and, if so, [you] may seek to use it as the source for further drug development. We note that on page 113, in the context of discussing your NDA for MCS-2 you indicate that if API-1 becomes available again the supplier's withdrawal of its consent to reference the DMF "does not mean [you] would not be able to use API-1 in later studies or as a basis for additional filings with the U.S. FDA." To the extent you intend to develop MCS-2 using API-1 if it becomes available again, please clarify that you will have to demonstrate comparability between API-1 prior to the relocation and subsequent to the relocation, or API-2 and API-1 subsequent to the relocation or perform additional clinical trials or otherwise advise. Please clarify that API-1 subsequent to the relocation would not be able to rely on clinical trials performed using API-1 available prior to the relocation without a further comparability determination.

4. You state on page 4 and 112 that PCP is under Phase II trials stage in Taiwan. Please explain the consequences if you are unable to identify an active pharmaceutical ingredient that the FDA agrees is comparable to API-1.

Risk Factors Summary, page 13

5. Please include a bullet point indicating that if you are unable to identify a supplier capable of producing API-2 that is sufficiently comparable to API-1, you will be required to repeat your clinical trials for MCS-2 and PCP, which will delay your product development efforts and result in increased costs.

Risk Factors
Our drug candidate may cause serious adverse,..., page 27

6. We note your response to prior comment 8. Please also identify the serious adverse event(s) reported that you were not able to conclude were unrelated to your product candidate(s).

Use of Proceeds, page 79

7. We note your use of proceeds discussion indicates your intent to use proceeds from the offering to fund the additional Phase III trials of MCS-2 (API-2). Please revise your disclosure to quantify proceeds that you will spend on earlier phase trials if you are unable to demonstrate comparability.

8. We note that as of June 30, 2024 you had a net working capital deficit of approximately $11.7 million, which included current liabilities of approximately $5 million and $3.1 million due to Taizhou Bay New District Administrative Committee and commitments with Taizhou Resources Bureau. Additionally, we note your plans to spend $2.9 million of the proceeds for the settlement of this litigation. Please clarify the source(s) of other funds you intend to use to pay these amounts owed. Please see Instruction 3 to Item 504 of Regulation S-K.

Research and Development Expenses, page 95

9. You state that you have asked the US FDA to provide a written response to questions focused on obtaining US FDA review and comments on a new, proposed Phase III clinical trial protocol for MCS-2 with API-2 and a pharmacokinetic study. Please also include disclosure stating that on May 23, 2024 you received a denial notice from the FDA stating that until the company can provide complete Chemistry, Manufacturing, and Controls (CMC) information on the active pharmaceutical ingredient-2 (API-2) and a plan to establish comparability between API-1 and API-2, the U.S. FDA is unable to reach agreement on protocols designed to establish the safety and efficacy of MCS-2, as you do on page 3.

Phase III Clinical Trials, page 127

10. We note your response to prior comment 11. We also note that you your disclosure stating that the FDA's concerns regarding reproducibility of some of the reported efficacy results for MCS-2-TWN-a can be resolved after you propose to re-analyze the MCS-2-TWN-a study data using CDISC data set that is matched with the U.S. FDA requested format remains. Therefore, we reissue the comment. This disclosure appears to assume the FDA will be satisfied with the results when you re-analyze the data. While indicating that you plan to re-analyze the data using the CDISC data sets matched with the FDA requested data format seems reasonable, your assumption that this will resolve the issue to the satisfaction of the FDA is speculative and not appropriate. Please revise your disclosure to remove the indication that this may resolve the FDA's concerns.

Legal Proceedings and Compliance
Taizhou Investment Dispute, page 145

11. In response to comment 13 you state that the on August 9, 2024 the High People’s Court of Zhejiang Province scheduled a hearing for your Taizhou appeal and later issued a judgement against you to sustain the ruling of the Taizhou Court. Based on this result, please clearly state the total amounts you are required to pay the Plaintiff. Further, you also state that you are actively negotiating with the Plaintiff for a settlement of this legal proceeding. Please clarify how you are still pursuing a settlement after a final judgement has been reached.

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.