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 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): ☐

INCORPORATION BY REFERENCE

Exhibit 99.1 to 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in the registration statements of Gracell on Form F-3 (No. 333-264545) and Form S-8 (No. 333-253486), to the extent not superseded by documents or reports subsequently filed.

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 16, 2022

Exhibit 99.1

PRESS RELEASE

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

- *On track to submit IND filings in U.S. and China for GC012F for the treatment of relapsed/refractory multiple myeloma (RRMM) in the fourth quarter 2022*
- *First clinical data from ongoing investigator-initiated trial (IIT) evaluating GC012F in newly-diagnosed multiple myeloma (NDMM) patients to be presented as oral session at 64th American Society of Hematology Annual Meeting and Exposition (ASH 2022)*
- *Continued patient enrollment and follow-up in the ongoing IIT evaluating GC012F in relapsed/refractory B-Cell non-Hodgkin lymphoma (r/r B-NHL)*
- *Dosed first patient in registrational Phase 2 clinical trial evaluating GC007g for the treatment of relapsed/refractory B-cell acute lymphoblastic leukemia (r/r B-ALL)*
- *Dosed first patients in IIT evaluating GC503 for the treatment of mesothelin-positive solid tumors*
- *Well-funded with cash runway for next 24 months*
- *Management to host conference call at 8:00 a.m. ET today*

SAN DIEGO, Calif. and SUZHOU and SHANGHAI, China, November 14, 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 third quarter unaudited financial results for the period ended September 30, 2022, and provided corporate updates.

"We continued to make important strides to advance our pipeline and remain on track to achieve key 2022 milestones. For our lead candidate GC012F, the BCMA/CD19 dual-targeting FasTCAR-T therapy, we look forward to submitting the IND filings for the treatment of RRMM in both the U.S. and China by the end of the year," said Dr. William (Wei) Cao, founder, Chairman, and CEO of Gracell. "We very much look forward to presenting the positive clinical data from the ongoing IIT evaluating GC012F in NDMM patients, as an oral session at the ASH annual meeting in December 2022. We have also started Gracell's first Phase 2 trial with the first patient dosed with GC007g, an HLA-matched donor-derived allogeneic CAR-T therapy. Gracell remains well positioned and well capitalized to bring game-changing cell therapy to the patients in need."

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, NDMM and B-NHL.

- First clinical data from ongoing IIT evaluating GC012F in NDMM patients to be presented as oral session at ASH 2022.
  - Presentation details: Session 704: Cellular Immunotherapies: Early Phase and Investigational Therapies: CAR T in Multiple Myeloma and T-cell Therapies After Allo-HCT on Saturday, December 10, 2022 at 5:15 pm CT.
  - As of the July 25, 2022 abstract data cutoff date, clinical data from this trial indicated 100% ORR and 100% MRD negativity in the 13 NDMM patients treated.

- On track to submit the IND applications in the U.S. and China in the fourth quarter 2022 to evaluate GC012F for the treatment of RRMM.
- 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.

- Updated data from single-arm, open-label IIT with longer follow-up of GC502 in B-ALL presented at EHA 2022.

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

- Dosed first patients in a China IIT to evaluate GC503 for the treatment of mesothelin-positive solid tumors.
- Plan to commence a China IIT for GC506 in CLDN18.2-positive solid tumors.

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.

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

Financial Results for Third Quarter Ended September 30, 2022

As of September 30, 2022, the Company had RMB1,629.6 million (US$229.1 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 RMB125.1 million (US$17.6 million) and long-term borrowings of RMB48.1 million (US$6.8 million) as of September 30, 2022.

Net loss attributable to ordinary shareholders for the three months ended September 30, 2022 was RMB171.9 million (US$24.2 million), compared to RMB129.3 million for the corresponding prior year period.

Research and development expenses for the three months ended September 30, 2022 were RMB133.4 million (US$18.7 million), compared to RMB88.6 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 for the three months ended September 30, 2022 were RMB36.4 million (US$5.1 million), compared to RMB42.9 million for the corresponding prior year period. The decrease was primarily driven by a decrease in professional service and a decrease in share-based compensation expenses.

Interest income for the three months ended September 30, 2022 was RMB3.6 million (US$0.5 million), compared to RMB3.0 million for the corresponding prior year period. Other income for the three months ended September 30, 2022 was RMB2.1 million (US$0.3 million), compared to RMB0.7 million for the corresponding prior year period.

Foreign exchange loss for the three months ended September 30, 2022 was RMB6.1 million (US$0.9 million), compared to a foreign exchange loss of RMB0.8 million for the corresponding prior year period. This increase in the foreign exchange loss of RMB5.3 million was primarily attributable to unfavorable foreign exchange rate fluctuating (RMB versus US dollar) during the quarter ended September 30, 2022, compared with the corresponding prior year period.

As of September 30, 2022, 338,425,069 ordinary shares, par value of US$0.0001 per share, were issued and outstanding. As of September 30, 2022, 18,815,761 options were granted and 15,255,399 options were outstanding, and 1,974,391 restricted share units (“RSUs”) were granted under the employee stock option plan. Each of the ADSs represents five ordinary shares.

Conference Call and Webcast Details:
Monday, November 14, 2022 @ 8:00 a.m. ET
Investor domestic dial-in: (800) 715-9871
Investor international dial-in: +1(646) 307-1963
Conference ID: 4840587
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^{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 7.1135 to US$1.00, the rate in effect as of September 30, 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 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	As of September 30, 2022	
	RMB	RMB	US$
ASSETS			
Current assets:			
Cash and cash equivalents	1,829,006	1,431,460	201,232
Short-term investments	3,615	198,160	27,857
Prepayments and other current assets	52,459	40,337	5,670
Total current assets	**1,885,080**	**1,669,957**	**234,759**
Property, equipment and software, net	123,818	123,780	17,401
Operating lease right-of-use assets	29,652	26,133	3,674
Other non-current assets	21,587	18,510	2,602
TOTAL ASSETS	**2,060,137**	**1,838,380**	**258,436**
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities:			
Accruals and other current liabilities	69,120	96,069	13,505
Short-term borrowings	66,100	117,600	16,532
Operating lease liabilities, current	17,527	21,699	3,050
Amounts due to related parties	—	3,674	517
Current portion of long-term borrowings	2,376	7,498	1,054
Total current liabilities	**155,123**	**246,540**	**34,658**
Operating lease liabilities, non-current	14,830	8,833	1,242
Long-term borrowings	54,349	48,149	6,769
Other non-current liabilities	8,464	7,908	1,112
TOTAL LIABILITIES	**232,766**	**311,430**	**43,781**
Shareholders' equity:			
Ordinary shares	223	223	31
Additional paid-in capital	2,902,856	2,922,604	410,853
Accumulated other comprehensive income/(loss)	(57,936)	98,710	13,877
Accumulated deficit	(1,017,772)	(1,494,587)	(210,106)
Total shareholders' equity	**1,827,371**	**1,526,950**	**214,655**
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	**2,060,137**	**1,838,380**	**258,436**

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,		
	2021	2022		2021	2022	
	RMB	RMB	US$	RMB	RMB	US$
Revenue						
Licensing and collaboration revenue	366	—	—	366	—	—
Expenses						
Research and development expenses	(88,617)	(133,350)	(18,746)	(219,317)	(372,245)	(52,329)
Administrative expenses	(42,861)	(36,434)	(5,122)	(105,043)	(103,090)	(14,492)
Loss from operations	**(131,112)**	**(169,784)**	**(23,868)**	**(323,994)**	**(475,335)**	**(66,821)**
Interest income	2,985	3,583	504	5,651	8,781	1,234
Interest expense	(1,089)	(1,864)	(262)	(3,736)	(4,946)	(695)
Other income	733	2,097	295	866	4,037	568
Foreign exchange loss, net	(802)	(6,089)	(856)	(1,903)	(9,484)	(1,333)
Others, net	—	130	18	(53)	132	19
Loss before income tax	**(129,285)**	**(171,927)**	**(24,169)**	**(323,169)**	**(476,815)**	**(67,028)**
Income tax expense	—	—	—	—	—	—
Net loss	**(129,285)**	**(171,927)**	**(24,169)**	**(323,169)**	**(476,815)**	**(67,028)**
Accretion of convertible redeemable preferred shares to redemption value	—	—	—	(1,989)	—	—
Net loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	**(129,285)**	**(171,927)**	**(24,169)**	**(325,158)**	**(476,815)**	**(67,028)**
Other comprehensive income/(loss)						
Foreign currency translation adjustments, net of nil tax	7,340	81,056	11,395	(3,798)	156,647	22,021
Total comprehensive loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	**(121,945)**	**(90,871)**	**(12,774)**	**(328,956)**	**(320,168)**	**(45,007)**
Weighted average number of ordinary shares used in per share calculation:						
—Basic	336,494,609	338,414,757	338,414,757	325,838,207	338,301,687	338,301,687
—Diluted	336,494,609	338,414,757	338,414,757	325,838,207	338,301,687	338,301,687
Net loss per share attributable to Gracell Biotechnologies Inc.'s ordinary shareholders						
—Basic	(0.38)	(0.51)	(0.07)	(1.00)	(1.41)	(0.20)
—Diluted	(0.38)	(0.51)	(0.07)	(1.00)	(1.41)	(0.20)