UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16 UNDER
THE SECURITIES EXCHANGE ACT OF 1934

For the month of June 2023

Commission file number: 001-39838

Gracell Biotechnologies Inc.

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People's Republic of China
(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F. Form 20-F ☒ Form 40-F ☐

INCORPORATION BY REFERENCE

This report on Form 6-K is hereby incorporated by reference in the registration statements of Gracell on Form F-3 (No. 333-264545) and Form S-8 (No. 333-253486), to the extent not superseded by documents or reports subsequently filed.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Gracell Biotechnologies Inc.

By: /s/ Yili Kevin Xie
Name: Yili Kevin Xie
Title: Chief Financial Officer

Date: June 5, 2023

Exhibit 99.1

Gracell Biotechnologies Presents Updated Data of Deep and Durable Responses for FasTCAR-T GC012F in Relapsed/Refractory Multiple Myeloma at 2023 ASCO Annual Meeting

Data on BCMA/CD19 dual-targeting FasTCAR-T GC012F showed 100% minimal residual disease (MRD) negativity and 82.8% MRD negative stringent complete response (sCR) in a predominantly high-risk relapsed/refractory multiple myeloma (RRMM) population

Data on GC012F for treatment of B-NHL will be presented on June 5 in a poster presentation at 2023 ASCO Annual Meeting

SAN DIEGO, Calif., and SUZHOU and SHANGHAI, China, June 3, 2023 -- Gracell Biotechnologies Inc. ("Gracell" or the "Company", NASDAQ: GRCL), a global clinical-stage biopharmaceutical company dedicated to developing innovative and highly efficacious cell and gene therapies for the treatment of cancer and autoimmune disease, today presented long-term follow-up data from a multicenter study evaluating GC012F, a B-cell maturation antigen (BCMA) and CD19 dual-targeted autologous CAR-T therapeutic candidate, in RRMM during an oral abstract presentation (abstract #8005) at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting.

In the single-arm, open label, multicenter investigator-initiated trial (IIT), 29 RRMM patients were enrolled and treated with GC012F, between October 2019 and January 2022, at three target dose levels of $1x10^5$, $2x10^5$, and $3x10^5$ cells/kg. Patients had a median of five prior lines of therapy (range: 2-9), with 97% (28/29) patients being triple-exposed to immunomodulatory drugs (IMiDs), proteasome inhibitor (PI) and anti-CD38 monoclonal antibody treatment. 90% (26/29) of patients were classified as high-risk based on mSMART 3.0 criteria.

As of the April 12, 2023 data cutoff date, with a median follow-up of 30.7 months (range: 14.6-43.6 months), patients treated with GC012F achieved the following:

- 93.1% (27/29) overall response rate (ORR), with 89.6% (26/29) of patients achieving a very good partial response (VGPR) or better;
- 82.8% (24/29) of patients achieved MRD- sCR;
- 100.0% (29/29) of treated patients achieved MRD negativity.

In this predominantly high-risk patient population, GC012F demonstrated durable responses:

- Median duration of response (DOR) was 37.0 months (95% CI: 11.0-NR);
- Median progression free survival (PFS) was 38.0 months (95% CI: 11.8-NR);
- Longer PFS was achieved in patients with 12-month sustained MRD negativity;
- 34% (10/29) of patients sustained MRD- sCR for more than 12 months and had an estimated PFS rate of 100% at 36 months.

GC012F continued to show a favorable safety profile:

- No new safety findings in the longer-term follow-up, including no any neurotoxicity;
- No second primary malignancies reported;
- Cytokine release syndrome (CRS) were mostly low grade (Grade 1/2: 79%). Grade 3 CRS was observed in two patients (2/29, 7%) with quick recovery after standard of care treatment. No Grade 4/5 CRS events occurred;
- No neurotoxicity or immune effector cell-associated toxicity (ICANS) of any grade was observed;

“Longer-term results for our evaluation of GC012F in patients with RRMM further demonstrate the potential of our lead candidate,” said Dr. Wendy Li, Chief Medical Officer of Gracell. “Empowered by the BCMA/CD19 dual-targeted approach and the FasTCAR-T next-day manufacturing technology, GC012F showed impressive clinical outcomes in a challenging patient population. We are highly encouraged by the depth and durability of responses shown in this study, including 93.1% ORR, 82.8% MRD- sCR, 100% MRD negativity rate and median PFS of 38 months. Notably, the patients with 12-month sustained MRD negativity demonstrated an estimated PFS of 100% at 36 months, reinforcing the clinical importance of achieving a deep response. We look forward to presenting additional results of GC012F in B-NHL at ASCO and again at the European Hematology (EHA) Congress in the coming week.”

On June 5, Gracell will also present updated results from the IIT evaluating GC012F for the treatment of B-cell non-Hodgkin's lymphoma (B-NHL) as a poster (abstract # 7562) during the Hematologic Malignancies – Lymphoma and Chronic Lymphocytic Leukemia poster abstract session at the 2023 ASCO Annual Meeting. The updated data from the ongoing IIT shows an ORR of 100% in all nine patients enrolled and treated, 100% (9/9) of which are diffuse large B-cell lymphoma (DLBCL) patients. The complete response (CR) rate was 77.8% (7/9) at Month 3 and 67.7% (6/9) at Month 6, respectively.

Additional information about the presentation and the 2023 ASCO Annual Meeting is available on the ASCO website.

About GC012F

GC012F is Gracell's FasTCAR-enabled BCMA/CD19 dual-targeting autologous CAR-T cell therapy, which aims to transform cancer and autoimmune disease treatment by driving fast, deep and durable responses with improved safety profile. GC102F is currently being evaluated in investigator-initiated trials in multiple myeloma and B-cell non-Hodgkin's lymphoma (B-NHL), and has demonstrated a consistently strong efficacy and safety profile. In February 2023, Gracell announced regulatory clearance of Investigational New Drug applications in the United States and China to commence clinical trials evaluating GC012F for the treatment of relapsed/refractory multiple myeloma. Gracell has also initiated an investigator-initiated trial evaluating GC012F for the treatment of systemic lupus erythematosus (SLE).

About FasTCAR

Introduced in 2017, FasTCAR is Gracell's revolutionary next-day autologous CAR-T cell manufacturing platform. FasTCAR is designed to lead the next generation of therapy for cancer and autoimmune diseases, and improve outcomes for patients by enhancing effect, reducing costs, and enabling more patients to access critical CAR-T treatment. FasTCAR drastically shortens cell production from weeks to overnight, potentially reducing patient wait times and probability for their disease to progress. Furthermore, FasTCAR T-cells appear younger and are more robust than traditional CAR-T cells, making them more proliferative and effective at killing cancer cells. In November 2022, FasTCAR was named the winner of the Biotech Innovation category of the 2022 Fierce Life Sciences Innovation Awards for its ability to address major industry obstacles.

About Gracell

Gracell Biotechnologies Inc. ("Gracell") is a global clinical-stage biopharmaceutical company dedicated to discovering and developing breakthrough cell therapies. Leveraging its pioneering FasTCAR and TruUCAR technology platforms and SMART CAR™ technology module, Gracell is developing a rich clinical-stage pipeline of multiple autologous and allogeneic product candidates with the potential to overcome major industry challenges that persist with conventional CAR-T therapies, including lengthy manufacturing time, suboptimal cell quality, high therapy cost, and lack of effective CAR-T therapies for solid tumors and autoimmune disease. For more information on Gracell, please visit www.gracellbio.com. Follow @GracellBio on LinkedIn.

Cautionary Noted Regarding Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements relating to the expected trading commencement and closing date of the offering. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including factors discussed in the section entitled "Risk Factors" in Gracell's most recent annual report on Form 20-F as well as discussions of potential risks, uncertainties, and other important factors in Gracell's subsequent filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Gracell specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise. Readers should not rely upon the information on this page as current or accurate after its publication date.

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