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 December 2022

Commission file number: 001-39838

Gracell Biotechnologies Inc.

Building 12, Block B, Phase II
Biobay Industrial Park
218 Sangtian St.
Suzhou Industrial Park, 215123
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 ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

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: December 16, 2022

Exhibit 99.1

Gracell Biotechnologies to Present First Clinical Data of FasTCAR-T GC012F for Newly Diagnosed Multiple Myeloma at 64th American Society of Hematology Annual Meeting & Exposition

BCMA/CD19 dual-targeting FasTCAR-T GC012F demonstrated 100% ORR and 100% MRD negativity in the 13 patients treated

SAN DIEGO, Calif. and SUZHOU and SHANGHAI, China (Nov. 3, 2022) – Gracell Biotechnologies Inc. ("Gracell" or the "Company", NASDAQ: GRCL), a global clinical-stage biopharmaceutical company dedicated to developing highly efficacious and affordable cell therapies for the treatment of cancer, today announced the first clinical data of its ongoing Phase 1, investigator-initiated study in China evaluating FasTCAR-enabled GC012F in newly diagnosed, transplant-eligible, high-risk multiple myeloma (NDMM) patients. The findings will be presented during an oral session at the 64th American Society of Hematology (ASH) Annual Meeting & Exposition, at 5:15pm CT on Dec. 10, 2022, in New Orleans, Louisiana.

GC012F is an autologous CAR-T therapeutic candidate dual-targeting B cell maturation antigen (BCMA) and CD19 and is developed using Gracell's proprietary FasTCAR next-day manufacturing platform.

As of the ASH abstract data cutoff date July 25, 2022, 13 transplant-eligible, NDMM patients had received GC012F infusion. All patients had one or more high-risk features. After receiving a conditioning chemotherapy of cyclophosphamide and fludarabine, patients were treated with GC012F as a single infusion of one of three dose levels: $1x10^5$ cells/kg (DL1), $2x10^5$ cells/kg (DL2) and $3x10^5$ cells/kg (DL3).

The study is ongoing. As of the ASH abstract data cutoff date, among the 13 efficacy-evaluable patients with a median follow-up time of 5.3 months (range 2.3-12.5 months):

- Overall response rate was 100%
- 69% of patients had achieved stringent complete response (sCR). Patients continue to be followed for deepening responses
- All patients had achieved minimal residual disease (MRD) negativity
- In the MRD assessment with EuroFlow for landmark analysis at month 1 and month 6, all evaluable patients were MRD negative at both timepoints
- All patients had experienced robust CAR-T cell expansion

The preliminary clinical data is also demonstrating an excellent safety profile:

- Only 23% (3/13) patients experienced Grade 1-2 cytokine release syndrome (CRS)
- No Grade 3 or higher CRS, and no immune effector cell-associated neurotoxicity syndrome (ICANS) of any grade had been observed

Presentation details:

- **Abstract title:** Phase I Open-Label Single-Arm Study of BCMA/CD19 Dual-Targeting FasTCAR-T Cells (GC012F) As First-Line Therapy for Transplant-Eligible Newly Diagnosed High-Risk Multiple Myeloma

- **Abstract ID:** 162295
- **Session Name:** 704. Cellular Immunotherapies: Early Phase and Investigational Therapies: CAR T in Multiple Myeloma and T-cell Therapies After Allo-HCT
- Session Date: Saturday, Dec. 10, 2022 from 4-5:30 p.m. CT
- **Presentation Time:** 5:15 p.m. CT
- **Location:** Ernest N. Morial Convention Center, Great Hall A/D

The abstract is now available online on the ASH website.

“We are excited to present the first clinical data evaluating GC012F as a first-line therapy for multiple myeloma at ASH 2022, a premier gathering of leading minds in hematology and oncology from around the world. We are thrilled to report that BCMA/CD19 dual targeting FasTCAR-T GC012F is showing a very favorable safety profile and encouraging efficacy in newly-diagnosed multiple myeloma patients," said Dr. Wendy Li, Gracell’s Chief Medical Officer. “We believe the data further validates our proprietary FasTCAR next-day manufacturing platform and the potential of GC012F in treatment for multiple myeloma. Treating newly diagnosed patients will be a new frontier for CAR-T, and we are committed to bringing paradigm-shifting innovation to patients in need.”

About GC012F

GC012F is a FasTCAR-enabled BCMA/CD19 dual-targeting CAR-T product candidate that is currently being evaluated in IIT studies in China for the treatment of multiple myeloma and B-cell non-Hodgkin's lymphoma. GC012F simultaneously targets CD19 and BCMA to drive fast, deep and durable responses, which can potentially improve efficacy and reduce relapse in multiple myeloma and B-NHL patients.

About FasTCAR

CAR-T cells manufactured on Gracell's proprietary FasTCAR platform appear younger, less exhausted and show enhanced proliferation, persistence, bone marrow migration and tumor cell clearance activities as demonstrated in preclinical studies. With next-day manufacturing, FasTCAR is able to significantly improve cell production efficiency which may result in meaningful cost savings, and, together with fast release time, enables enhanced accessibility of cell therapies for cancer patients.

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 CART^{TM} 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. 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. 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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