

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

DIVISION OF CORPORATION FINANCE

January 13, 2021

Zheng Wei, Ph.D. Chief Executive Officer Connect Biopharma Holdings Limited Science and Technology Park East R&D Building, 3rd Floor 6 Beijing West Road, Taicang Jiangsu Province, China 215400

> Re: Connect Biopharma Holdings Limited Draft Registration Statement on Form F-1 Submitted December 17, 2020 CIK No. 0001835268

Dear Dr. Wei:

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.

Draft Registration Statement on Form F-1

Prospectus Summary Overview, page 1

1. We note your disclosure here and in the Business section that CBP-201 is potentially more effective and convenient than dupilumab and that you believe that CBP-201 has the potential to bring improved therapeutic benefit to AD patients with greater efficacy, faster onset of action and less frequent dosing than the current standard of care. Findings of efficacy and safety are solely within the authority of the FDA or similar foreign regulators, and qualifying language that statements of safety and efficacy are expressions

> of the company's beliefs or expectations do not address this concern. Please revise these and any similar statements. We will not object to reasonable statements explaining why you believe your product candidates may work in a different way or may provide different results than current treatments.

- 2. We note several comparisons to certain product candidates and approved therapies in the Summary and in the Business section, including Figures 12 and 14. Since it does not appear that you have conducted head-to-head trials, please revise your disclosure to clearly state this fact and disclose why you believe these comparisons are appropriate. If you provide disclosure regarding results from other trials, expand your disclosure to provide the other information regarding these trials that would help an investor make a meaningful comparison and understand the supporting trials and any limitations and qualifications associated with such trials (e.g., number of patients and whether any patients dropped out of the trial or were otherwise excluded and the reasons, patient population, dosage, how the baseline was measured in each study, the phase of the trial, serious adverse events, etc.). Please also make it clear whether you are comparing your product candidate to another product candidate or an approved therapy.
- 3. Please remove the references to the 2019 sales of dupilumab and fingolimod as such disclosure is not appropriate for the Summary.
- 4. Please remove references to "promising" preliminary clinical responses or "favorable" preclinical results and Phase 1 results throughout the prospectus. Please also remove the references to "promising efficacy" and "improved safety profiles" on page 124 since you are discussing product candidates that have yet to receive marketing approval.

## Our Pipeline, page 2

5. The pipeline table should graphically demonstrate the current status of your product candidates. A textual discussion is more appropriate for the next steps or plans for your product candidates. As such, please revise your table to eliminate the color coding for "planned" trials and shorten the lines for CBP-201 in asthma and CRSwNP since you have yet to initiate the Phase 2 trial and for CBP-174 since you have yet to initiate the Phase 1 trial. We note that note 1 to the table indicates that a Phase 2 trial for CBP-307 in Crohn's Disease was terminated early due to COVID-19 related enrollment changes. Please clarify whether you will need to begin a new Phase 2 trial or whether you will be able to restart the paused trial. If you will need to begin a new Phase 2 trial, please shorten the line for this product candidate and indication accordingly. We note your disclosure on page 3 that CBP-233 is still in the discovery phase. Please explain why it is sufficiently material to your business to warrant inclusion in your pipeline table or remove it from the table.

## Our Strategy, page 3

6. Please remove the references throughout your prospectus to potential "first-in-class" or "best-in-class" product candidates as this statement implies an expectation of regulatory

approval and is inappropriate given the length of time and uncertainty with respect to securing marketing approval.

## Summary of Risk Factors, page 5

7. Please revise to disclose the risk that the approval of the China Securities Regulatory Commission may be required for this offering and the potential consequences since you do not intend to seek such approval as discussed in the risk factor on page 63.

# **Risk Factors**

# Our business benefits from certain financial incentives..., page 69

8. We note your disclosure here that you have benefited from certain financial incentives in China in the past and your disclosure on page 100 that you have funded your operations primarily through equity financing and the receipt of government subsidies and tax credits in China and Australia. If this financial assistance is reimbursable, please revise to disclose the maximum amount that you would have to reimburse the Chinese and Australian governments should you fail to comply with the conditions of these financial incentives.

# Use of Proceeds, page 89

- 9. Please disclose how far you expect the proceeds from the offering to allow you to proceed in the development of each of your programs.
- 10. Please revise your second bullet point to clarify if proceeds from your offering will be used to further the development of CBP-233.

# <u>Critical Accounting Policies and Estimates</u> <u>d) Ordinary Share Valuation, page 108</u>

11. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the initial public offering and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features. Please discuss with the staff how to submit your response.

# Our Product Candidates, page 116

12. We note your disclosure in this section regarding the results of your Phase 1a and Phase 1b trials for CBP-201 and your Phase 1 trial for CBP-207. To place the disclosed trial results in context, please clarify whether each result from these trials is statistically significant and whether you utilized a p-value that the FDA typically requests for purposes of assessing efficacy. For your CBP-201 product candidate, please also disclose any

results from any Phase 2a trial that you conducted or revise to make clear why you are proceeding to Phase 2b from your Phase 1 trials.

### Intellectual Property, page 133

13. Please revise to disclose the material foreign jurisdictions where you own patents or have pending patent applications.

### Licensing Agreement, page 135

14. We note your disclosure on page 14 that as your product candidates progress through development and toward commercialization, you will need to make milestone payments to the licensors and other third parties from whom you have in-licensed or acquired your product candidates, including Arena. Please revise to disclose the aggregate amount of milestone payments that may be payable.

### Corporate Governance Practices, page 166

15. We note your disclosure in this section that a quorum required for and throughout a meeting of shareholders consists of one or more shareholders holding shares which carry in aggregate not less than one-half of all votes attaching to all of your shares in issue and entitled to vote. We also note your disclosure on page 177 that a quorum required for any general meeting of shareholders consists of one or more shareholders present in person or by proxy, holding shares which carry in aggregate not less than one-third of all votes attaching to all of our shares in issue and entitled to vote. Please revise to reconcile your disclosure. If your quorum requirement will be for a minority quorum and voting may be conducted by a show of hands, please add a separate risk factor as appropriate.

### General

16. 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.

You may contact Eric Atallah at 202-551-3663 or Vanessa Robertson at 202-551-3649 if you have questions regarding comments on the financial statements and related matters. Please contact Ada D. Sarmento at 202-551-3798 or Tim Buchmiller at 202-551-3635 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences

cc: Patrick A. Pohlen, Esq.