
**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 March 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: March 14, 2023

PRESS
RELEASE



Gracell Biotechnologies Reports Fourth Quarter and Full Year 2022 Unaudited Financial Results, and Provides Corporate Update

- Plan to commence Phase 1b/2 clinical trial in US evaluating FasTCAR-T GC012F for the treatment of relapsed/refractory multiple myeloma (RRMM) in the second quarter of 2023 after receipt of FDA clearance for Investigational New Drug (IND) application in January 2023
- On track to commence Phase 1/2 clinical trial in China evaluating FasTCAR-T GC012F in RRMM in the third quarter 2023 following receipt of NMPA clearance for IND application in February 2023
- Continuing patient enrollment and follow-up in the ongoing IIT evaluating FasTCAR-T GC012F in relapsed/refractory B-Cell non-Hodgkin lymphoma (r/r B-NHL)
- On track to commence a China IIT for SMART CAR-T GC506 in Claudin18.2-positive solid tumors in first half of 2023
- 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, March 13, 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, today reported fourth quarter and full year 2022 unaudited financial results for the period ended December 31, 2022, and provided corporate updates.

“Our lead candidate GC012F, the BCMA/CD19 dual-targeting FasTCAR-T therapy, has demonstrated encouraging efficacy and differentiated safety profile in the 48 patients treated across three indications in three studies. This gives us a high level of conviction in the significant therapeutic potential of GC012F in a wide range of hematology and immunology indications. We recently received IND clearances from both the US FDA and China NMPA, and are on track to commence enrollment in these two Company-sponsored trials in RRMM in the coming months,” said Dr. William (Wei) Cao, founder, Chairman and CEO of Gracell. “Moreover, we plan to provide an important clinical data update on the response durability of GC012F in RRMM in mid-year 2023.”

Dr. Cao continued, “Concurrently, we are expanding Gracell’s clinical pipeline across our technology platforms, including initiating a China IIT for SMART CAR-T GC506 in Claudin18.2-positive solid tumors in first half of 2023.”

Pipeline Updates

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

GC012F: Autologous CAR-T therapy candidate dual-targeting B cell maturation antigen (BCMA) and CD19, currently being evaluated for the treatment of RRMM, newly-diagnosed multiple myeloma (NDMM) and r/r B-NHL.

- Company-sponsored Phase 1b/2 clinical trial in US evaluating GC012F for the treatment of RRMM on track to initiate in the second quarter 2023.
 - o Received FDA clearance for IND application in January 2023.
 - o Phase 1b portion of the trial is designed to evaluate the safety and tolerability of GC012F in two dose levels in approximately 12 patients and to determine the recommended Phase 2 dose (RP2D).
 - o In the current protocol, the Phase 2 portion is intended to evaluate the efficacy in approximately 50 patients and further characterize the safety.
- Company-sponsored Phase 1/2 clinical trial in China evaluating GC012F in RRMM expected to initiate in the third quarter 2023.
 - o Received China NMPA clearance for IND application in February 2023
 - o Phase 1 portion of the trial is designed to evaluate the safety and tolerability of GC012F in two dose levels in approximately nine patients and to determine the RP2D.
 - o In the current protocol, the Phase 2 portion is intended to evaluate the efficacy in up to 98 patients and further characterize the safety.
- Presented at ASH 2022 the first clinical data from ongoing investigator-initiated (IIT) evaluating GC012F in transplant-eligible, high risk NDMM
 - o Demonstrated a 100% overall response rate (ORR) and 100% minimal residual disease (MRD) negativity in all 16 treated patients across all dose levels. 75% of the treated patients did not experience any grade of cytokine release syndrome.
 - o Enrollment and follow-up continuing in the ongoing IIT.
- Enrollment and follow-up progressing in the IIT in China evaluating GC012F in r/r B-NHL.

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 an ongoing Phase 1 IIT in China for the treatment of B-cell malignancies. GC502 is manufactured from T cells of non-human leukocyte antigen (HLA) matched healthy donors.

- Presented at EHA 2022 the updated data from single-arm, open-label IIT with longer follow-up of GC502 in B-cell acute lymphoblastic leukemia (B-ALL).

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.

- Plan to commence a China IIT for GC506 in Claudin18.2-positive solid tumors in first half of 2023.
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GC007g for the treatment of B-ALL: 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.

- Phase 2 portion of the registration Phase 1/2 clinical trial in China evaluating GC007g for the treatment of r/r B-ALL is ongoing.

Financial Results for the Fourth Quarter and Full Year 2022

As of December 31, 2022, the Company had RMB1,458.2 million (US\$211.4 million) in cash and cash equivalents and short-term investments.

Net loss attributable to ordinary shareholders for the three months ended December 31, 2022 was RMB130.7 million (US\$18.9 million), compared to RMB128.6 million for the same period in 2021. Net loss attributable to ordinary shareholders for the full year ended December 31, 2022 was RMB607.5 million (US\$88.1 million), compared to RMB453.7 million for the same period in 2021.

Research and Development Expenses

Research and development expenses for the three months ended December 31, 2022 were RMB113.1 million (US\$16.4 million), as compared to RMB107.6 million for the same period in 2021. For the full year ended December 31, 2022, research and development expenses were RMB485.4 million (US\$70.4 million), compared to RMB326.9 million for the same period in 2021. 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 in support of continuing expansion of research and development activities.

Administrative Expenses

Administrative expenses for the three months ended December 31, 2022 were RMB36.2 million (US\$5.2 million), compared to RMB32.0 million for the same period in 2021. For the full year ended December 31, 2022, administrative expenses were RMB139.3 million (US\$20.2 million), compared to RMB137.0 million for the same period in 2021. The increase was primarily driven by an increase in payroll and personnel expenses due to the expansion of administrative functions.

As of December 31, 2022, 338,498,819 ordinary shares, par value of US\$0.0001 per share, were issued and outstanding. As of December 31, 2022, 18,865,761 options were granted and 15,162,546 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, March 13, 2023 @ 8 a.m. ET

Investor domestic dial-in: (800) 715-9871

Investor international dial-in: +1(646) 307-1963

Conference ID: 5617240

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, increasing the accessibility of cell therapies for cancer patients.

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™

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 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 6.8972 to US\$1.00, the rate in effect as of December 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. 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,		
	2021	2022	
	RMB	RMB	US\$
ASSETS			
Current assets:			
Cash and cash equivalents	1,829,006	1,454,645	210,904
Short-term investments	3,615	3,559	516
Prepayments and other current assets	52,459	37,551	5,443
Total current assets	1,885,080	1,495,755	216,863
Property, equipment and software, net	123,818	123,126	17,852
Operating lease right-of-use assets	29,652	21,546	3,124
Other non-current assets	21,587	15,849	2,298
TOTAL ASSETS	2,060,137	1,656,276	240,137
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities:			
Accruals and other current liabilities	69,120	85,991	12,467
Short-term borrowings	66,100	104,600	15,166
Operating lease liabilities, current	17,527	17,545	2,544
Amounts due to related parties	—	4,662	676
Current portion of long-term borrowings	2,376	7,844	1,137
Total current liabilities	155,123	220,642	31,990
Operating lease liabilities, non-current	14,830	6,485	940
Long-term borrowings	54,349	46,505	6,743
Other non-current liabilities	8,464	6,879	997
TOTAL LIABILITIES	232,766	280,511	40,670
Shareholders' equity:			
Ordinary shares	223	223	32
Additional paid-in capital	2,902,856	2,927,295	424,418
Accumulated other comprehensive income/(loss)	(57,936)	73,528	10,661
Accumulated deficit	(1,017,772)	(1,625,281)	(235,644)
Total shareholders' equity	1,827,371	1,375,765	199,467
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	2,060,137	1,656,276	240,137

Unaudited Condensed Consolidated Statements of Comprehensive Loss

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

	For the three months ended December 31,			For the years ended December 31,		
	2021	2022		2021	2022	
	RMB	RMB	US\$	RMB	RMB	US\$
Revenue						
Licensing and collaboration revenue	—	—	—	366	—	—
Expenses						
Research and development expenses	(107,582)	(113,143)	(16,404)	(326,899)	(485,388)	(70,375)
Administrative expenses	(31,998)	(36,180)	(5,246)	(137,040)	(139,270)	(20,192)
Loss from operations	(139,580)	(149,323)	(21,650)	(463,573)	(624,658)	(90,567)
Interest income	3,466	15,136	2,194	9,116	23,917	3,468
Interest expense	(1,327)	(1,791)	(260)	(5,063)	(6,737)	(977)
Other income	8,254	3,964	575	9,120	8,001	1,160
Foreign exchange gain/(loss), net	606	1,315	191	(1,297)	(8,169)	(1,184)
Others, net	(4)	27	4	(57)	159	23
Loss before income tax	(128,585)	(130,672)	(18,946)	(451,754)	(607,487)	(88,077)
Income tax expense	—	(22)	(3)	—	(22)	(3)
Net loss	(128,585)	(130,694)	(18,949)	(451,754)	(607,509)	(88,080)
Accretion of convertible redeemable preferred shares to redemption value	—	—	—	(1,989)	—	—
Net loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	(128,585)	(130,694)	(18,949)	(453,743)	(607,509)	(88,080)
Other comprehensive income/(loss)						
Foreign currency translation adjustments, net of nil tax	(30,225)	(25,183)	(3,651)	(34,024)	131,464	19,060
Total comprehensive loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	(158,810)	(155,877)	(22,600)	(487,767)	(476,045)	(69,020)
Weighted average number of ordinary shares used in per share calculation:						
—Basic	337,853,025	338,457,977	338,457,977	328,866,599	338,342,051	338,342,051
—Diluted	337,853,025	338,457,977	338,457,977	328,866,599	338,342,051	338,342,051
Net loss per share attributable to Gracell Biotechnologies Inc.'s ordinary shareholders						
—Basic	(0.38)	(0.39)	(0.06)	(1.38)	(1.80)	(0.26)
—Diluted	(0.38)	(0.39)	(0.06)	(1.38)	(1.80)	(0.26)