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 November 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: November 16, 2022

Exhibit 99.1

Gracell Biotechnologies Wins
2022 Fierce Life Sciences Innovation Award

FasTCAR next-day manufacturing autologous CAR-T platform recognized with prestigious biotech innovation award

SAN DIEGO, Calif. and SUZHOU and SHANGHAI, China (Nov. 15, 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 its FasTCAR Autologous CAR-T Platform was named the winner of the Biotech Innovation category of the 2022 Fierce Life Sciences Innovation Awards.

FasTCAR enables next-day manufacturing for autologous CAR-T and aims to address major obstacles to effective and accessible cell therapy. By cutting the manufacturing time from weeks to overnight, the FasTCAR platform could potentially revolutionize several key aspects of the CAR-T logistics and treatment paradigm, including bringing therapies to patients more quickly, reducing costs, and providing T cells with enhanced quality that could lead to better outcomes.

Gracell's lead FasTCAR candidate, GC012F, is a CAR-T cell therapy dual-targeting B-cell maturation antigen (BCMA) and CD19. It is currently being studied in multiple investigator-initiated trials evaluating its safety and efficacy in relapsed/refractory multiple myeloma (RRMM), newly-diagnosed multiple myeloma (NDMM), and B-cell non-Hodgkin's lymphoma. At the European Hematology Association 2022 Hybrid Congress, Gracell presented longer-term follow-up clinical data of GC012F in RRMM that showed a 100% minimal residual disease (MRD) negativity rate in all patients treated. The first clinical data for GC012F in NDMM patients will be presented as oral session at the 64th American Society of Hematology Annual Meeting & Exposition in December 2022. As of the abstract cutoff date, GC012F has demonstrated a 100% overall response rate (ORR) and a 100% MRD negativity rate in treated patients.

The Fierce Life Sciences Innovation Awards identify and showcase outstanding innovation that is driving improvements and transforming the industry. An expert panel of judges reviews all submissions and determines which companies demonstrate innovative technologies and services that have the potential to make the greatest impact for biotech and pharma.

"We are honored that the FasTCAR next-day manufacturing platform has been recognized by the prestigious Fierce Life Sciences Innovation Awards," said Dr. Cao. "The past 12 months have been especially momentous for Gracell, as the U.S. Food and Drug Administration granted orphan drug designation to FasTCAR-enabled BCMA/CD19 dual-targeting GC012F and our clinical trials yielded very encouraging data. We owe this achievement to the entire Gracell team, and I especially hope to extend my appreciation and congratulations to key members, Mr. Jiaping He, our VP of Technology Development for the co-conception of FasTCAR platform, and Dr. Lianjun Shen, our SVP of Research and Development, for co-design and development of BCMA/CD19 dual-targeting GC012F. We founded Gracell with a mission to develop highly efficacious and affordable breakthrough cell therapies that address vast unmet needs and we look forward to further advancing our FasTCAR platform and the rich therapeutic pipeline."

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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