
**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 May 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: May 17, 2022

PRESS RELEASE



**Gracell Biotechnologies Reports First Quarter 2022 Unaudited Financial Results
and Provides Corporate Update**

- *Presented early clinical data from a first-in-human Phase 1 investigator-initiated trial (IIT) of allogeneic TruUCAR candidate GC502 for relapsed/refractory B-cell acute lymphoblastic leukemia (r/r B-ALL) at AACR 2022; updated data to be presented at EHA 2022*
- *Oral presentation to highlight longer-term follow-up data from an IIT evaluating GC012F for relapsed/refractory multiple myeloma (RRMM) at ASCO 2022 and EHA 2022*
- *Plan to present initial data from an ongoing IIT evaluating GC012F for relapsed/refractory B-cell Non-Hodgkin's lymphomas (r/r B-NHL) at EHA 2022*
- *Plan to file IND for GC012F for RRMM with US FDA and China CDE during the second half 2022*
- *Well-funded with cash runway into 2024*
- *Management to host conference call at 8:00 a.m. ET today*

SAN DIEGO, Calif. and SUZHOU and SHANGHAI, China, May 16, 2022 – Gracell Biotechnologies Inc. (NASDAQ: GRCL) (“Gracell” or “Company”), a global clinical-stage biopharmaceutical company dedicated to discovering and developing highly efficacious and affordable cell therapies for the treatment of cancer, today reported first quarter unaudited financial results for the three months ended March 31, 2022, and provided corporate updates.

“We were very encouraged about our early results from a first-in-human IIT study of our allogeneic TruUCAR candidate GC502 in patients with relapsed/refractory B-ALL, which we presented at AACR in early April. After a single infusion of the CD19/CD7 dual-directed off-the-shelf allogeneic CAR-T therapy GC502, three out of four patients achieved MRD- CR/CRi, and patients continue to be followed for ongoing response assessment,” said Dr. William (Wei) Cao, founder, Chairman, and CEO of Gracell. “We are dedicated to advancing our rich clinical pipeline with multiple IIT proof-of-concept trials as well as two IND-approved studies underway. We look forward to the upcoming oral and poster presentations at ASCO 2022 and EHA 2022, highlighting the clinical data for our BCMA/CD19 dual-targeting CAR-T candidate GC012F in two indications of RRMM and B-NHL, and allogeneic CAR-T candidate GC502 in B-ALL.”

Pipeline Highlights

FasTCAR Platform: Next-day manufacturing for autologous CAR-T cell therapy

GC012F: autologous CAR-T therapeutic candidate dual-targeting B cell maturation antigen (BCMA) and CD19, currently being evaluated for the treatment of RRMM and B-NHL.

- Updated clinical data from an IIT evaluating GC012F for the treatment of RRMM selected for oral abstract presentation on June 5 at 2022 American Society of Clinical Oncology Annual Meeting (ASCO 2022) and on June 12 at European Hematology Association 2022 Congress (EHA 2022).
- Plan to present Initial data from an ongoing IIT evaluating GC012F for the treatment of r/r B-NHL as a poster presentation on June 10 at EHA 2022.
- Plan to submit the U.S. and China IND filings for RRMM in the second half of 2022.

TruUCAR Platform: Novel designs enabling “off-the-shelf” allogeneic CAR-T therapy

GC502: TruUCAR-enabled CD19/CD7 dual-directed allogeneic CAR-T cell therapy being studied in an ongoing Phase 1 IIT in China for the treatment of B-cell malignancies. GC502 is manufactured from T cells of non-HLA (human leukocyte antigen) matched healthy donors.

- First-in-human data from China IIT study in B-ALL patients were presented at AACR on April 12, 2022. As of the January 28, 2022 data cutoff date, four patients enrolled had received a single dose of GC502, including one patient at dose level 1 (DL1) 1.0×10^7 cells/kg and three patients at dose level 2 (DL2) 1.5×10^7 cells/kg. 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. In two different formulation groups, safety profile appeared to be manageable and feasible.
- Plan to present updated data with longer follow-up of GC502 in B-ALL on June 10 at EHA 2022.

GC027: TruUCAR-enabled CD7-targeted allogeneic CAR-T cell therapy for the treatment of T cell acute lymphoblastic leukemia (T-ALL).

- Target to have regulatory interactions globally and in China in the next 12 months.

SMART CARTTM Technology: With unique construct to take advantage of the suppressive tumor microenvironment (TME) and effectively combat solid tumors, SMART CARTTM is designed to enhance CAR-T cell proliferation and duration of killing, and to resist exhaustion with improved persistence of CAR-T cells.

- On track to commence patient enrollment in a China IIT for GC503 in mesothelin-positive solid tumors in 2022.
- Plan to commence a China IIT for GC506 in CLDN18.2-positive solid tumors.

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

- Registrational Phase 1/2 clinical trial under a China IND is ongoing for the treatment of r/r B-ALL. Enrolling patients in the second dosing cohort prior to entering the Phase 2 part of the seamless-design study.

Corporate Highlights

- Opened the Company's R&D Center in San Diego, Calif., during the first quarter of 2022.

Financial Results for the First Quarter Ended March 31, 2022

As of March 31, 2022, the Company had RMB1,694.7 million (US\$267.3 million) in cash and cash equivalents and short-term investments. In addition, the Company had short-term borrowings and current portion of long-term borrowings of RMB88.4 million (US\$13.9 million) and long-term borrowings of RMB54.3 million (US\$8.6 million).

Net loss attributable to ordinary shareholders for the three months ended March 31, 2022 was RMB158.6 million (US\$25.0 million), compared to RMB99.7 million for the corresponding prior year period.

Research and Development Expenses

Research and development expenses for the three months ended March 31, 2022 were RMB121.8 million (US\$19.2 million), compared to RMB65.4 million in the corresponding prior year period. The increase was primarily due to the increased spending on research, development, and clinical trials, as well as higher payroll and personnel expenses attributable to increased headcount, and higher facility-related costs.

Administrative Expenses

Administrative expenses for the three months ended March 31, 2022 were RMB37.9 million (US\$6.0 million), compared to RMB31.8 million for the corresponding prior year period. The increase was primarily driven by an increase in professional service as well as an increase in payroll and personnel expenses due to the expansion of administrative functions.

As of March 31, 2022, 338,023,356 ordinary shares, par value of US\$0.0001 per share, were issued and outstanding. As of March 31, 2022, 16,682,761 options were granted and 14,999,857 options were outstanding, and 1,974,391 restricted share units ("RSUs") were granted under our employee stock option plan. Each of our ADS represents five ordinary shares.

Interest income for the three months ended March 31, 2022 was RMB2.5 million (US\$0.4 million), compared to RMB0.9 million for the corresponding prior year period. Other income for the three months ended March 31, 2022 was RMB0.1 million (US\$0.02 million), compared to RMB0.1 million for the corresponding prior year period.

Conference Call and Webcast Details:

Monday, May 16, 2022 @ 8:00 a.m. ET

Investor domestic dial-in: 833-693-0545

Investor international dial-in: +1 661-407-1586

Conference ID: 2093503

Live webcast link: <https://ir.gracellbio.com/news-events/events-and-presentations>

A replay of the webcast will be available on ir.gracellbio.com shortly after the conclusion of the event for 90 days.

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 turnaround time, it enables enhanced accessibility of cell therapies for cancer patients.

About TruUCAR

TruUCAR is Gracell's proprietary technology platform and is designed to generate CAR-T cell therapies from high quality allogeneic T cells that can be administered "off-the-shelf" at lower cost and with improved accessibility of cell therapies for cancer patients. With differentiated design enabled by gene editing of unique genes, TruUCAR is designed to control host vs graft rejection (HvG) as well as graft vs host disease (GvHD) without the need of being co-administered with additional strong immunosuppressant after conventional lymphodepletion. The novel dual-CAR design allows tumor antigen-CAR moiety to target malignant cells, while the CD7 CAR moiety is designed to suppress rejection of allogeneic CAR-T cells by host T and NK cells (HvG).

About SMART CART™

SMART CART™ is Gracell's proprietary technology module designed to strengthen the functionality of CAR-T cells further, and aims to overcome tumor microenvironment (TME). SMART CART™ includes altered expression of the receptor and signaling mechanism of an inhibitory TME molecule to enhance expansion and persistence and to reduce the exhaustion of CAR T cells. This design reverses and turns immunosuppressive signals of TME into stimulatory reactions of CAR-T cells. SMART CART™ technology can be applied to many targets for the treatment of solid tumors.

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 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

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Exchange Rate Information

This announcement contains translations of certain RMB amounts into U.S. dollars at a specified rate solely for the convenience of the reader. Unless otherwise noted, all translations from Renminbi to U.S. dollars are made at a rate of RMB 6.3393 to US\$1.00, the rate in effect as of March 31, 2022 published by the Federal Reserve Board.

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. These statements include, but are not limited to, statements relating to the offering’s expected trading commencement and closing date. The words “anticipate,” “look forward to,” “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. Gracell specifically disclaims any obligation to update any forward-looking statement, whether due to 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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Unaudited Condensed Consolidated Balance Sheets
(All amounts in thousands, except for share and per share data)

	As of December 31, 2021 RMB	As of March 31, 2022 RMB US\$	
ASSETS			
Current assets:			
Cash and cash equivalents	1,829,006	1,621,119	255,725
Short-term investments	3,615	73,580	11,607
Prepayments and other current assets	52,459	66,603	10,506
Total current assets	1,885,080	1,761,302	277,838
Property, equipment and software	123,818	118,536	18,699
Operating lease right-of-use assets	29,652	25,548	4,030
Other non-current assets	21,587	27,855	4,394
TOTAL ASSETS	2,060,137	1,933,241	304,961
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities:			
Short-term borrowings	66,100	86,000	13,566
Operating lease liabilities, current	17,527	16,596	2,618
Current portion of long-term borrowings	2,376	2,376	376
Amounts due to related parties	—	4,579	722
Accruals and other current liabilities	69,120	77,571	12,236
Total current liabilities	155,123	187,122	29,518
Long-term borrowings	54,349	54,349	8,573
Operating lease liabilities, non-current	14,830	11,568	1,825
Other non-current liabilities	8,464	7,677	1,211
TOTAL LIABILITIES	232,766	260,716	41,127
Commitments and contingencies			
Shareholders' equity:			
Ordinary shares	223	223	35
Additional paid-in capital	2,902,856	2,913,030	459,519
Accumulated other comprehensive loss	(57,936)	(64,373)	(10,155)
Accumulated deficit	(1,017,772)	(1,176,355)	(185,565)
Total shareholders' equity	1,827,371	1,672,525	263,834
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	2,060,137	1,933,241	304,961

Unaudited Condensed Consolidated Statements of Comprehensive Loss

(All amounts in thousands, except for share and per share data)

	For the three months ended March 31,		
	2021	2022	
	RMB	RMB	US\$
Expenses			
Research and development expenses	(65,433)	(121,837)	(19,219)
Administrative expenses	(31,759)	(37,890)	(5,977)
Loss from operations	(97,192)	(159,727)	(25,196)
Interest income	932	2,496	394
Interest expense	(1,235)	(1,425)	(225)
Other income	128	143	23
Foreign exchange loss, net	(298)	(71)	(11)
Others, net	—	1	—
Loss before income tax	(97,665)	(158,583)	(25,015)
Income tax expense	—	—	—
Net loss	(97,665)	(158,583)	(25,015)
Accretion of convertible redeemable preferred shares to redemption value	(1,989)	—	—
Net loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	(99,654)	(158,583)	(25,015)
Other comprehensive income			
Foreign currency translation adjustments, net of nil tax	23,629	(6,437)	(1,015)
Total comprehensive loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	(76,025)	(165,020)	(26,030)
Weighted average number of ordinary shares used in per share calculation:			
—Basic	304,488,419	338,131,447	338,131,447
—Diluted	304,488,419	338,131,447	338,131,447
Net loss per share attributable to Gracell Biotechnologies Inc.'s ordinary shareholders			
—Basic	(0.33)	(0.47)	(0.07)
—Diluted	(0.33)	(0.47)	(0.07)