



DIVISION OF
CORPORATION FINANCE

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

December 11, 2020

William Wei 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.
Amendment No. 1 to Draft Registration Statement on Form F-1
Submitted November 24, 2020
CIK No. 0001826492**

Dear Dr. Wei Cao:

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 submitted on November 24, 2020

Prospectus Summary, page 1

1. Please revise the risk factors on pages 76 and 93 and the related disclosure in the Summary to clarify if the PRC could prevent you from seeking foreign approval and commercialization of any of your product candidates. Revise also to disclose in the Summary any research and development activities your wholly foreign-owned enterprise Graycell Bioscience is engaged in, whether any research and development at any of the

VIEs may be attributable to Graycell Bioscience, and the basis to support your determination that the prohibition under the Negative List does not apply to your operations. Please also revise to define the term "WFOE" at its first use.

Additionally, please expand your disclosure to address the following risks, as applicable:

- intellectual property rights and protections may be insufficient to protect your intellectual property in China;
- the increased global focus on environmental and social issues and China's potential adoption of more stringent standards in these areas may adversely impact your operations;
- potential adverse tax-consequences to shareholders if you are determined to be a resident enterprise for PRC tax purposes; and
- Chinese governmental authorities have significant discretion that can be used to influence how you conduct your business and operations.

Refer to the Division of Corporation Finance Disclosure Guidance Topic No. 10 "Disclosure Considerations for China-Based Issuers."

Overview, page 1

2. We note your response to comment 2 and reissue with respect to references to potentially enhanced safety and efficacy and disclosure that implies the safety profile of your product candidates has been established.
3. We note your response to comment 4 and reissue with respect to references to product candidates as potentially "first-in-class."
4. We note your response to comment 22 indicating that you do not have access to data from the Phase 1 investigator-initiated trials until the data is published. Please revise your disclosure in the Summary to highlight this limitation. It should be clear from your disclosure throughout your prospectus that you do not have access to data while the trials are being conducted and are dependent on receiving published data. Revise any references to partnering on these studies to explain your involvement. Similarly, revise your pipeline table presentation to convey the limited scope of your involvement and that you do not have access to data from the investigator-initiated studies until the data is published. Lastly, please highlight the risks associated with your lack of access to the data under an appropriate heading in the Risk Factors section.

Risk Factors, page 18

5. To the extent any risk factor included in your prospectus could involve any registrant or any offering, revise this section to relocate all such risk factors at the end of this section under the caption "General Risk Factors." Refer to Item 3 of form F-1 and 105(a) of Regulation S-K and Section II.D. of Release No. 33-10825, "Modernization of Regulation S-K Items 101, 103, and 105" (Oct. 8, 2020).

Dilution , page 115

6. Please provide the information added to the Capitalization table in response to prior comment 12 to the corresponding section of the Dilution table.

Management's Discussion and Analysis of Financial Condition and Results of Operations

Results of Operations

Comparison of Nine Months Ended September 30, 2019 and 2020

Operating Expenses

Administrative Expenses, page 130

7. Please tell us why "research and development activities" are included in your discussion regarding changes in your administrative expenses or revise.

Loan Agreements, page 134

8. We note your response to comment 13 and do not agree with your conclusion that your loan agreements are not material contracts required to be filed as exhibits. In this regard, we note that you have a history of losses, will continue to incur research and development expenses and may not be profitable in the near future. Please file your loan agreements with Bank of China, China Construction Bank and China Merchants Bank as exhibits to your registration statement.

Critical Accounting Policies, Judgments and Estimates

Research and Development Expenses, page 140

9. Your revised disclosure presents research and development expenses for each of your significant product candidates and separately by the major components of your research and development expenses. Please clarify how these two tables are integrated or revise to incorporate both tables into one table that reconciles to total research and development expense on the Consolidated Statements of Comprehensive Loss.

Share-Based Compensation, page 143

10. 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 IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation. Please discuss with the staff how to submit your response.

Business, page 145

11. We note your response to comment 20 and reissue the comment to the extent you have not revised the disclosure to define Grade 1 and higher adverse events as discussed in your response.

12. We reissue comment 22 in part. To the extent you do not have access to study data for the studies you describe in your response, revise this section to explain your limited access. Tell us how you have access to the data you do have, and whether you have any agreement regarding the sharing of data or information. Tell us when, if ever, you expect to obtain access to full information on the studies, including not only results but the underlying data collected. For example, tell us whether you will obtain access to the information prior to submitting your IND applications to the FDA. In addition, revise to state what actions you have taken in the studies for which you do not have access to the data. For example, you continue to state "our trial" (page 163) and "we observed" (page 164) with respect to the GC012F study, and "we administered all patients with a single infusion" in the GC027 study, on page 167. To be clear that you are not conducting these studies, revise throughout this section to avoid the passive voice and state who is taking the actions you describe.

Intellectual Property, page 173

13. We note your response to comment 23 and do not agree with your conclusion that your license agreement with ProMab is an ordinary course contract not required to be filed as an exhibit to your registration statement. Further, we note your disclosure on page 64 that "[i]f we fail to comply with the obligations . . . our licensors may have the right to terminate the license," and, if terminated, you "may not be able to develop, manufacture, market or sell the product covered by our agreements," which "could materially adversely affect the value of the product candidates being developed under any such agreement." Please file your license agreement with ProMab as an exhibit to your registration statement.
14. We reissue comment 24 in part. Revise to describe the scope of patent protection you seek with respect to your patent applications described in this section.

Taxation, page 245

15. We reissue comment 28 in part. Revise the discussion of PRC tax consequences to provide an opinion of counsel as to the material PRC tax consequences of the ownership of your ordinary shares represented by American Depositary Shares.

William Wei Cao, Ph.D.
Gracell Biotechnologies Inc.
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You may contact Frank Wyman at 202-551-3660 or Sasha Parikh at 202-551-3627 if you have questions regarding comments on the financial statements and related matters. Please contact Abby Adams at 202-551-6902 or Christine Westbrook at 202-551-5019 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Will Cai, Esq.