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 2023

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 16, 2023

Exhibit 99.1

PRESS RELEASE

Gracell Biotechnologies Reports First Quarter 2023 Unaudited Financial Results, and Provides Corporate Update

- *Presenting longer-term follow-up data from investigator-initiated trial (IIT) evaluating BCMA/CD19 dual-targeting FasTCAR-T GC012F in relapsed/refractory multiple myeloma (RRMM) at 2023 ASCO and EHA2023*
- *On track to commence a Phase 1b/2 clinical trial in U.S. and a Phase 1/2 clinical trial in China evaluating GC012F for the treatment of RRMM in the second quarter and third quarter of 2023, respectively*
- *Launched the new IIT evaluating GC012F in systemic lupus erythematosus (SLE)*
- *Presenting updated data from the ongoing IIT evaluating GC012F in relapsed/refractory B-cell non-Hodgkin lymphoma (r/r B-NHL) at 2023 ASCO and EHA2023*
- *Presenting the Phase 1 clinical data of donor-derived allogeneic CAR-T GC007g in relapsed/refractory B-cell acute lymphoblastic leukemia (r/r B-ALL) at EHA2023*
- *Hosting KOL call on May 22 at 9:00 am ET to highlight unmet clinical need for RRMM in U.S.*
- *Well-funded with cash runway to the end of 2024*
- *Management to host conference call at 8:00 a.m. ET today*

SAN DIEGO, Calif. and SUZHOU and SHANGHAI, China, May 15, 2023 – Gracell Biotechnologies Inc. (NASDAQ: GRCL) ("Gracell" or the "Company"), a global clinical-stage biopharmaceutical company dedicated to discovering and developing highly efficacious and affordable cell therapies for the treatment of cancer and autoimmune diseases, today reported first quarter unaudited financial results for the period ended March 31, 2023, and provided corporate updates.

"We continue to focus our efforts on the advancement of our lead candidate GC012F, a FasTCAR-enabled autologous CAR-T therapy candidate dual-targeting B cell maturation antigen (BCMA) and CD19. We look forward to showcasing the updated clinical data of GC012F in two indications RRMM and r/r B-NHL at both 2023 ASCO and EHA2023, including in two oral presentations. We are on track to initiate the U.S. IND trial for GC012F in RRMM in the second quarter of 2023," said Dr. William (Wei) Cao, founder, Chairman and CEO of Gracell. "We are also pleased to present the first clinical data from the Phase 1/2 clinical trial evaluating the donor-derived allogeneic CAR-T GC007g for the treatment of r/r B-ALL at EHA2023, demonstrating a 100% minimal residual disease negative complete response or complete response with incomplete count recovery (MRD- CR/CRi) in a challenging set of patients."

Dr. Cao continued, "We are excited to announce our strategic decision to pursue clinical development in systemic lupus erythematosus (SLE) for GC012F. We believe the FasTCAR-T GC012F is well positioned as an ideal candidate for a wide range of autoimmune indications, given its CD19/BCMA dual-targeting capability, consistently favorable safety profile demonstrated in the over 50 patients treated across three IITs, and the proprietary FasTCAR manufacturing technology. We recently commenced an IIT in China in refractory SLE patients and plan to file IND in U.S. and China subsequently."

Pipeline Updates

FasTCAR Platform: Next-day manufacturing for autologous CAR-T cell therapy with enhanced cell fitness.

GC012F: FasTCAR-enabled autologous CAR-T therapy candidate dual-targeting BCMA and CD19, currently being evaluated for the treatment of RRMM, newly-diagnosed multiple myeloma (NDMM) and B-NHL.

- Longer term follow-up from a multicenter IIT evaluating GC012F for the treatment of RRMM in heavily pretreated, mostly high-risk patients will be presented as oral presentation at 2023 American Society of Clinical Oncology Annual Meeting (2023 ASCO) and as poster presentation at European Hematology Association 2023 Congress (EHA2023).

- Company-sponsored Phase 1b/2 clinical trial in U.S. (NCT05850234) evaluating GC012F in RRMM on track to initiate in the second quarter of 2023.

- Company-sponsored Phase 1/2 clinical trial in China evaluating GC012F in RRMM expected to initiate in the third quarter of 2023.

- Follow-up continued in the ongoing IIT evaluating GC012F in NDMM.
  - The first clinical data presented at ASH 2022 demonstrated that one single infusion of GC012F achieved a 100% overall response rate (ORR) and 100% minimal residual disease (MRD) negativity in 16 newly-diagnosed, high risk, transplant eligible patients across all dose levels. 75% of the treated patients did not experience any cytokine release syndrome.
  - On track to share updated clinical data in 2023.

- Enrollment and follow-up continued in the IIT in China evaluating GC012F in r/r B-NHL.
  - Updated data to be presented as oral presentation at EHA2023 and as poster presentation at 2023 ASCO.

- Initiated a new IIT evaluating GC012F in refractory SLE.

GC007g for the treatment of B-ALL: Allogeneic CD19-targeted CAR-T cell therapy, derived from human leukocyte antigen (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.

- Phase 1 data to be presented at EHA2023 in a poster presentation.
  - Between March 2021 and May 2022, nine r/r B-ALL patients were enrolled and treated in the Phase 1 portion of the registrational Phase 1/2 clinical trial at two different dose levels.
  - At day 28 after infusion, 100% patients achieved MRD- CR/CRi.
  - With a median follow-up duration of 445 days (range 218-649 days), seven of nine (78%) patients remained in CR/CRi.
- Phase 2 portion of the registration Phase 1/2 clinical trial in China is ongoing.

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

GC502: CD19/CD7 dual-directed allogeneic CAR-T cell therapy candidate being studied in a Phase 1 IIT in China for the treatment of B-cell malignancies. GC502 is manufactured from T cells of non-HLA-matched healthy donors.

- Data from an IIT evaluating GC502 in r/r B-ALL patients were presented at EHA2022. Three of four patients achieved MRD- CR/CRi at day 28 post-infusion.

SMART CART™ Technology Module*:* With unique construct to take advantage of the suppressive tumor microenvironment (TME) and effectively combat solid tumors, SMART CART™ 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 a China IIT for GC506 in Claudin18.2-positive solid tumors in the second quarter of 2023.

Financial Results for the First Quarter Ended March 31, 2023

As of March 31, 2023, the Company had RMB1,277.3 million (US$186.0 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 RMB122.4 million (US$17.8 million) and long-term borrowings of RMB41.7 million (US$6.1 million).

Net loss attributable to ordinary shareholders for the three months ended March 31, 2023 was RMB151.7 million (US$22.1 million), compared to RMB158.6 million for the corresponding prior year period.

Research and Development Expenses

Research and development expenses for the three months ended March 31, 2023 were RMB137.5 million (US$20.0 million), compared to RMB121.8 million in the corresponding prior year period. The increase was primarily due to the increased spending on research, development, and clinical trials, including license expenses with Seagen Inc.

Administrative Expenses

Administrative expenses for the three months ended March 31, 2023 were RMB29.1 million (US$4.2 million), compared to RMB37.9 million for the corresponding prior year period. The decrease was primarily driven by a decrease in professional service as well as a decrease in share-based compensation expenses.

Interest income for the three months ended March 31, 2023 was RMB14.6 million (US$2.1 million), compared to RMB2.5 million for the corresponding prior year period. Interest expense for the three months ended March 31, 2023 was RMB1.7 million (US$0.2 million), compared to RMB1.4 million for the corresponding prior year period.

As of March 31, 2023, 338,573,189 ordinary shares (excluding 24,817,479 ordinary shares issued to depositary bank as of March 31, 2023, for bulk issuance of American depository shares (ADSs) reserved for future issuances upon the exercise or vesting of awards granted under our share incentive plans), par value of US$0.0001 per share, were issued and outstanding. As of March 31, 2023, 18,927,261 options were granted and 15,049,943 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.

Conference Call and Webcast Details:
Monday, May 15, 2023 @ 8:00am ET
Investor domestic dial-in: (800) 715-9871
Investor international dial-in: (646) 307-1963
Conference ID: 2756776

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

Introduced in 2017, FasTCAR is Gracell's revolutionary next-day autologous CAR-T cell manufacturing platform. FasTCAR is designed to lead the next generation of cancer and autoimmune disease therapy and improve outcomes for patients by enhancing efficacy, reducing costs, and enabling more patients to access critical CAR-T treatment. FasTCAR drastically shortens cell production from weeks to overnight, potentially reducing patient wait times and probability for their disease to progress. Furthermore, FasTCAR T-cells appear younger and are more robust than traditional CAR-T cells, making them more proliferative and effective at killing cancer cells. In November 2022, FasTCAR was named the winner of the Biotech Innovation category of the 2022 Fierce Life Sciences Innovation Awards for its ability to address major industry obstacles.

About TruUCAR

TruUCAR is Gracell's proprietary technology platform and is designed to generate high-quality allogeneic CAR-T cell therapies that can be administered "off-the-shelf" at lower cost and with greater convenience. 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 immunosuppressive drugs.

About SMART CART^{TM}

SMART CART^{TM} 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^{TM} 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^{TM} 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^{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 and follow @GracellBio on LinkedIn.

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 6.8676 to US$1.00, the rate in effect as of March 31, 2023 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. 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 U.S. 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, 2022	As of March 31, 2023	
	RMB	RMB	US$
ASSETS			
Current assets:			
Cash and cash equivalents	1,454,645	1,273,688	185,463
Short-term investments	3,559	3,572	520
Prepayments and other current assets	37,551	47,531	6,922
Total current assets	**1,495,755**	**1,324,791**	**192,905**
Property, equipment and software, net	123,126	119,958	17,467
Operating lease right-of-use assets	21,546	17,100	2,490
Other non-current assets	15,849	11,759	1,712
TOTAL ASSETS	**1,656,276**	**1,473,608**	**214,574**
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities:			
Accruals and other current liabilities	85,991	73,630	10,721
Short-term borrowings	104,600	109,700	15,974
Operating lease liabilities, current	17,545	14,171	2,063
Amounts due to related parties	4,662	1,439	210
Current portion of long-term borrowings	7,844	12,657	1,843
Total current liabilities	**220,642**	**211,597**	**30,811**
Operating lease liabilities, non-current	6,485	4,399	641
Long-term borrowings	46,505	41,692	6,071
Other non-current liabilities	6,879	5,383	784
TOTAL LIABILITIES	**280,511**	**263,071**	**38,307**
Shareholders' equity:			
Ordinary shares	223	223	32
Additional paid-in capital	2,927,295	2,931,677	426,885
Accumulated other comprehensive income	73,528	55,646	8,103
Accumulated deficit	(1,625,281)	(1,777,009)	(258,753)
Total shareholders' equity	**1,375,765**	**1,210,537**	**176,267**
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	**1,656,276**	**1,473,608**	**214,574**

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,		
	2022	2023	
	RMB	RMB	US$
Expenses			
Research and development expenses	(121,837)	(137,506)	(20,022)
Administrative expenses	(37,890)	(29,088)	(4,236)
Loss from operations	**(159,727)**	**(166,594)**	**(24,258)**
Interest income	2,496	14,627	2,130
Interest expense	(1,425)	(1,656)	(241)
Other income	143	631	92
Foreign exchange gain/(loss), net	(71)	1,281	187
Others, net	1	(1)	—
Loss before income tax	**(158,583)**	**(151,712)**	**(22,090)**
Income tax expense	—	(16)	(2)
Net loss	**(158,583)**	**(151,728)**	**(22,092)**
Net loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	**(158,583)**	**(151,728)**	**(22,092)**
Other comprehensive loss			
Foreign currency translation adjustments, net of nil tax	(6,437)	(17,882)	(2,604)
Total comprehensive loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	**(165,020)**	**(169,610)**	**(24,696)**
Weighted average number of ordinary shares used in per share calculation:			
—Basic	338,131,447	338,552,074	338,552,074
—Diluted	338,131,447	338,552,074	338,552,074
Net loss per share attributable to Gracell Biotechnologies Inc.'s ordinary shareholders			
—Basic	(0.47)	(0.45)	(0.07)
—Diluted	(0.47)	(0.45)	(0.07)