United States securities and exchange commission logo

December 30, 2021

Yu-Hsin Lin
Chief Executive Officer
BELITE BIO, INC
5820 Oberlin Drive, Suite 101
San Diego, CA 92121

Re: BELITE BIO, INC
Draft Registration Statement on Form F-1
Submitted December 1, 2021
CIK No. 0001889109

Dear Dr. Lin:

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

Cover Page

1. Please disclose prominently on the prospectus cover page that you are not a Chinese operating company but a Cayman Islands holding company with operations conducted by your subsidiaries, including by your Chinese subsidiary.
2. Provide prominent disclosure about the legal and operational risks associated with the company s 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. 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. Please disclose whether your auditor is subject to the determinations
announced by the PCAOB on December 16, 2021 and whether and how the Holding
Foreign Companies Accountable Act and related regulations will affect your company.
Your prospectus summary should address, but not necessarily be limited to, the risks
highlighted on the prospectus cover page.
3. Clearly disclose how you will refer to the holding company and subsidiaries when
providing the disclosure throughout the document so that it is clear to investors which
entity the disclosure is referencing and which subsidiaries or entities are conducting the
business operations. For example, disclose, if true, that your subsidiaries conduct
operations in China and that the holding company does not conduct operations. Disclose
clearly the entity (including the domicile) in which investors are purchasing their interest.
4. Provide a description of how cash is transferred through your organization. State whether
any transfers, dividends, or distributions have been made to date between the holding
company and its subsidiaries, or to investors, and quantify the amounts where applicable.
5. We note your disclosure on page 80 that you are a controlled company under the Nasdaq
Stock Market Rules. If you intend to qualify as a controlled company after the offering,
please provide related disclosure on the cover page.

Overview, page 1

6. We note your disclosure here that your lead product candidate, LBS-008, was developed
from your RBP4 platform technology. Please expand your disclosure in the prospectus
summary as well as in the business section to describe the key aspects of this platform
technology and how it is used to develop your product candidates.
7. We note your disclosure here and in the business section in which you make statements
related to potential safety and efficacy, which are premature given the stage of
development of the company's product candidates. For example:

- LBS-008 is a treatment "that can reduce and maintain the delivery of vitamin A (retinol) to the eye in a safe and effective manner";
- LBS-008 has demonstrated its "safety, potency and consistency that we believe is clinically meaningful to treat STGD1 patients";
- LBS-008 can "achieve mean RBP4 level reduction of > 70% without observing any significant side-effects";
- LBS-008 is "expected to have a positive treatment effect in a significant portion of this population of dry AMD patients";
- LBS-008 has a "proven mechanism of action";
- LBS-008 treatment "is effective to reduce serum RBP4 by > 70%"; and
- All dose levels of LBS-008 in the Phase 1 Clinical Trial in Dry AMD "were determined to be safe and well tolerated."

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 throughout your document, including but not limited to the statements noted

above, 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.

Prospectus Summary, page 1

8. Disclose in your prospectus summary each permission that you or your subsidiaries are required to obtain 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.

9. Provide a clear description of how cash is transferred through your organization in your prospectus summary. Quantify any cash flows and transfers of other assets by type that have occurred between the holding company and its subsidiaries, and direction of transfer. Quantify any dividends or distributions that a subsidiary has made to the holding company, which entity made such transfer, and their tax consequences. Similarly quantify dividends or distributions made to U.S. investors, the source, and their tax consequences. Your disclosure should make clear if no transfers, dividends or distributions have been made to date. Describe any restrictions on foreign exchange and your ability to transfer cash between entities, across borders, and to U.S. investors. Describe any restrictions and limitations on your ability to distribute earnings from the company, including your subsidiaries, to the parent company and U.S. investors.

10. Your summary should provide a balanced and factual presentation of your business. Please balance your disclosure with reference to competition from product candidates in development to treat the same indications as LBS-008, as referenced on pages 24 and 127. Additionally, please expand your disclosure on page 2 to disclose the portion of proceeds from any sale of a priority review voucher you are obligated to pay to Columbia

University under your license agreement, as referenced on page 126. Please make

corresponding revisions to your disclosure concerning the license agreement in the
business section.
Our Strategies, page 5

11. We note your reference to rapidly advancing the development of LBS-008 through
clinical trials and regulatory approval. Please revise this statement here and throughout
your prospectus to remove any implication that you will be successful in developing and
receiving approval for your product candidate in a rapid or accelerated manner
Our Strengths , page 5

12. Your statement that two of your strengths include a "first-in-class oral therapy" and a
"proven mechanism of action" implies the likelihood of regulatory approval and
comparisons to other product candidates. Please remove the "first-in-class" and
"proven" references here and throughout the prospectus as appropriate as the statements
are speculative in light of the regulatory status of the product candidates you are currently
pursuing.
Summary of Risk Factors, page 6

13. In your summary of risk factors, disclose the risks that your corporate structure and the
company s operations in China poses to investors. In particular, describe the 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.
Additionally, please organize your summary risk factors and your risk factor section so
that risks related to doing business in China appear first.
14. Please add a bullet point highlighting the risks associated with the concentration of
ownership by your principal shareholder, as referenced on page 70.
Implications of Being an Emerging Growth Company, page 7

15. We note your disclosure that you have elected to take advantage of the benefits of the
extended transition period for complying with new or revised accounting standards under

Section 102(b)(1). Please also include risk factor disclosure explaining that the election
allows for the delay of the adoption of new or revised accounting standards that have

different effective dates for public and private companies until those standards apply to
private companies and that as a result of this election, your financial statements may not
be comparable to companies that comply with public company effective dates with similar
disclosure.

Risk Factors

Risks Related to Our Industry, Business and Operations

Our internal computer systems, or those used by our CROs or other contractors or consultants,
may fail or suffer security breaches, page 56

16. We note your disclosure here that "[you] have on occasion experienced, and will continue
to experience, threats to [y]our data and systems." To the extent you have been materially
impacted by a cybersecurity breach, please include a description of the incident, costs, and
other consequences. For additional guidance, please refer to CF Disclosure Guidance
Topic No. 2 on Cybersecurity.

Failure to comply with existing or future laws and regulations related to privacy or data security
could lead to government enforcement, page 57

17. We note your disclosure here that makes reference to the Cyberspace Administration of
China and its various rules and regulations with respect to 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..., page 58

18. We note your disclosure that you have experienced delays in the enrollment of patients in
your clinical trials due to COVID-19. Please revise to provide additional detail concerning
the impact of COVID-19 on your clinical trial enrollment and risks to your development
plans highlighted on page 5.

Risks Related to Doing Business in China, page 64

19. We note from the audit opinion that you have a U.S. based auditor that is registered with
the PCAOB and subject to PCAOB inspection. Please disclose any material risks to the
company and investors if it is later determined that the PCAOB is unable to inspect or
investigate completely your auditor because of a position taken by an authority in a
foreign jurisdiction. For example, disclose the risk that lack of inspection could cause
trading in your securities to be prohibited under the Holding Foreign Companies
Accountable Act and as a result an exchange may determine to delist your securities.

20. Please expand your risk factors to disclose that the United States Senate has passed the
Accelerating Holding Foreign Companies Accountable Act, which, if enacted, would
decrease the number of non-inspection years from three years to two years, and thus,
would reduce the time before your securities may be prohibited from

trading or delisted.
Update your disclosure to reflect that the Commission adopted rules to implement the
HFCAA and that, pursuant to the HFCAA, the PCAOB has issued its report notifying the
Commission of its determination that it is unable to inspect or investigate completely
accounting firms headquartered in mainland China or Hong Kong.
21. We note your disclosure in a risk factor on page 57 concerning risks related to your
compliance with data security laws that makes reference to the Cyberspace Administration
of China and its various rules and regulations. 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.
Use of Proceeds, page 84

22. Please revise this section to provide more specific detail regarding the use of the funds to
be allocated to the clinical development of LBS-008 for the treatment of STGD1 and for
dry AMD, respectively, including reference to how far into the development processes the
proceeds will enable you to reach, as applicable.
Management's Discussion and Analysis of Financial Condition and Results of Operations
Results of Operations , page 100

23. We note that you did not provide a discussion of your results of operations for the year
ended December 31, 2020. Please revise your filing to discuss the significant components
of your operating expenses for the year ended December 31, 2020. Refer to Item 5 of
Form 20-F.
Critical Accounting Policies and Estimates
Share-Based Compensation, page 107

24. 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.

Business
Clinical Development, page 120

25. To the extent not disclosed, please revise your discussion of the preclinical and clinical
trials for each of your product candidates conducted to date to specify the primary and
secondary endpoints of the different trials, the results as they relate to the endpoints and
any statistical analysis that was done. Also add an explanation of how statistical
significance relates to the approval process of the FDA and other regulators.

Patents, page 124

26. Please revise to disclose for each material patent and patent application the specific products to which such patents or patent applications relate, whether the patents are owned or licensed, the type of patent protection, the expiration dates, and applicable material jurisdictions, including any foreign jurisdiction. Consider disclosure in tabular format by patent family or otherwise in addition to the narrative provided. We also note your disclosure on page 40 that "[y]our licensed and co-owned patents and pending patent applications have been generated through the use of U.S. government funding," which could subject you to "march-in rights." Please identify here any patents or pending patent applications that are or would be subject to march-in rights.

Patent License Agreement with The Trustees of Columbia University in the City of New York, page 125

27. We note your disclosure on page 135 outlining your license agreement with The Trustees of Columbia University. Please expand your disclosure to describe all material terms of the agreement including:
- quantification of the upfront license issue fee previously paid;
- quantification of the minimum annual royalty; and
- with respect to the royalty term, when the last-to-expire patent is anticipated to expire.

Facilities, page 127

28. We note your disclosure in a risk factor on page 54 that you have facilities in California, Australia, Taiwan and China, however, here you only provide information for facilities in California, Taiwan and China. Please clarify whether you also have facilities in Australia and revise your disclosure to reflect information concerning any such facility.

Management
Share Incentive Plans, page 166

29. We note your disclosure here describing your 2020 Share Incentive Plan as well as your 2021 Performance Incentive Plan, which you plan to adopt in connection with this offering. Additionally, we note you intend to file as Exhibit 10.1 the Belite Bio, Inc. Amended and Restated Share Option Plan. Please clarify whether this exhibit relates to the 2020 Share Incentive Plan or to the 2021 Performance Incentive Plan. Furthermore, please ensure that both incentive plans are filed as exhibits or advise us why such agreement is not required to be filed. Refer to Item 601(b)(10) of Regulation S-K.

Principal Shareholders, page 168

30. Please revise the information here regarding options to include the exercise price and the purchase price, if any, of the options. Refer to Item 6.E. of Form 20-F.

Related Party Transactions
2021 LBS-008 R&D Services Agreement, page 172

31. We note your disclosure here describing the terms of your current R&D services agreement with your ultimate controlling shareholder, Lin Bioscience,

Inc. Please file this
agreement as an exhibit or advise us why this agreement is not
required to be filed. Refer
to Item 601(b)(10) of Regulation S-K.
Description of Share Capital
Exclusive Forum, page 179

32. We note your disclosure that indicates that the deposit agreement
provides that the U.S.
District Court for the Southern District of New York shall be the
exclusive forum for the
resolution of any complaint asserting a cause of action arising under
the Securities Act
and the Exchange Act. Please include a risk factor that highlights the
risks associated with
this provision and other impacts on shareholders, which may include
increased costs to
bring a claim and that these provisions may discourage claims or limit
shareholders'
ability to bring a claim in a judicial forum that they find favorable.
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. Address in your risk factor disclosure that
there is uncertainty as to
whether a court would enforce such provision.
General

33. 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 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.