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 April 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: April 11, 2022

Exhibit 99.1

PRESS RELEASE

Gracell Biotechnologies to Present Data at AACR Annual Meeting 2022 Showcasing Early First-in-Human Results for GC502 in r/r B-ALL

Allogeneic, off-the-shelf CAR-T therapy with CD19/CD7 dual-directed CAR shows promising early results in patients with r/r B-ALL

PALO ALTO, Calif. and SUZHOU, China (April 8, 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 early results of a first-in-human clinical study of GC502, an allogeneic CD19/CD7 dual-directed chimeric antigen receptor (CAR) T cell therapy for the treatment of relapsed/refractory B-cell acute lymphoblastic leukemia (r/r B-ALL). Gracell will share the data in a poster presentation at the American Association for Cancer Research (AACR) Annual Meeting 2022 on April 12.

GC502 leverages the novel dual-directed CAR design of Gracell's proprietary TruUCAR platform, designed to generate high-quality allogeneic CAR-T cell therapies that can be administered "off-the-shelf" at lower cost and with faster patient's access. TruUCAR-enabled GC502 utilizes the dual-directed CAR design with one CAR targeting CD19 on malignant cells and a second CAR targeting CD7 to suppress host-versus-graft rejection. An enhancer molecule is embedded in the basic construct of TruUCAR to enhance proliferation of TruUCAR T cells.

"We are very excited to present our data on GC502 at this year's AACR annual meeting. CD19 is a validated target in the treatment of r/r B-ALL," said Dr. Martina Sersch, Chief Medical Officer of Gracell. "As an allogeneic, off-the-shelf CAR-T therapy, GC502 has the potential to provide patients who may not be eligible for autologous CAR-T therapy with hope to achieve a deep response. The early results show the potential of GC502 and warrant further evaluation in the ongoing clinical investigator-initiated-trial (IIT). Being the second product candidate from our allogeneic TruUCAR platform, GC502 further validates TruUCAR's platform approach and potential wide applicability."

Between September 2021 and January 2022, four r/r B-ALL patients were enrolled and treated in an open-label, non-randomized, prospective IIT study in China in two different dose levels and with two different formulations. Patients were heavily pretreated, and all had previously received either autologous or donor derived CD19 or CD19/CD22 targeted CAR-T therapy. As of the January 28, 2022 data cutoff date, all four patients had received a single dose of GC502, including one patient at dose level 1 (DL1) $1.0x10^7$ cells/kg and three patients at dose level 2 (DL2) $1.5x10^7$ cells/kg. Patients received a Flu/Cy based lymphodepletion regimen prior to treatment with GC502.

As highlighted in the AACR poster, three out of four patients achieved minimal residual disease negative complete response or complete response with incomplete count recovery (MRD- CR/CRi), and one patient achieved a partial response at month one and subsequently received allogeneic hematopoietic stem-cell transplantation (allo-HSCT) on day 39.

Cytokine release syndrome (CRS) presented as Grade 2 and Grade 3 with no Grade 4 or 5 events. No immune effector cell-associated neurotoxicity syndrome (ICANS) or acute graft-versus-host disease (aGvHD) were observed.

For more information on the ongoing trial, refer to the ClinicalTrials.gov Identifier: NCT05105867.

Details of the presentation are as follows:

- **Presentation Title:** Early results of a safety and efficacy study of allogeneic TruUCAR GC502 in patients with relapsed/refractory B-cell acute lymphoblastic leukemia (r/r B-ALL)
- **Session Title:** Phase I Clinical Trials 2
- **Session Date and Time:** Tuesday, April 12, from 9:00AM – 12:30PM CT
- **Location:** New Orleans Convention Center, Exhibit Halls D-H, Poster Section 33
- **Poster Board Number:** 21
- **Permanent Abstract Number:** CT196

Additional meeting information is available on the AACR website. The full text of the abstract is available on the AACR Online Itinerary Planner and the e-poster is viewable to registered attendees on the AACR's e-poster website through Wednesday, July 13, 2022.

About GC502

GC502 is a TruUCAR-enabled CD19/CD7 dual-directed, off-the-shelf allogeneic CAR-T product candidate that is being studied in an ongoing Phase 1 IIT in China for the treatment of B-cell malignancies. GC502 is manufactured using T cells from non-human leukocyte antigen (HLA) matched healthy donors. An enhancer molecule is embedded in the basic construct of TruUCAR to enhance proliferation of TruUCAR T cells. Optimized for CD19/CD7 dual-CAR functionality and *in vivo* durability, GC502 has demonstrated robust anti-tumor effects with potential to suppress host versus graft (HvG) rejection in preclinical models.

About B-ALL

Acute lymphoblastic leukemia (ALL) is a type of blood cancer characterized by proliferation of immature lymphocytes in the bone marrow, which can involve either T lymphocytes (T-ALL), or B lymphocytes (B-ALL). Globally, approximately 64,000 patients are diagnosed with ALL every year with an estimated 6,660 new cases to be diagnosed in the United States in 2022[1]. B-ALL accounts for 75% of ALL diagnoses in adults.

About TruUCAR

TruUCAR is Gracell's proprietary technology platform and is designed to generate high-quality allogeneic CAR-T cell therapies that can be administered "off-the-shelf" at lower cost and with greater convenience. With differentiated design enabled by gene editing, TruUCAR is designed to control host versus graft rejection (HvG) as well as graft versus host disease (GvHD) without the need for being co-administered with additional immunosuppressive drugs after standard lymphodepletion. The novel dual-CAR design allows tumor antigen-CAR moiety to target malignant cells, while the CD7 CAR moiety is designed to suppress HvG response.

1 Data source: American Cancer Society

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™ technology modules, 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 production 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. 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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