



DIVISION OF
CORPORATION FINANCE

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

June 9, 2023

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

Re: Jyong Biotech Ltd.
Amendment No. 1 to Draft Registration Statement on Form F-1
Submitted May 22, 2023
CIK No. 0001954488

Dear Fu-Feng Kuo:

We have reviewed your amended 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.

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

Prospectus Summary

Overview, page 2

1. We note your response to prior comment 4 indicating that your two leading drug candidates MCS-2 and PCP contain the same “drug substances.” Please revise to disclose this point. Recognizing that you are targeting two different indications and utilizing two different drug names, revise to explain whether and, if so how MCS-2 and PCP differ in terms of composition. For instance, and with reference to your disclosure on page 52, explain whether they contain the same or different active ingredients, dosage form, strength and/or route of administration. To the extent that differences exist, please explain

whether FDA has indicated its agreement that the same Phase 1 safety data can be used for purposes of approving MCS-2 and PCP.

2. We refer to prior comment 17 and note your revised disclosure in the Overview section indicating that MCS-2 and PCP are “patented pharmaceutical composition of carotenoids” and that they are “plant-based.” Please revise to identify the active pharmaceutical ingredient(s) contained in these candidates or advise. In this regard, we note that your response to comment 7 references active pharmaceutical ingredient(s) and your clinical trial disclosures on pages 103 and 110 discuss measurement of unidentified “active ingredients.”
3. With reference to your response to prior comment 7, please revise your Summary presentation and pipeline table to highlight that your NDA application for your lead candidate MCS-2 is not complete. Clarify the reason(s) why you must submit additional data to FDA and your plan to submit this related data in 2024. Explain the work you must complete in order to prepare this submission. In this regard, please identify the active pharmaceutical ingredient (API) that was in short supply due to COVID-19 and clarify whether you need to conduct additional/new clinical trials using the API contained in MCS-2 or present data to FDA showing that the replacement API should be deemed a valid replacement for purposes of FDA approval. As applicable, discuss feedback received from FDA on the status of the application and the related data you must submit.
4. We note your response to our previous comment 6. Please revise the Summary to explain the meaning of the term "bespoke development strategies." With reference to your revised disclosure on page 97, revise your Summary disclosure to explain the term "I-PSS" at first use.

If we encounter delays..., page 17

5. We note your revised disclosure in response to prior comment 10. Please reconcile your revised disclosure on page 17 with your disclosure on page 18 indicating that you have experienced delays in the enrollment of patients in your clinical trials due to government orders and site policies on account of the COVID-19 pandemic and the monkeypox outbreak.

Industry Overview

Benign Prostatic Hyperplasia, page 91

6. We note your response to our previous comment 14. Please revise the table beginning on page 91 to reflect, if true, that FDA and/or comparable regulatory bodies have approved each of the five competitive products and that MCS-2 has not been similarly approved. Further, in the pros section for MCS-2 please remove statement that MCS-2 has a "good clinical safety profile" as safety determinations are solely within the authority of the FDA or applicable foreign regulator.

Business

Overview, page 97

7. We note your response to our previous comment 16 and reissue. You make several assertions regarding the safety and efficacy of your product candidates MCS-2 and PCP. Safety and efficacy determinations are solely within the authority of the FDA or applicable foreign regulator. You may present clinical trial end points and objective data resulting from trials without concluding efficacy and you may state that your product candidate is well tolerated, if accurate. Please revise or remove statements/inferences throughout your prospectus that your product candidate is safe and/or effective. For instance, and without limitation, we note the following statements about your drug candidates:
- "It is a new drug developed for BH/LUTS treatment with safety and efficacy." (pg. 78, 91,101)
 - "MCS-2 showed safety in both short-term and long-term" (pg. 97)
 - "which shew (sic) good safety profile of MCS-2." (pg. 105)
 - "According to the results of phase III OLEs, MCS-2 softgels showed safety" (pg. 107)

Our Drug Candidates

Drug Candidate

MCS-2

Mechanism of Action, page 102

8. We note your response to our previous comment 5 and the inclusion of the graph on page 103. Please revise the graphic and accompanying text to explain how the graph shows that MCS-2 has anti-inflammatory activity. In this regard, please revise to define LPS, BDS, and the symbols used above the bar graph.

Phase I Clinical Studies

Pharmacokinetics, page 103

9. For the table on page 103 indicating the concentration of active ingredients in the serum, please define AUC, C, t and the accompanying subscripts. Identify the active ingredients.

Clinical Data, page 104

10. We note your use of P-values and R-values on pages 104 and 106. Please explain what the disclosed P-values and R-values indicate about statistical significance and correlation.
11. We note your response to prior comment 19 and reissue. Please revise your disclosure to explain why your clinical trials were not conducted in sequential order and why the NDA submission was made four years after the last clinical trial was completed.

Clinical Drug-Drug Interaction, page 104

12. We note your response to our previous comment 23 and reissue. Please expand to discuss bupropion and midazolam and the significance of your results in this study as well as the clinical drug interaction study of PCP on page 110. In this regard, please clarify what indication or indications are treated with bupropion and/or midazolam.

PCP

Anti-inflammatory Activity, page 110

13. We note the inclusion of the graph on page 110 in response to our previous comment 30. Please amend to include a brief description of the symbols used within the graph.

Patents, page 116

14. Please revise to disclose the patent numbers for your two granted US composition of matter patents. Tell us whether MCS-2 are PCP are covered by the same or different composition of matter patents. Also indicate whether IC is covered by one of these two granted patents.

Management

Directors and Executive Officers, page 151

15. Please revise to disclose the duration of Mr. Ming Tsan Hsu tenure as deputy chairman of the board of directors at Joyear Construction Co., Ltd and supervisor of Duennien Construction Co., Ltd.

Consolidated Financial Statements, page F-1

16. Please update your financial statements and corresponding financial information throughout the filing to comply with Item 8.A.4 of Form 20-F.

Notes to Consolidated Financial Statements

17. Commitments and Contingencies

Litigation, page F-24

17. You disclose that the Group is not aware of any current pending legal matters or claims except for those disclosed in this prospectus. Please revise to provide disclosure related to the TaiZhou litigation matter pursuant to ASC 450-20-50 since the case appears to be ongoing. Tell us also how you considered including a discussion of this matter in your subsequent events note on page F- 24.

Fu-Feng Kuo
Jyong Biotech Ltd.
June 9, 2023
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You may contact Ibolya Ignat at 202-551-3636 or 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 Joe McCann at 202-551-6262 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Yang Ge