



DIVISION OF  
CORPORATION FINANCE

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

April 4, 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.**  
**Registration Statement on Form F-1**  
**Filed March 7, 2024**  
**File No. 333-277725**

Dear Fu-Feng Kuo:

We have reviewed your 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.

Registration Statement on Form F-1

Overview, page 1

1. We note your reference to MCS-2 as your "new botanical drug candidate developed for treatment of BPH/LUTS" and PCP as your "new botanical drug candidate developed for the prevention of prostate cancer." Please revise your disclosure to clarify when you initiated the development of MCS-2 and PCP. We note that you initiated a Phase II trial for MCS-2 in 2004 and trials for PCP began as early as 2015.
2. Please balance your statement that you "voluntarily" withdrew your NDA on November 30, 2022 with a discussion of the likely consequences if you had not withdrawn your NDA given that the FDA had identified that your Phase III trial failed to show a difference between the primary efficacy endpoint in the intent-to-treat population and the botanical drug substance used in your clinical trial, which was the basis for your NDA, was not available. Identify all other substantive issues the FDA had conveyed regarding

your NDA.

3. You state that the US FDA granted your WRO meeting request. Please state if the FDA has responded to your WRO request, if so please discuss any additional information provided by the FDA.
4. We note your statement that the FDA informed you that the information you provided about API-2 was not sufficient to demonstrate comparability to API-1, "including with respect to a statistically significant difference between MCS-2 and placebo in the primary efficacy endpoint in a clinical study." Please identify the clinical study indicating the statistical difference between MCS-2 and the placebo. Additionally, clarify why you would be assessing the comparability of API-2 to API-1 on individual studies. With respect to the statement that "without new clinical information, any NDA resubmission for MCS-2 would be at risk of the agency refusing to accept the application," clarify whether the additional required clinical information is with respect to the comparability of API-1 and API-2 or the efficacy of MCS-2.
5. We note that your pipeline table includes a line item for MCS-2 (API-1), which indicates that all required US testing has been completed. We also note your disclosure indicating that the Phase III clinical trial for MCS-2 in the U.S. failed to show a difference between the treatment groups for the primary efficacy endpoint in the intent-to-treat population. Additionally, we note that the December 5, 2023 amendment to your prior registration statement, which was withdrawn, indicated that you had not completed all Phase III clinical trials. Please clarify how you continue to develop MCS-2 (API-1) without conducting additional clinical trials given that one of your trials failed to show efficacy and why you previously indicated you had not completed Phase III trials and now indicated you have completed Phase III trials.
6. With respect to the MCS-2 (API-2) line item in your pipeline table, you indicate that you have completed Phase I and Phase II trials even though the FDA considers MCS-2 (API-2) a new drug development program, and that new Phase 1 PK and Phase 3 studies are required. It is clear from your discussion beginning on page 115 that the pharmacokinetic study described was conducted using API-1. Please include a discussion of the pharmacokinetic study conducted using API-2 or revise your table to clarify that it has not been completed. Additionally, clarify your basis for indicating that your Phase II trials have been completed for MCS-2 (API-2).
7. Given that API-1 is currently unavailable and that MCS-2 (API-2) appears to be designed to treat the same indication in the same population, please clarify whether you still intend to continue to develop MCS-2 (API-1). If you do not, please remove the separate line item from your pipeline table.
8. Your pipeline table here and on page 106 includes a drug candidate MCS-2 (API-2) for the indication of PK. Please explain if this is a different candidate than the MCS-2 (API-2) for the indication of BPH-LUTS identified above. If not, please remove such candidate from your pipeline table.

9. Please explain the significance of retaining your NDA application number in the event you resubmit your NDA.
10. You state that "the US FDA also identified the fact that API-1, the botanical drug substance used in [y]our clinical trials and that was the basis for [y]our NDA, was not available." Please also discuss here, and wherever else applicable, that the supplier of API-1 withdrew its consent for you to reference their Drug Master File on file with the FDA as you do on page 125.
11. We note your statement that you have identified an additional source for the botanical drug substance API-2. Please clarify whether you must perform studies demonstrating that the sources of API-2 are sufficiently similar botanical drug substances.

Our Strengths, page 5

12. Please provide balance to your summary by providing a discussion of your weaknesses immediately following the discussion of your strengths.

Market and Industry Data, page 8

13. We note that you have not independently verified the accuracy or completeness of the data contained in industry reports relied on in preparing your disclosure. Please note that it is not appropriate to disclaim liability for information included in your registration statement, please revise your disclosure accordingly. Similarly, delete the statement on page 99 that neither you nor any other party involved in this offering makes any representation as to the accuracy or completeness of the information and data presented in the industry overview. While you may caution viewers about forward-looking statements, much of the information included in the Industry Overview is prior or current information. Please revise your disclosure accordingly.

If clinical trials of our key drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities..., page 21

14. Your risk factor discussion is written as if this is a hypothetical despite the fact that the US FDA concluded that one of your Phase III trials failed to demonstrate a statistically significant difference between MCS-2 with API-1 and placebo in the primary efficacy endpoint in the MCS-2-US-a study. Please revise the discussion to discuss the consequences of the FDA's determination in terms of the additional work and expense that is now required and the time required to complete this work.

The incidence and prevalence for target populations of our drug candidates are based on estimates and third party sources..., page 29

15. We note your disclosure that your market size information is subject to a high degree of uncertainty and risk due to a variety of factors discussed in the prospectus. Please tell us where these factors are discussed.

Certain of our facilities were mortgaged. If the mortgagees enforce the mortgage, our business could be materially and adversely impacted., page 37

16. We note your statement, "In case the mortgagees enforce the mortgage, we may not be able to continue using our properties." Please clarify whether you are current on mortgages secured by your properties and if there are circumstances under which the mortgagee can require immediate repayment or foreclose on the mortgaged properties. Disclose the activities that you conduct at these properties. Also, please file the mortgage agreements as exhibits or tell us why you believe they are not required to be filed as exhibits.

We rely on third parties to supply the drug raw materials for our developing and manufacturing activities..., page 52

17. Please expand the last paragraph of this risk factor discussion to more specifically describe the potential consequences of a potential shortage of raw materials, including API-2, such as the need to find an alternative botanical drug substance and perform more clinical trials if you are unable to demonstrate that the alternative botanical drug substance is sufficiently comparable to API-2.

Use of Proceeds, page 71

18. Please provide the approximate dollar amount intended to be used for each purpose listed and indicate how far in the development process you expect to progress with the proceeds from this offering. To the extent you are planning to develop MCS-2 using both API-1 and API-2, please separately indicate the proceeds you plan to allocate to developing these programs. Please note that if any material amounts of other funds are necessary to accomplish the specified purposes, state the amounts of such other funds needed for such specified purpose and the sources thereof. See Instruction 3 to Item 504 of Regulation S-K.

Industry Overview

Benign Prostatic Hyperplasia, page 100

19. We note your table comparing commonly used BPH drugs and MCS-2. Specifically, we note that you refer to MCS-2 being in the Phase III clinical trial stage. Given that you have yet to perform clinical trials for MCS-2 (API-2), please clarify that this information is with respect to MCS-2 (API-1) and clarify your future plans with respect to MCS-2 (API-1).

Integrate in-house capabilities that well position us for pharmaceutical innovation..., page 109

20. Your statement that "the full integration of these functionalities allows us to bring our drug candidates efficiently from bench to bedside, which enables us to identify and address potential clinical, manufacturing and commercial opportunities as well as issues

early in the development process, so we can direct our efforts towards drugs with the best potential to become clinically active, cost-effective and commercially viable drugs," appears premature and speculative given that, at this point, none of your drug candidates have received regulatory approval. Please revise our disclosure accordingly.

21. Please delete your statement that you have "outstanding clinical results" for our innovative drug candidates. You should provide a discussion of your clinical trials and the trial observations without indicating whether the results demonstrate efficacy.

#### Our Strategies

##### Leverage differentiated approaches to advance our development.... page 111

22. 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:
- "promising safety results observed in Phase II clinical trials of PCP[.]" (pg. 111)
  - "midazolam and bupropion was generally safe..." (pg. 115)
  - "the coadministration of MCS-2 with midazolam and bupropion was generally safe..." (pg. 115)
  - "The result presented a dose-related response." (pg. 116)
  - "For subjects with moderate and severe BPH/LUTS, or to say, for those with I-PSS larger than 10 points (inclusive), taking one MCS-2 softgel (15 mg) per day helped to achieve a 16.3% and a 22.1% I-PSS decrease after 12 weeks..." (pg. 116)
  - "The overall results indicated that MCS-2 softgels could relieve LUTS caused by BPH..." (pg. 116)

#### Our Drug Candidates

##### MCS-2

##### Clinical Data, page 112

23. We note that you conducted Phase I clinical studies of MCS-2 focused on pharmacokinetics and clinical drug-drug interaction studies in the US which were completed on April 24, 2017. Please clarify that the Phase I clinical studies conducted were for MCS-2 using API-1 and that you will be conducting additional studies using API-2.

##### Phase III Clinical Studies, page 117

24. Please clarify that the results presented are for your Phase III trials MCS-2 (API-1). Additionally, clarify whether your proposed trial plans for Phase 1 PK and Phase 3

have been approved by the FDA.

25. You state that for your Phase III clinical trials "[t]he overall results indicated that MCS-2 softgels could relieve LUTS caused by BPH and had excellent tolerability." You also state on page 106, and throughout your filing, that "[y]our pivotal Phase III clinical trial for MCS-2 in the U.S. failed to show the difference between treatment groups for the primary efficacy endpoint in the intent-to-treat population." Please explain this inconsistency.
26. We note your discussion of your Phase III trials. Please state the trial completion date, disclose the trial endpoint(s), and include a discussion of results including adverse events and serious adverse events, if any. Further, please clarify if the Phase III trials were powered for statistical significance. If so, please provide p-values for the results of the trial.

Suppliers, page 125

27. You state that you do not consider any of your suppliers to be material to your business and that you can select other suppliers in the market to replace current ones at your sole discretion. You also state that your API-1 supplier withdrew their consent for you to reference their Drug Master File on file with the FDA which caused you to withdraw your NDA, identify an additional source for your botanical drug substance (API-2), and conduct additional clinical studies using the new source API-2. Please explain how your API supplier is not considered material to your business given your inability to obtain API-1, the challenges in demonstrating that API-1 and API-2 are sufficiently comparable, and your risk factor discussion indicating that the quality control of botanical drug products is very complex due to the variability of raw materials. To the extent you have a supply agreement with the supplier of API-2, file it as an exhibit to your registration statement. Alternatively, explain why you believe it is not required to be filed.

Consolidated financial statements

Consolidated balance sheets, page F-28

28. Please clarify why you classify part of your Bank loans as Long-term liabilities given your statements on pages 4 and 34 that "loans from banks of approximately US\$7.8 million ... will be due within the next twelve months."

Notes to consolidated financial statements

18. Subsequent events, page F-52

29. Please revise your disclosure to address the subsequent legal developments surrounding your failure to initiate and conclude the construction of the Factory Project in accordance with the schedule stipulated by the 2019 Taizhou agreement, currently discussed in Note 17. Disclose the expected financial statement impact of such developments on your reported balances, and related disclosures as required by ASC 855-10-50-2.b, if material. We note that you plan to use approximately 10.0% of the net proceeds of your initial public offering for (i) a possible settlement of the litigation with Taizhou Bay New

District Administrative Committee, including the return of government subsidy, litigation expenses and interest expenses, and (ii) commitments with Taizhou Resources Bureau, including liquidated damages and land idling fees, which implies that you may be able to quantify the financial statement impact. Provide us supplementally the details of the accounting treatment applicable for the subsequent legal developments.

General

30. 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.

We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

Refer to Rules 460 and 461 regarding requests for acceleration. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

Please 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 Suzanne Hayes at 202-551-3675 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences

cc: Ross Carmel, Esq.