



DIVISION OF
CORPORATION FINANCE

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

December 30, 2020

William Cao, Ph.D.
Chief Executive Officer
Gracell Biotechnologies Inc.
Building 12, Block B. Phase II
Biobay Industrial Park
218 Sangtian St.
Suzhou Industrial Park, 215123
People's Republic of China

Re: Gracell Biotechnologies Inc.
Registration Statement on Form F-1
Filed December 18, 2020
File No. 333-251494

Dear Dr. Cao:

We have reviewed your 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 amending your registration statement and providing the requested information. 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 any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

Registration Statement on Form F-1

Overview, page 1

1. We reissue comment 1 in part. Please revise the summary to include information about each of the risks for which we sought disclosure in the summary in comment 1, in particular the risk that shareholders may be required to file a return and be taxed by the PRC (as discussed on page 82), and the risks related to the discretion of Chinese governmental authorities to influence your business and operations addressed in the last bullet point of your response. Finally, revise the summary to include the risk of being delisted (discussed on pages 89-90).

2. We reissue comment 2. The disclosure changed from the initial claims of safety, efficacy and potency, to "potentially enhanced efficacy and safety," to the current disclosure regarding "potentially enhanced therapeutic effects" and similar language. The revisions still claim some degree of safety and/or efficacy, which are determinations solely within the authority of the FDA and comparable foreign regulators, and determined throughout all phases of clinical trials. Please remove all such references.
3. We reissue comment 3 insofar as you continue to state that the product "is first-in-class in its design" on page 163.
4. We reissue comment 4. Revise your pipeline table to equally prominently label the arrows representing those product candidates in development in investigator-initiated trials in China, i.e., label the blue arrows as you have done the green arrows. To further avoid misinterpretation, revise to provide separate arrows for planned INDs in the United States, indicating the preclinical status of each of those product candidates. Also revise the table to clearly convey the limited scope of your involvement in the investigator-initiated studies and lack of access to those studies. Revise the added disclosure on page 8 to disclose that you do not have access to the data from these studies, and to balance your statement of your intent to "expedite [y]our global clinical development activities" with disclosure clarifying there are no guarantees this strategy will be successful or will speed development.
5. To avoid confusion with the FDA's Center for Drug Evaluation and Research (CDER), where you first mention the Center for Drug Evaluation, on page 6, revise to clarify that it is a division of the NMPA. Define NMPA and FDA at their first use in the new disclosure on page 5. Revise throughout your document to make these distinctions clear.

Risks Related to this Offering, Our Securities and Our Status as a Public Company, page 93

6. Refer to the added exclusive forum risk factor on page 100. You disclose that the United States District Courts will be the exclusive forum for Securities Act claims. 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. Revise to state that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Risk Factors

General Risk Factors, page 102

7. We note your revised disclosure in response to comment 5. To the extent your operations and the investigator-initiated trials are located in China and the pandemic could affect your clinical trials, it appears at least that portion of the risk factor should be addressed more prominently in another part of the risk factors, rather than as a "general" risk that any company could face.

Intellectual Property, page 176

8. Refer to comment 13. We note you filed the licensing agreements as requested in comment 23 of our initial letter; however, you did not expand your disclosure here or elsewhere, as appropriate, to provide the material terms of the license agreement with ProMab, as referenced on page 68. Revise to provide this disclosure.

Taxation, page 239

9. We reissue comment 15. Your disclosure continues to describe what potential tax consequences are "likely," *if* certain events occur. You must provide an opinion of counsel. To the extent the tax consequences are subject to uncertainty, counsel may describe what the tax consequences "should" or are "more likely than not" to be, but counsel must also describe why it cannot give a "will" opinion, and describe the degree of uncertainty. In addition, revise statements such in this subsection, to avoid statements such as "our company," so it is clear this section provides the opinion of tax counsel, not the company.

Exhibits

10. Revise Exhibit 5.1, the Cayman Islands legal opinion, to remove all inappropriate assumptions and qualifications, including those reflected in Schedules 1, 2 and the third item of Schedule 3. Revise paragraph 3 to clarify that the shares will be non-assessable. Refer to Section II.B.1.a. of Staff Legal Bulletin No. 19 for guidance.
11. Revise Exhibit 99.2 to provide an unqualified opinion. The language "[b]ased on our understanding of the current PRC Laws," and the noted "substantial uncertainties" outlined are inappropriate. Clarify in the opinion and the accompanying text in the registration statement that counsel has opined on the material tax consequences under PRC law, not that counsel opines the summary is accurate. Revise the penultimate paragraph to clarify "your use," so that it is clear that security holders are entitled to rely on this opinion.

William Cao, Ph.D.
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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.

You may contact Franklin Wyman at (202) 551-3660 or Sasha Parikh at (202) 551-3627 if you have questions regarding the financial statements and related matters. Please contact Abby Adams at (202) 551-6902 or Celeste Murphy at (202) 551-3257 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Will Cai, Esq.