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 October 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: October 18, 2022

Exhibit 99.1

Gracell Biotechnologies Doses First Patient in Phase 2 Portion of Registrational Phase 1/2 Clinical Trial Evaluating GC007g for Treatment of B-cell Acute Lymphoblastic Leukemia

Clinical trial assessing allogeneic, HLA-matched, donor-derived allogeneic CAR-T therapy

SAN DIEGO, Calif. and SUZHOU and SHANGHAI, China (October 17, 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 that the first patient has been dosed in the Phase 2 portion of its registrational Phase 1/2 clinical trial evaluating GC007g for the treatment of Relapsed/Refractory B-cell Acute Lymphoblastic Leukemia (r/r B-ALL) being conducted in China.

GC007g is Gracell's allogeneic, human leukocyte antigen (HLA)-matched, donor-derived, CD19-directed CAR-T cell therapy candidate under development for the treatment of a subset of B-ALL patients who relapsed after allogeneic human stem cell transplant (allo-HSCT). This donor-derived CAR-T approach has been designed for r/r B-ALL patients who may not be eligible for autologous CAR-T therapy due to poor cell fitness, infections, and other unsuitable conditions.

Data from the Phase 1 trial showed encouraging efficacy and a favorable safety profile. The registrational Phase 2 trial is being conducted in China and will further assess the safety and efficacy of GC007g in r/r B-ALL patients at the recommended Phase 2 dose.

"B-ALL patients that relapse after allo-HSCT therapy often face poor prognoses, and remain a patient population with a clear unmet medical need. Donor-derived CAR-T therapy could provide a new option to some of these patients who might be ineligible for other treatments including autologous CAR-T therapy," said Dr. Wendy Li, Chief Medical Officer of Gracell. "We believe GC007g is a potential first-in-class donor-derived allogeneic CAR-T therapy in China. GC007g is also Gracell's first therapeutic candidate to enter a registrational trial, marking an important milestone in our quest to transform cell therapy."

About GC007g

GC007g is an allogeneic CD19-targeted CAR-T cell therapy, derived from HLA-matched donors, under development for the treatment of r/r B-ALL patients who failed transplant and may not be eligible for autologous CAR-T therapy.

About 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.

[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^{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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