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 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

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 22, 2021

PRESS RELEASE

Gracell Biotechnologies Granted FDA Orphan Drug Designation for FasTCAR-enabled BCMA/CD19 Dual-targeting CAR-T Cell Therapy Candidate GC012F for the Treatment of Multiple Myeloma

SUZHOU and SHANGHAI, China, and PALO ALTO, Calif., Nov. 19, 2021 /PRNewswire/ — 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, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for GC012F, Gracell's FasTCAR-enabled BCMA/CD19 dual-targeting CAR-T cell therapy for the treatment of multiple myeloma.

"As our lead candidate currently being developed on Gracell's FasTCAR next-day manufacturing technology platform, GC012F is a unique BCMA and CD19 dual-targeting CAR-T cell therapy," commented Dr. Martina Sersch, Chief Medical Officer of Gracell. "GC012F has demonstrated fast, deep and durable responses in patients with Relapsed/Refractory Multiple Myeloma in an ongoing IIT study in China with most patients on study being high risk according to mSMART 3.0 criteria, a difficult-to-treat patient population. We are very excited about being granted Orphan Drug Designation for the treatment of Multiple Myeloma by the U.S. FDA, another key milestone in advancing our program globally. Multiple Myeloma patients are in need of more efficacious and tolerable therapies providing deep and durable responses and ultimately extending progression free and overall survival."

The long-term follow-up data for GC012F was presented in June at the ASCO 2021 Annual Meeting and the EHA 2021 Congress. GC012F is currently being evaluated in investigator-initiated trials in China, including in newly diagnosed Multiple Myeloma patients. The tech transfer to Lonza to support manufacturing of GC012F in the U.S. is currently ongoing, with U.S. IND filing targeting the first half of 2022.

Granted by the U.S. FDA, Orphan Drug Designation incentivizes the development of innovative drugs and biologics for the safe and effective treatment of rare diseases and conditions that affect fewer than 200,000 people in the U.S. Orphan Drug Designation qualifies the sponsor of the therapy for certain development incentives, including up to seven years of market exclusivity upon regulatory approval, as well as tax credits for clinical testing and reduction of or exemption from prescription drug user fees.

About Multiple Myeloma

Multiple myeloma (MM) is the third most common type of blood cancer in the United States, originating from plasma cells, a type of immune cell that is typically responsible for secreting antibodies to fight infection. Globally, approximately 160,000 patients are diagnosed with MM every year with over 32,000 expected to be diagnosed in the United States in 2020. In recent years, many advances have been made to treat MM, however, the disease is still considered incurable.

Multiple myeloma patients with certain cytogenetic and other abnormalities are classified by the International Myeloma Working Group (IMWG) and Mayo Stratification for Myeloma and Risk-Adapted Therapy (mSMART) criteria as high-risk patients. They represent 20-30% of the overall MM patient population. High-risk patients have a much higher risk of early relapse and shorter progression free and overall survival. These patients are considered the most difficult-to-treat MM patients, typically with a poor prognosis.

About GC012F

GC012F is a FasTCAR-enabled dual-targeting CAR-T product candidate that is currently being studied in an ongoing investigator-initiated Phase 1 trial across multiple centers in China for the treatment of MM. GC012F tackles MM by simultaneously targeting both malignant plasma cells expressing BCMA and early progenitor cells expressing CD19 in order to drive fast, deep and durable responses in MM 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, 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 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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