United States securities and exchange commission logo

November 15, 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.
Draft Registration Statement on Form F-1
Submitted October 19, 2020
CIK No. 0001826492

Dear Dr. Wei Cao:

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 submitted October 19, 2020

Prospectus Summary, page 1

1. We note several references here and throughout the prospectus to Gracell Biotechnology being a "leading cell and gene therapy company and entering into partnerships with leading biopharmaceutical companies. You also state on page 141 that you plan to continue your "leadership position" in cell therapy. Please substantiate your claims or revise them to state that these are your beliefs. Refer to Item 4.B.7. of Form 20-F.

2. We note several references here to your product candidates having achieved a complete response" in clinical trials, as well as "promising" preclinical data, show[ing] proliferation potency, tissue migration and tumor clearance effect, having superior efficacy, and enhanc[ing] the efficacy of [y]our CART-T cell therapies in addition to later disclosure, including on pages 121 and 137, claiming potency, fast, deep and

durable responses, including multiple stringent complete responses, and "enhanced
efficacy and safety. Further, you reference "demonstrated superior engraftment and
anti-leukemia efficacy," "demonstrated superior in vivo proliferation as well as duration
of expansion in the peripheral blood of treated animals, which was correlated with its
robust anti-leukemia efficacy," "GC007 has shown favorable safety and efficacy results,"
"manageable safety profile" and "compelling" data. You also state on page 162 that "data
indicate GC007 is a safe and effective CAR-T therapy against CD19+ B cell
malignancy." As safety and efficacy determinations are solely within the authority of the
U.S. Food and Drug Administration (FDA) and comparable foreign regulators, and are
evaluated throughout all phases of clinical trials, please remove these and similar
references throughout your prospectus. In the Business section, you may present
objective data resulting from your trials without including conclusions related to efficacy.

3. Your summary should provide a balanced and factual presentation of your business.
Please place your selected disclosure under the headings "Overview" and "Our Proprietary
Technology Platforms" in appropriate context with an equally prominent discussion of the
early-stage nature of your development programs, the challenges you face in developing
novel therapeutics, your limited trial data to date and that all of your clinical development
has been conducted outside the U.S. In your revised disclosure, discuss that regulators
may not accept data from investigator-initiated trials, as referenced on page 26.

4. We note references throughout your prospectus to your product pipeline or various
product candidates as being "first-in-class" and revolutionary. These terms suggest that
the product candidates are effective and likely to be approved. Please delete these
references throughout your registration statement. If your use of these terms was intended
to convey your belief that the products are based on a novel technology or approach
and/or is further along in the development process, you may discuss how your technology
differs from technology used by competitors and, if applicable, that you are not aware of
competing products that are further along in the development process. Statements such as
these should be accompanied by cautionary language that the statements are not intended
to give any indication that the product candidates have been proven effective or that they
will receive regulatory approval.

5. Please revise to briefly discuss the nature of the "investigator-initiated" studies you
reference, your role/responsibility, if any, in the these studies, and identify the
investigator(s) and sponsor(s).

6. Please revise your pipeline table to accurately reflect the development status of each
product candidate in each jurisdiction. Your disclosure on page 157 indicates that
GC007F is being studied in an ongoing Phase 1 trial. Accordingly, the arrow

corresponding to GC007 should not indicate that you have completed Phase 1

development.
7. Please revise your disclosure to remove any implication that you will be successful in obtaining regulatory approval for your product candidates in an accelerated manner. We note, for example, your statement of strategy on page 5 and later on page 141 to [r]apidly advance [y]our lead product candidates through clinical development and regulatory approval by leveraging [y]our global clinical development capabilities. We note also your claims on page 4 that your strategy "expedites the initial demonstration of safety and efficacy" for your product candidates, and on page 154 that regulatory pathways for this subgroup of patients may enable you to adopt a "fast-to-market" strategy.
8. Revise your summary risk factors to highlight the following risks:
- From pages 73 and 90, the risks that your operations may be subject to the negative list, as [t]he 2020 Negative List provides that foreign investment is prohibited in the development and application of human stem cell or gene diagnostic and therapeutic technologies, as you disclose on page 90. Explain that, if this category applies, Gracell Bioscience would be prohibited from engaging in the research or development of such technologies.
- The risks related to your intellectual property portfolio, including that you do not own or license any issued patents that cover any of your platforms or product candidates, as referenced on page 57, and that you are aware of third-party patents and patent applications that may be construed to cover your technology and product candidates, including GC012F and GC027, as referenced on page 60.
- The risks related to concentration of share ownership by Dr. William Wei Cao, as referenced on page 198.

9. We note from page 10 that your reporting currency is Renminbi (RMB). We note numerous amounts throughout the document that are included in currencies other than dollars. Please reflect such amounts in U.S. dollars in addition to the foreign currency.

Risk Factors
Risks Related to Our Corporate Structure
ADS holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement...., page 96

10. We note your disclosure on page 96 that indicates that the deposit agreement provides that ADS holders waive the right to a jury trial, "including claims under federal securities laws." Please amend your risk factor to disclose other risks, which may include increased costs to bring a claim. Please also clarify whether purchasers of your ADSs in a secondary transaction would be subject to the jury trial waiver provision.

Use of Proceeds, page 107

11. To the extent you do not expect the proceeds, together with existing cash, will be sufficient to fund each of the referenced trials through regulatory approval, please indicate how far in research and development the proceeds of the offering, together with your

existing cash, will allow you to proceed. Refer to Item 3.C.1 of Form 20-F.

Capitalization, page 110

12. In footnote (1) to the capitalization table, you noted that you did not include the impact of share-based compensation expense for share options which you expect to record upon the completion of this offering in your unaudited pro forma and pro forma as adjusted information. Please tell us why this compensation is not reflected as a pro-forma adjustment to your accumulated deficit in the capitalization table.

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

Loan Agreements, page 127

13. Please file the loan agreements with the Bank of China, the three loan agreements with China Construction Bank, and the loan agreement with China Merchants Bank as exhibits to your registration statement or tell us why you believe such filing is not required. Refer to Item 601(b)(10) of Regulation S-K.

Capital Expenditure, page 130

14. Revise to provide additional information regarding the property and equipment purchased. Refer to Items 4.D. and 5.B.3. of Form 20-F.

Holding Company Structure, page 131

15. Please add a risk factor discussing the regulations that require an enterprise in China to set aside at least 10% of its after-tax profit based on PRC accounting standards each year to its general reserves until its cumulative total reserve funds reaches 50% of its registered capital, and state the current percentage you have achieved.

Critical Accounting Policies, Judgments and Estimates

Research and Development Expenses, page 134

16. Please disclose the costs incurred during each period presented for each of your key research and development projects. If you do not track your research and development costs by project, please disclose that fact and explain why you do not maintain and evaluate research and development costs by project. Provide other quantitative or qualitative disclosure that provides more transparency as to the type of research and development expenses incurred (i.e. by nature or type of expense) which should reconcile to total research and development expense on the Consolidated Statements of Comprehensive Loss.

Emerging Growth Company Status, page 136

17. In this discussion of your Emerging Growth Company status, please clarify that you have elected to take advantage of such exemptions as noted on page 7.

18. In addition, please provide a risk factor explaining that this election allows you to delay adopting new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. Also disclose that as a result of this election, your financial statements may not be comparable to companies that comply with public company effective dates.

Business, page 137

19. Please revise the description of your programs to eliminate the reliance on overly technical language so investors can understand the nature of your product candidates. For example, on page 137, you state with respect to GC012F, As of the July 2020 data cutoff date, 15 of 16 evaluable r/r MM patients achieved a response, resulting in an overall response rate, or ORR, of 93.8%, with all six patients, or 100%, from the highest dose cohort achieving a sCR, which was maintained through the landmark analysis at six months after CAR-T infusion. In addition, briefly describe cytokine release syndrome and the standard of care treatment, graft versus host disease, allogeneic therapies, evaluable patients and similar technical terms. In the first graph on page 147, explain PD-1+Lag3+Tim3+ and its significance in measuring exhaustion of FasTCAR T cells, and what you mean by exhaustion.

20. In several places you address deep and durable responses, stringent complete responses, and complete responses. Please revise your document to define these terms and disclose how these responses were measured. Also revise to define Grade 1, Grade 2 and Grade 3 or higher adverse events.

21. Revise the graphic at the bottom of page 147 to increase the font and resolution so the graphics are readable.

22. Expand your disclosure of the phase 1 trials in China to indicate when each trial was conducted. Also, expand to discuss the duration of the trial, how the drug candidate was administered, who conducted and/or sponsored the trial, and all serious adverse events that were experienced, including the number of patients experiencing serious adverse events. To the extent you have not done so, disclose the number of patients enrolled and state the primary and secondary endpoints related to safety, tolerability, pharmacokinetics and dosage.

23. Under an appropriate heading, please expand your disclosure to provide the material terms of your license agreement with ProMab Biotechnologies, Inc., as referenced on page 66, and file such agreement as an exhibit or tell us why you believe such filing is not required.

Intellectual Property, page 164

24. With respect to your patent applications, please disclose the specific products, product groups and technologies to which such applications relate, whether the technology is owned or licensed, the type of patent protection you seek, and the applicable jurisdictions.

Regulation, page 167

25. You have provided disclosure with respect to regulations in the United States and China. We note on page 141 you reference leveraging your relationships in Europe as well. To the extent you intend to seek regulatory approval in Europe or other jurisdictions, please expand this section to briefly discuss the regulations and approval processes in those jurisdictions.

Management

Employment Agreements and Indemnification Agreements, page 195

26. Revise to disclose the material terms of any compensation agreement with any member of management or director that will be in effect at the time of this offering on an individual basis. Refer to Item 6.B. of Form 20-F.

Principal Shareholders, page 198

27. Please identify the natural person or persons who directly or indirectly exercise sole or shared voting and/or dispositive power with respect to the common stock held by TLS Beta Pte. Ltd. and entities affiliated with Kington. Refer to Item 7.A of Form 20-F.

Taxation, page 230

28. It is not sufficient to provide only a description of the tax law of a particular jurisdiction. Revise the discussions of each jurisdiction to clearly identify each material tax consequence, provide an opinion on each and the basis for that opinion. We note, for example, that the introduction on page 230 states it is a general summary of certain Cayman Islands, People s Republic of China and United States federal income tax consequences and, with respect to U.S. taxation, the following discussion is a summary of certain material U.S. Federal income tax considerations. Revise these statements to be clear that you are addressing the material tax consequences. Clarify who is providing the opinion with respect to the U.S. federal tax consequences. With respect to each jurisdiction, 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 as [w]e believe that we should not be considered . . . to clarify that it is the opinion of counsel, not the company by avoiding we believe. Refer to Section III.C. of Staff Legal Bulletin 19.

Notes to the Consolidated Financial Statements

9. Share-Based Compenation, page F-29

29. In your table presenting share option activity, you provide the weighted average exercise price in US$ but present the weighted-average grant date fair value in RMB. For consistency, please revise to also provide the weighted-average grant date fair value in US$.

30. Also, quantify the total unrecognized compensation cost related to:
    - the vested but not exercisable options that will be recognized upon completion of the listing; and
    - the non-vested options. In addition, disclose the weighted-average period share-based compensation that will be recognized for the non-vested options.

    Refer to ASC 718-10-50.

31. Please disclose what happens to the options granted if a listing is not achieved.

General

32. 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 Franklin 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

Office of Life