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 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 ☐

INCORPORATION BY REFERENCE

This report on Form 6-K is hereby incorporated by reference in the registration statements of Gracell on Form F-3 (No. 333-264545 and No. 333-274191) to the extent not superseded by documents or reports subsequently filed.

EXHIBITS

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/ Kevin Yili Xie
Name: Kevin Yili Xie
Title: Chief Financial Officer

Date: November 14, 2023

Exhibit 99.1

PRESS RELEASE

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

- *Dosed first patient in Phase 1b/2 clinical trial in the US evaluating FasTCAR-T GC012F for the treatment of relapsed/refractory multiple myeloma (RRMM)*
- *Expect to commence Phase 1/2 clinical trial in China evaluating GC012F for the treatment of RRMM in the fourth quarter 2023*
- *Presented longer-term follow-up data from an ongoing Phase 1 investigator-initiated trial (IIT) evaluating GC012F as a frontline treatment for patients with transplant-eligible, high-risk, newly diagnosed multiple myeloma (NDMM); updated data to be reported as an oral presentation at the 65th American Society of Hematology Annual Meeting & Exposition (ASH 2023)*
- *On track to submit IND filings for planned Phase 1 clinical trials in the US and China of GC012F in refractory systemic lupus erythematosus (rSLE) in 2023*
- *Anticipate to release data from the ongoing investigator-initiated trial (IIT) evaluating GC012F in rSLE in first half of 2024*
- *Presented preclinical data evaluating SMART CART™ cells in solid tumor models at Society for Immunotherapy of Cancer (SITC) 38th Annual Meeting*
- *Extended cash runway into the second half of 2026 with the completion of private placement of ordinary shares and warrants to generate $100 million upfront and up to $50 million tied to exercise of warrants*
- *Management to host conference call at 8:00 a.m. ET today*

SAN DIEGO, Calif. and SUZHOU and SHANGHAI, China, November 13, 2023 – Gracell Biotechnologies Inc. (NASDAQ: GRCL) ("Gracell" or the "Company"), a global clinical-stage biopharmaceutical company dedicated to developing innovative and highly efficacious cell therapies for the treatment of cancer and autoimmune diseases, today reported third quarter unaudited financial results for the period ended September 30, 2023, and provided corporate updates.

"We are encouraged to see the continued advancement of FasTCAR-T GC012F, our highly differentiated lead candidate. Currently, patient dosing is underway for the company-sponsored Phase 1b/2 trial in the U.S., with more sites to be activated in the near term. It was an honor to present our updated findings from the ongoing IIT trial on NDMM at the 20th International Myeloma Society Annual Meeting as we highlighted the 100% MRD- sCR rate among the 19 NDMM patients treated with GC012F, combined with a highly favorable safety profile. We look forward to presenting an update with more details at ASH 2023," commented Dr. William (Wei) Cao, founder, Chairman and CEO of Gracell.

"We are highly optimistic about CAR-T's transformative potential in treating autoimmune diseases. GC012F is ideally positioned as a game-changing candidate combining its CD19/BCMA dual-targeting capability, faster and consistent product delivery, and safety track record from 60 patients treated in several IITs. Today, we are delighted to share compelling data from translational research on the IIT patient samples, supporting the strong scientific rational of using GC012F to treat SLE. Our team is diligently focused on advancing the clinical development in rSLE, including furthering the IIT study and submitting the IND filings in the US and China this year. "

Pipeline Summary

FasTCAR-T GC012F: Autologous BCMA/CD19 dual targeting CAR-T therapy candidate utilizing FasTCAR next-day manufacturing to shorten patient wait times and enhance cell fitness

FasTCAR-T GC012F in relapsed refractory multiple myeloma (RRMM):

- Company-sponsored Phase 1b/2 clinical trial in the US (NCT05850234) evaluating GC012F in RRMM underway
  - Dosed first patient in Phase 1b portion of the open-label multi-center trial

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

FasTCAR-T GC012F in newly diagnosed multiple myeloma (NDMM):

- Presented longer-term follow-up data from an ongoing Phase 1 IIT at the 20th International Myeloma Society (IMS) Annual Meeting
  - Among 19 transplant-eligible, high-risk NDMM patients, GC012F demonstrated a 100% overall response rate (ORR) and a 100% minimal residual disease negative stringent complete response (MRD- sCR) rate as of the data cutoff date of August 1, 2023

- Updated results from this study, including longer follow-up and additional patients, to be presented at 65th ASH Annual Meeting & Exposition as an oral presentation

FasTCAR-T GC012F in refractory systemic lupus erythematosus (rSLE):

- Advancing translational research based on patient samples from the ongoing IIT trial
  - BCMA/CD19 dual-targeting CAR-T demonstrates more effective elimination of antibody-secreting cells, in comparison to CD19 single-targeting CAR-T
  - Short-term follow-up of initial patients treated with GC012F shows B cell restored to naïve phenotype, providing early evidence of immune reset

- IIT evaluating GC012F in rSLE underway in China
  - Patient enrollment and dosing progressing
  - On track to release initial data in the first half of 2024

- On track to submit IND filings for planned Phase 1 clinical trials in 2023 in both the US and China

SMART CART™ GC506: Suppressive Molecule Activated and Rejuvenated T cells (SMART CART™) is designed to enhance CAR-T cell proliferation, persistence and duration of killing in the suppressive tumor microenvironment (TME).

- Presented preclinical data evaluating SMART CART cells in solid tumor models at Society for Immunotherapy of Cancer (SITC) 38th Annual Meeting

- SMART CART cells demonstrated resistance to immunosuppressive TME and maintained long-term proliferation and cytotoxicity both *in vitro* and *in vivo*. In mouse models, SMART CART cells exhibited better killing activities in tumor re-challenge studies and high tumor burden studies, compared with conventional CAR-T.

· Commenced an IIT in China for GC506 in patients with Claudin18.2 positive solid tumors

Reprioritization of Pipeline: In line with the ongoing strategic review of its clinical pipeline and to focus our resources on the most innovative, differentiated product candidates, including GC012F and GC506 discussed above, the Company suspended the Phase 2 trial evaluating GC007g, HLA-matched donor-derived allogeneic CD19-targeted CAR-T cell therapy, for the treatment of B-cell acute lymphoblastic leukemia. GC007g is an HLA-matched, donor-derived CAR-T candidate and does not leverage the Company's FasTCAR and TruUCAR technology platforms or the SMART CART module.

Financial Results for Third Quarter Ended September 30, 2023

As of September 30, 2023, the Company had RMB1,707.9 million (US$234.1 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 RMB69.6 million (US$9.5 million) and long-term borrowings of RMB33.5 million (US$4.6 million).

Net loss attributable to ordinary shareholders for the three months ended September 30, 2023 was RMB67.6 million (US$9.3 million), compared to RMB171.9 million for the corresponding prior year period.

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2023 were RMB90.1 million (US$12.3 million), compared to RMB133.4 million in the corresponding prior year period. The decrease was primarily due to the decreased spending on research, development and clinical trials.

Administrative Expenses

Administrative expenses for the three months ended September 30, 2023 were RMB31.7 million (US$4.3 million), compared to RMB36.4 million for the corresponding prior year period. The decrease was primarily driven by decreases in payroll and professional service fees.

Interest income for the three months ended September 30, 2023 was RMB9.9 million (US$1.4 million), compared to RMB3.6 million for the corresponding prior year period.

Foreign exchange gain for the three months ended September 30, 2023 was RMB3.2 million (US$0.4 million), compared to a foreign exchange loss of RMB6.1 million for the corresponding prior year period. This increase in the foreign exchange gain of RMB9.3 million was primarily attributable to favorable foreign exchange rate fluctuations (US dollar versus RMB) during the quarter ended September 30, 2023, compared with the corresponding prior year period.

The private placement was closed on August 10, 2023. The Company received $100 million in proceeds from the private placement of ordinary shares as of August 31, 2023, and up to an additional $50 million if the warrants are fully exercised. The warrants remain exercisable at any time at the election of the investors within 24 months after the closing of the private placement. The warrants are measured at fair value, with changes in fair value recognized in earnings. The fair value of warrants decreased by RMB39.9 million (US$ 5.5 million) for the three months ended September 30, 2023, and was recorded as a gain in the income statement.

As of September 30, 2023, 479,632,139 ordinary shares (excluding 22,658,527 ordinary shares issued to depositary bank as of September 30, 2023, for bulk issuance of ADSs reserved for future issuances upon the exercise or vesting of awards granted under the Company's share incentive plans), par value of US$0.0001 per share, were issued and outstanding. As of September 30, 2023, 19,549,166 options were granted and 14,610,518 options were outstanding, and 5,038,056 restricted share units ("RSUs") were granted under the employee stock option plans.

Conference Call and Webcast Details:

Monday, November 13, 2023 @ 8:00 am ET
Investor domestic dial-in: (800) 715-9871
Investor international dial-in: (646) 307-1963
Conference ID: **3201224**

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 GC012F

GC012F is Gracell's FasTCAR-enabled BCMA/CD19 dual-targeting autologous CAR-T cell therapy, which aims to transform cancer and autoimmune disease treatment by driving fast, deep and durable responses with improved safety profile. GC012F is currently being evaluated in clinical studies in multiple hematological cancers as well as autoimmune diseases, and has demonstrated a consistently strong efficacy and safety profile. Gracell has initiated a Phase 1b/2 trial evaluating GC012F for the treatment of relapsed/refractory multiple myeloma in the United States and a Phase 1/2 clinical trial in China is to be commenced imminently. Gracell has also launched an IIT evaluating GC012F for the treatment of refractory systemic lupus erythematosus (rSLE).

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 therapy for cancer and autoimmune diseases, and improve outcomes for patients by enhancing effect, 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 SMART CART™

Suppressive Molecule Activated and Rejuvenated T cells (SMART CART™) is Gracell's proprietary technology module designed to further strengthen the functionality of CAR-T cells and aims to overcome tumor microenvironment (TME). SMART CART™ includes altered expression of the receptor and signaling mechanism of an inhibitory TME molecule, transforming growth factor-β (TGF-β), 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 for the treatment of cancers and autoimmune diseases. Leveraging its innovative 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 and autoimmune diseases. The lead candidate BCMA/CD19 dual-targeting FasTCAR-T GC012F is currently being evaluated in clinical studies for the treatment of multiple myeloma, B-NHL and systemic lupus erythematosus (SLE). For more information on Gracell, please visit www.gracellbio.com. 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 7.296 to US$1.00, the rate in effect as of September 30, 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)

	As of December 31, 2022	As of September 30, 2023	
	RMB	RMB	US$
ASSETS			
Current assets:			
Cash and cash equivalents	1,454,645	1,677,393	229,906
Short-term investments	3,559	30,465	4,176
Prepayments and other current assets	37,551	66,396	9,100
Total current assets	**1,495,755**	**1,774,254**	**243,182**
Property, equipment and software, net	123,126	99,587	13,649
Operating lease right-of-use assets	21,546	9,078	1,244
Other non-current assets	15,849	7,038	965
TOTAL ASSETS	**1,656,276**	**1,889,957**	**259,040**
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities:			
Accruals and other current liabilities	85,991	67,783	9,290
Warrant liabilities	—	77,524	10,626
Short-term borrowings	104,600	55,000	7,538
Operating lease liabilities, current	17,545	10,846	1,487
Amounts due to a related party	4,662	3,716	509
Current portion of long-term borrowings	7,844	14,608	2,002
Total current liabilities	**220,642**	**229,477**	**31,452**
Operating lease liabilities, non-current	6,485	1,830	251
Long-term borrowings	46,505	33,540	4,597
Other non-current liabilities	6,879	4,017	551
TOTAL LIABILITIES	**280,511**	**268,864**	**36,851**
Shareholders' equity:			
Ordinary shares	223	324	44
Additional paid-in capital	2,927,295	3,498,397	479,495
Accumulated other comprehensive income	73,528	113,940	15,617
Accumulated deficit	(1,625,281)	(1,991,568)	(272,967)
Total shareholders' equity	**1,375,765**	**1,621,093**	**222,189**
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	**1,656,276**	**1,889,957**	**259,040**

Unaudited Condensed Consolidated Statements of Comprehensive Loss

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

	For the three months ended September 30,			For the nine months ended September 30,		
	2022	2023		2022	2023	
	RMB	RMB	US$	RMB	RMB	US$
Expenses						
Research and development expenses	(133,350)	(90,054)	(12,343)	(372,245)	(331,363)	(45,417)
Administrative expenses	(36,434)	(31,701)	(4,345)	(103,090)	(98,139)	(13,451)
Loss from operations	**(169,784)**	**(121,755)**	**(16,688)**	**(475,335)**	**(429,502)**	**(58,868)**
Interest income	3,583	9,906	1,358	8,781	29,801	4,085
Interest expense	(1,864)	(1,290)	(177)	(4,946)	(4,650)	(637)
Other income	2,097	2,756	378	4,037	9,294	1,274
Foreign exchange gain/(loss), net	(6,089)	3,212	440	(9,484)	(6,524)	(894)
Change in fair value of warrant liabilities	—	39,915	5,471	—	39,915	5,471
Others, net	130	(356)	(49)	132	(4,582)	(628)
Loss before income tax	**(171,927)**	**(67,612)**	**(9,267)**	**(476,815)**	**(366,248)**	**(50,197)**
Income tax expense	—	(13)	(2)	—	(39)	(5)
Net loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	**(171,927)**	**(67,625)**	**(9,269)**	(476,815)	(366,287)	(50,202)
Other comprehensive income						
Foreign currency translation adjustments, net of nil tax	81,056	(4,149)	(569)	156,647	40,412	5,539
Total comprehensive loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	**(90,871)**	**(71,774)**	**(9,838)**	(320,168)	(325,875)	(44,663)
Weighted average number of ordinary shares used in per share calculation:						
—Basic	338,414,757	419,623,404	419,623,404	338,301,687	366,800,916	366,800,916
—Diluted	338,414,757	419,623,404	419,623,404	338,301,687	366,800,916	366,800,916
Net loss per share attributable to Gracell Biotechnologies Inc.'s ordinary shareholders						
—Basic	(0.51)	(0.16)	(0.02)	(1.41)	(1.00)	(0.14)
—Diluted	(0.51)	(0.16)	(0.02)	(1.41)	(1.00)	(0.14)