



DIVISION OF
CORPORATION FINANCE

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

February 4, 2022

Hao-Yuan Chuang
Chief Financial Officer
BELITE BIO, INC
5820 Oberlin Drive, Suite 101
San Diego, CA 92121

Re: BELITE BIO, INC
Amendment No. 1 to Draft Registration Statement on Form F-1
Submitted January 21, 2022
CIK No. 0001889109

Dear Mr. Chuang:

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

Cover Page

1. We note your response to our prior comment 1 and reissue the comment in part. We also note that you have amended your cover page to state that "[a]ll of [y]our operations are outside of PRC as of the date of this prospectus." Please revise your disclosure here as well as elsewhere throughout the prospectus where you make similar statements such as on pages 63 and 64 to clearly state that you have incorporated subsidiaries in China and Hong Kong.
2. We note your revised disclosure here as well as similar disclosure elsewhere throughout the registration statement, such as on pages 63 and 65, where you state that "in the event that [you] elect to carry out clinical trials in China and/or expand [y]our operations into

China in the future, there may be certain legal and operational risks associated with having certain operations in China [...]." Please revise these statements to clarify this disclosure with reference to plans you state elsewhere in the registration statement such as your plans to conduct a Phase 3 clinical trial of LBS-008 in patients with STGD1 in Asia as well as plans for a Phase 2 or 3 clinical trial of LBS-008 for the treatment of dry AMD in the Asia Pacific as disclosed on pages 126 and 128, respectively.

3. We note your response to our prior comment 4 as well as your revised disclosure starting on the bottom of page 8 where you state that "[a]s of the date of this prospectus, [you] have provided US\$10.06 million to [y]our subsidiaries via capital contribution, including US\$0.5 million intercompany loans that have been repaid by the subsidiary via the issuance of ordinary shares" and that "[n]o transfer of cash or other types of assets has been made between [y]our Cayman Islands holding company and subsidiaries as of the date of this prospectus." Please revise your disclosure beginning on page 8 to clarify what amounts have been provided to your China-based subsidiary via capital contribution or intercompany loans. Please also revise your disclosure here on your cover page to include these amounts.
4. We note your response to our prior comment 2 and your response to comment 1 indicating that your Chinese subsidiary has not commenced operations. We note also from your response that you have been in discussions with the NMPA on how you shall submit an application to conduct Phase 3 clinical trials in China. Please provide prominent disclosure about the legal and operational risks associated with your expanding your operations in China. Your disclosure should make clear whether these risks could result in a material change in your operations and/or the value of your ADSs or could significantly limit or completely hinder your ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless. For example, we will not object to disclosure stating that there is no indication as to whether NMPA would approve your proposed application or when such NMPA approval could be obtained, as referenced in your response. Additionally, your disclosure should address how recent statements and regulatory actions by China's government, such as those related to the use of variable interest entities and data security or anti-monopoly concerns, has or may impact the company's ability to conduct its business, accept foreign investments, or list on an U.S. or other foreign exchange. Your prospectus summary should address, but not necessarily be limited to, the risks highlighted on the prospectus cover page.

Prospectus Summary, page 1

5. We note your response to our prior comment 8 and your response to comment 1 indicating that your Chinese subsidiary has not commenced operations. Disclose in your prospectus summary each permission that you or your subsidiaries are required to obtain, or will be required to obtain if you commence operations, from Chinese authorities to operate your business and to offer the ADSs to foreign investors. State whether you or your subsidiaries

are covered by permissions requirements from the China Securities Regulatory Commission (CSRC), Cyberspace Administration of China (CAC) or any other governmental agency that is required to approve of you or your subsidiaries' operations, and state affirmatively whether you have received all requisite permissions or approvals and whether any permissions or approvals have been denied. Please also describe the consequences to you and your investors if you or your subsidiaries: (i) do not receive or maintain such permissions or approvals, (ii) inadvertently conclude that such permissions or approvals are not required, or (iii) applicable laws, regulations, or interpretations change and you are required to obtain such permissions or approvals in the future. For example, we will not object to disclosure stating that there is no indication as to whether NMPA would approve your proposed application to conduct Phase 3 clinical trials in China or when such NMPA approval could be obtained.

LBS-008, page 3

6. We note your response to our prior comment 7 and reissue the comment in part. We note that you have revised your disclosure here and on page 115 to state that "[i]n the US SAD study, [you] found that single doses of 10–50 mg LBS-008 were well tolerated and effective to reduce mean serum RBP4 level by around 70% from baseline." We also note that you have revised your disclosure on page 127 to state that "[t]he DSMC for the Phase 1b portion of the study commented that the overall safety profile looks good." Conclusions regarding efficacy and safety are determinations that only the FDA or a foreign government equivalent has the authority to make. Please revise your disclosure to eliminate the implication that your product candidates have been or will ultimately be determined safe and/or effective or have demonstrated safety and/or efficacy for purposes of approval by the FDA or comparable agency. Alternatively, we advise you that you may present the objective data from pre-clinical and clinical trials without drawing a conclusion from the results. For example, you may note that a candidate was well tolerated, the absence of serious adverse events or the number of trial participants who met the identified trial endpoints.
7. We note your response to prior comment 10. In order for investors to evaluate your disclosure, please provide a range or other approximation of the proportion of revenue you would be obligated to pay to Columbia University in respect of any sale of a priority review voucher.

Summary of Risk Factors, page 7

8. We note your response to our prior comment 13 as well as your response to comment 1 indicating that your Chinese subsidiary has not commenced operations. Please provide risk factor disclosure in the summary risk factors and in the risk factor section that discusses the risks of your expanding your operations in China. In particular, describe in your summary risk factors any significant regulatory, liquidity, and enforcement risks with cross-references to the more detailed discussion of these risks in the prospectus. For example, specifically discuss risks arising from the legal system in China, including risks

and uncertainties regarding the enforcement of laws and that rules and regulations in China can change quickly with little advance notice; and the risk that the Chinese government may intervene or influence your operations at any time, or may exert more control over offerings conducted overseas and/or foreign investment in China-based issuers, which could result in a material change in your operations and/or the value of your ADSs. Acknowledge any risks that any actions by the Chinese government to exert more oversight and control over offerings that are conducted overseas and/or foreign investment in China-based issuers could significantly limit or completely hinder your ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless.

Risk Factors

Failure to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement, page 59

9. We note your response to our prior comment 17 as well as your response to comment 1 indicating that your Chinese subsidiary has not commenced operations. Please revise your risk factor disclosure here to discuss the risks of expanding your operations in China as those risks relate to privacy or data security. In light of recent events indicating greater oversight by the Cyberspace Administration of China over data security, particularly for companies seeking to list on a foreign exchange, please revise your disclosure to explain how this oversight impacts your business and your offering and to what extent you believe that you are compliant with the regulations or policies that have been issued by the CAC to date.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses, page 60

10. We note your response to our prior comment 17 and reissue the comment in part. Please revise to provide additional detail concerning the risks to your development plans highlighted on page 6.

Certain judgments obtained against us by our shareholders may not be enforceable. , page 77

11. We note your disclosure that “some” of your directors and executive officers are nationals and/or residents of countries other than the U.S. Your disclosure on page 91 states that “most” of your directors and officers are nationals or residents of jurisdictions other than the U.S. Please revise to reconcile your disclosure.

The deposit agreement provides that the United States District Court for the Southern District of New York , page 79

12. We note your response to our prior comment 32 and we reissue the comment in part. Please amend your risk factor disclosure here to also highlight the risk to shareholders of increased costs to bring a claim associated with this provision. We also note that you

have removed the summary of the exclusive forum provision from your disclosure on page 184 of the amended draft registration statement. Please revise your disclosure in the section describing your ADSs beginning on page 191 to clearly and prominently describe the exclusive forum provision that appears in your deposit agreement, including the relevant forum for litigation and any subject matter jurisdiction carve out. Please disclose whether this provision applies to actions arising under the Securities Act or Exchange Act. If so, please also state that there is uncertainty as to whether a court would enforce such provision. If the provision applies to Securities Act claims, please also state that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. In that regard, we note that Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. If this provision does not apply to actions arising under the Securities Act or Exchange Act, please also ensure that the exclusive forum provision in the governing documents and Deposit Agreement states this clearly.

Patent License Agreement with The Trustees of Columbia University in the City of New York, page 134

13. We note your response to our prior comment 27 and reissue the comment in part. Please expand your disclosure to describe with respect to the royalty term, when the last-to-expire patent is anticipated to expire.

Principal Shareholders, page 173

14. We note your response to our prior comment 30 your revised disclosure here stating that "[t]he exercise price of the outstanding options granted to the directors and executive officers named above are US\$0.1191 and US\$0.4386 per share." Please revise your disclosure throughout the footnotes to the table to specify the exercise price that corresponds to the options for each director or executive officer.

You may contact Eric Atallah at 202-551-3663 or Brian Cascio at 202-551-3676 if you have questions regarding comments on the financial statements and related matters. Please contact Jessica Ansart at 202-551-4511 or Christine Westbrook at 202-551-5019 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Portia Ku, Esq.