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 2021

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
99.2	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 6, 2021

PRESS RELEASE

Gracell Biotechnologies Signs Agreement with Lonza to Manufacture Gracell's FasTCAR Product Candidates in the U.S.

The collaboration will help Gracell leverage Lonza's worldwide integrated services and expertise in CAR-T cell therapy manufacturing

SUZHOU, China and PALO ALTO, California, March. 31, 2021 /PRNewswire/— Gracell Biotechnologies Inc. (NASDAQ:GRCL)("Gracell"), a global clinical-stage biopharmaceutical company dedicated to discovering and developing highly efficacious and affordable cell therapies for the treatment of cancer, today announced that the company has entered into a Manufacturing Service Agreement (MSA) with Lonza (SIX:LONN) for clinical manufacturing of Gracell's FasTCAR-enabled CAR-T cell product candidates in the U.S.

Gracell is advancing its innovative CAR-T pipeline globally for difficult-to-treat cancers, including its lead program for GC012F, a BCMA/CD19 dual-targeting CAR-T therapy for multiple myeloma. This autologous CAR-T product candidate is manufactured on Gracell's proprietary FasTCAR technology platform, which significantly reduces the manufacturing time from an industry norm of two to six weeks down to next day. Gracell will leverage Lonza's integrated services in CAR-T manufacturing and establish state of the art cGMP process, a critical component of Gracell's IND enabling clinical development programs.

"Gracell has developed some highly innovative CAR-T manufacturing platforms, including our FasTCAR platform enabling next day manufacturing of autologous CAR-T products. With Lonza's experience in CAR-T therapy manufacturing and excellent reputation, they are an ideal strategic collaborator for advancing our pioneering, proprietary FasTCAR platform globally," stated Dr. William Wei Cao, Chief Executive Officer of Gracell. Dr. Martina Sersch, M.D., Chief Medical Officer of Gracell, added, "We are pleased to enter into this collaboration with Lonza and are currently building our international presence, including clinical operations to advance our product candidates and bring them to more patients globally. We are hoping to expand our programs in close collaboration with Lonza's capabilities. In addition, we look forward to a strategic relationship with Lonza to support IND-filing and clinical manufacturing in the U.S."

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, increasing the 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, 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 Note 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: the clinical results of our product candidates, actions of regulatory agencies, which may affect the initiation, timing and progress of our clinical trials and marketing approval, our ability to achieve commercial success if any of our product candidates is approved, our ability to obtain and maintain protection of intellectual property for our product candidates and technology platforms, the future developments of the COVID-19 outbreaks, and other factors more fully discussed in the “Risk Factors” section of the final prospectus filed with the Securities and Exchange Commission (the “SEC”) and in any subsequent filings made by the Company with the SEC. 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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PRESS RELEASE

Gracell Biotechnologies Announces Enrollment of First Patient in Registrational Phase 1/2 Clinical Study for GC007g, an Allogeneic CAR-T Cell Therapy for the Treatment of Relapsed or Refractory B-ALL

SUZHOU and SHANGHAI, China, March 31, 2021 — Gracell Biotechnologies Inc. (NASDAQ: GRCL) ("Gracell"), a global clinical-stage biopharmaceutical company dedicated to developing highly efficacious and affordable cell therapies for the treatment of cancer, announced that they have enrolled the first patient in their pivotal Phase 1/2 clinical study of GC007g, an allogeneic donor-derived anti-CD19 chimeric antigen receptor (CAR)-T cell therapy for the treatment of B-cell acute lymphoblastic leukemia (B-ALL).

GC007g is an allogeneic HLA (human leukocyte antigen)-matched donor-derived CAR-T therapy. Gracell obtained IND approval for GC007g for the treatment of B-ALL from China's National Medical Products Administration (NMPA) and the approval for the pivotal Phase 1/2 clinical study in December 2020. The open-label, single-arm Phase 1/2 study is evaluating the safety and efficacy of GC007g in r/r B-ALL patients.

"We are thrilled to announce the enrollment of the first patient into our registrational Phase 1/2 trial for the allogeneic donor-derived CD19-targeted CAR-T therapy, GC007g, for the treatment of patients with B-ALL," said Dr. Martina Sersch, M.D., Chief Medical Officer of Gracell. "GC007g is a unique treatment approach for B-ALL patients who relapse after allogeneic stem cell transplantation and are not eligible for standard-of-care. With Gracell's innovative portfolio, we are excited to bring novel CAR-T therapies to more patients with high unmet medical need."

About GC007g

GC007g is a donor-derived CD19-directed allogeneic CAR-T cell therapy that has been studied for the treatment of r/r B-ALL in a completed investigator-initiated Phase 1 trial in China, where CAR-T cells were manufactured using T cells from an HLA-matched healthy donor.

About B-ALL

B-ALL, a major form of acute lymphoblastic leukemia (ALL), is one of the most common forms of cancer in children between the ages of two and five and adults over the age of 50.[1] In 2015, ALL affected around 837,000 people globally and resulted in 110,000 deaths worldwide.[2] It is also the most common cause of cancer and death from cancer among children.

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1 https://www.cancer.org/cancer/acute-lymphocytic-leukemia/about/key-statistics.html
2 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5055577/