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 2021

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: November 16, 2021

PRESS RELEASE

Gracell Biotechnologies Reports Third Quarter 2021 Unaudited Financial Results and Provides Corporate Update

SUZHOU, China and PALO ALTO, Calif., Nov. 15, 2021 (GLOBE NEWSWIRE) – Gracell Biotechnologies Inc. (NASDAQ: GRCL) ("Gracell"), a global clinical-stage biopharmaceutical company dedicated to discovering and developing highly efficacious and affordable cell therapies for the treatment of cancer, today reported its unaudited financial results for the third quarter of the year and provided recent business highlights.

"We continue to deliver strong research and clinical execution across our pipeline this quarter, furthering our clinical programs as well as advancing innovative preclinical product candidates to clinical stage," commented Dr. William (Wei) Cao, founder, Chairman, and CEO of Gracell. "Our autologous and allogeneic T cell therapies are designed to offer differentiated approaches that aim to provide significant improvements in manufacturing, production, efficacy, and cost. We remain focused on building solid clinical foundations across our lead programs, advancing R&D efforts and new preclinical candidates, and enhancing our manufacturing capabilities to provide therapies with reduced cost and increased accessibility to patients."

"Our lead FasTCAR candidate GC012F, a unique BCMA/CD19 dual-targeting autologous CAR-T cell therapy for the treatment of multiple myeloma developed using the next-day manufacturing FasTCAR platform, has demonstrated fast, deep and durable responses at all dose levels in a predominantly high risk, difficult to treat patient population. We continue advancing with the tech transfer to Lonza to support manufacturing of GC012F in the U.S., an instrumental step towards our US IND filing targeting the first half of 2022. We continue expanding this program including into earlier lines of therapy. GC027, our lead TruUCAR candidate, an off-the-shelf, allogeneic CAR-T cell therapy for the treatment of T-cell malignancies reported encouraging longer-term follow-up data at AACR, and we continue to enroll patients in our ongoing Phase I IIT trial in China for this candidate. We expanded our TruUCAR platform with GC502, a CD19/CD7 dual-directed allogeneic TruUCAR-enabled CAR-T therapy for the treatment of r/r B-ALL and B-NHL recently advancing to clinical stage with the initiation of an IIT study in China. GC502 leverages the unique dual CAR capabilities of the TruUCAR platform, with the CD7 CAR designed to suppress host versus graft rejection, and the second CAR that can have scFv swapped to target different tumor antigens such as CD19, making TruUCAR platform widely applicable. GC502 comprehensively exemplifies the TruUCAR design that aims for optimized persistence without the need of being co-administered with additional immunosuppressive drugs. We look forward to highlighting the preclinical data that lead to advancing this program into the clinic in a poster presentation at ASH 2021. Our donor-derived allogeneic CD19-targeted CAR-T for B-ALL, GC007g, is currently being advanced to the second dose cohort in our pivotal IND Phase 1/2 study in China."

"We have actively expanded our SMART CART™ solid tumor program, including exploring CLDN18.2 as a target in collaboration with FutureGen, and using preclinical learnings presented at SITC 2021 conference to inform on the optimization of second-generation CAR-T candidates entering clinical stage in the first half of 2022. Gracell's SMART CART™ technology is designed to incorporate unique cytokine signaling to improve persistence, and reverse and turn immunosuppressive signals of the solid tumor microenvironment into stimulatory reactions of CAR-T cells."

"Lastly, we will also continue building a strong manufacturing and R&D foundation with the ongoing expansion of our US R&D capabilities and the development of a significantly larger facility for the commercial phase in Suzhou, China in addition to our state-of-the-art, 66,000 sq. ft. GMP manufacturing facility. These clinical, R&D and manufacturing developments will further support our abilities to deliver therapeutic solutions across hematological malignancies and solid tumors that have the potential for optimized cost-efficiency, faster manufacturing, and superior efficacy and safety," Dr. Cao concluded.

Third Quarter 2021 and Subsequent Highlights

GC502 for the treatment of adult relapsed/refractory B-cell acute lymphoblastic leukemia and B cell non-Hodgkin lymphoma (r/r B-ALL and B-NHL): *GC502 is a 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 adult r/r B-ALL and B-NHL. GC502 is manufactured from T cells of non-human leukocyte antigen (HLA)-matched healthy donors.*

- **Clinical IIT initiated.** IIT study was initiated in China in adult patients with r/r B-ALL and B-NHL.
- **Preclinical data presentation at ASH.** Preclinical data for GC502 will be featured as a poster presentation at ASH 2021. (Press Release November 2021)

GC007g for the treatment of B-ALL: *GC007g is a donor-derived CD19-targeted allogeneic CAR-T cell therapy for the treatment of r/r B-ALL patients who failed transplant and may not be eligible for autologous CAR-T therapy. The allogeneic approach, utilizing T-cells from an HLA-matched healthy donor, has the potential to provide a novel treatment approach to patients not eligible for standard of care.*

- **Open IND in China and ongoing pivotal Phase 1/2.** Pivotal Phase 1/2 clinical study ongoing in China for the treatment of r/r B-ALL patients. (Press Release March 2021).
- **Enrolling in second dosing cohort.** Successful enrollment of first dosing cohort in the phase 1/2 seamless design study was completed and the study is currently enrolling into second dosing cohort.

SMART CART™ candidates for the treatment of solid tumors: *SMART CART™ is our second-generation Enhanced CAR-T platform designed for overcoming tumor microenvironment (TME). SMART CART™ includes altered expression of the receptor and signaling mechanism of an inhibitory TME molecule to enhance CAR-T cell proliferation and persistence, and to reduce exhaustion of CAR-T cells in order to effectively combat solid tumors.*

- **Favorable clinical IIT data with first generation Enhanced CAR-T.** Preliminary clinical IIT data of Gracell's first generation Enhanced CAR-T for solid tumors has shown tolerability and preliminary efficacy. (Publication August 2021)
- **Collaboration with FutureGen.** Ongoing collaboration with FutureGen to develop CAR-T therapies targeting Claudin 18.2. (Press Release August 2021)
- **Preclinical data presentation at SITC 2021.** Preclinical data showing the positive impact of the IL-2 variant on CAR-T functionality and efficacy against solid tumors has been presented as a poster presentation at SITC 2021.

Financial Results for the Third Quarter Ended September 30, 2021

Research and development expenses for the three months ended September 30, 2021 were RMB88.6 million (US$13.7 million), as compared to RMB40.0 million in the corresponding prior year period. This increase was primarily driven by increases of RMB16.3 million (US$2.5 million) in labor costs due to the further expansion in business as well as increases of RMB2.7 million (US$0.4 million) and RMB19.6 million (US$3.0 million) in depreciation expenses of research and development facilities and in costs incurred to advance preclinical and clinical pipeline, respectively, an increase of RMB6.1 million (US$0.9 million) in professional service expenses and an increase of RMB3.9 million (US$0.6 million) in recognition of share-based compensation expenses upon the completion of initial public offering.

Administrative expenses for the three months ended September 30, 2021 were RMB42.9 million (US$6.7 million), compared to RMB8.2 million for the corresponding prior year period. This increase was primarily related to an increase of RMB20.5 million (US$3.2 million) in recognition of share-based compensation expenses upon the completion of initial public offering, an increase of RMB4.3 million (US$0.7 million) attributable to labor costs due to expansion of administrative functions, an increase of RMB3.6 million (US$0.6 million) in financial and legal consulting fee, an increase of RMB2.2 million (US$0.3 million) of insurance expense for the employees and also an increase of RMB2.4 million (US$0.4 million) in lease-related expense. Other miscellaneous expenses increased by RMB1.7million (US$0.3 million).

Interest income for the third quarter of 2021 was RMB3.0 million (US$0.5 million) as compared to RMB0.3 million for the corresponding prior year period.

Foreign exchange loss for the three months ended September 30, 2021 was RMB0.8 million (US$0.1 million), compared to a foreign exchange loss of RMB2.2 million for the corresponding prior year period. This decrease in the foreign exchange loss of RMB1.4 million was primarily attributable to favorable foreign exchange rate fluctuating (RMB versus US dollar) during the quarter ended September 30, 2021 compared with the corresponding prior year period.

Net loss attributable to ordinary shareholders for the three months ended September 30, 2021 was RMB129.3 million (US$20.1 million), compared to RMB68.9 million for the corresponding prior year period.

Balance Sheet Highlights

As of September 30, 2021, the Company had RMB1,957.5 million (US$303.8 million) in cash and cash equivalents and short-term investments. During the first half of the year, the Company completed an initial public offering of 11,000,000 American Depositary Shares ("ADSs"), each representing five ordinary shares, at a public offering price of $19.00 per ADS. In connection with the initial public offering, the Company granted the underwriters an option to purchase up to an additional 1,650,000 ADSs at the initial public offering price, which was exercised in full by the underwriters. The net proceeds from these transactions were approximately US$220 million.

The Company early adopted ASU 2016-02, Lease (Topic 842), in the first quarter of 2021. As of September 30, 2021, the Company had operating lease liabilities of RMB36.7 million (US$5.7 million) and operating lease right-of-use assets of RMB32.7 million (US$5.1 million).

In the first quarter of 2021, the Company received a payment from the depositary bank in the amount of RMB14.5 million (US$2.2 million) mostly to reimburse the expenses related to the establishment of the ADS facility. The payment is initially recognized as a liability and is being amortized over the facility arrangement period. As of September 30, 2021, the Company had the related other current liabilities of RMB2.9 million (US$0.5 million) and other non-current liabilities of RMB9.4 million (US$1.5 million).

In addition, as of September 30, 2021, the Company had short-term borrowings and current portion of long-term borrowings of RMB58.1 million (US$9.0 million) and long-term borrowings of RMB55.6 million (US$8.6 million).

As of September 30, 2021, 337,496,901 ordinary shares, par value of US$0.0001 per share, were issued and outstanding. As of September 30, 2021, 11,770,935 options were granted and 10,856,480 options were outstanding, and 1,373,820 restricted share units (“RSUs”) were granted under our employee stock option plan. Each of our ADS represents five ordinary shares.

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, 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 platform 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 to increase proliferation and persistence, and to reduce 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, TruUCAR and SMART CAR™ technology platforms, 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 production 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 6.4434 to US$1.00, the rate in effect as of September 30, 2021 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 expected trading commencement and closing date of the offering. 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, and Gracell specifically disclaims any obligation to update any forward-looking statement, whether as a result of 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, 2020	As of September 30, 2021	
	RMB	RMB	US$
ASSETS			
Current assets:			
Cash and cash equivalents	754,308	1,953,924	303,244
Short-term investments	18,743	3,599	559
Prepayments and other current assets	42,418	60,930	9,457
Total current assets	**815,469**	**2,018,453**	**313,260**
Property, equipment and software	119,083	123,456	19,160
Operating lease right-of-use assets	—	32,697	5,074
Other non-current assets	30,398	22,238	3,451
TOTAL ASSETS	**964,950**	**2,196,844**	**340,945**
LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' DEFICIT			
Current liabilities:			
Short-term borrowings	49,990	56,090	8,705
Operating lease liabilities, current	—	17,904	2,779
Current portion of long-term borrowings	970	1,978	307
Accruals and other current liabilities	42,401	61,313	9,516
Total current liabilities	**93,361**	**137,285**	**21,307**
Long-term borrowings	51,926	55,646	8,636
Operating lease liabilities, non-current	—	18,799	2,918
Other non-current liabilities	—	9,435	1,464
TOTAL LIABILITIES	**145,287**	**221,165**	**34,325**
Commitments and contingencies			
Mezzanine equity:			
Series A convertible redeemable preferred shares	110,468	—	—
Series B-1 convertible redeemable preferred shares	142,481	—	—
Series B-2 convertible redeemable preferred shares	495,799	—	—
Series C convertible redeemable preferred shares	658,788	—	—
Total mezzanine equity	**1,407,536**	—	—
Shareholders' deficit:			
Ordinary shares	68	223	35
Additional paid-in capital	—	2,892,354	448,886
Accumulated other comprehensive loss	(23,912)	(27,711)	(4,301)
Accumulated deficit	(564,029)	(889,187)	(138,000)
Total shareholders' deficit	**(587,873)**	**1,975,679**	**306,620**
TOTAL LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' DEFICIT	**964,950**	**2,196,844**	**340,945**

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,		
	2020	2021		2020	2021	
	RMB	RMB	US$	RMB	RMB	US$
Revenue						
Licensing and collaboration revenue	—	366	57	—	366	57
Expenses						
Research and development expenses	(39,986)	(88,617)	(13,753)	(108,137)	(219,317)	(34,037)
Administrative expenses	(8,184)	(42,861)	(6,652)	(20,781)	(105,043)	(16,302)
Loss from operations	**(48,170)**	**(131,112)**	**(20,348)**	**(128,918)**	**(323,994)**	**(50,282)**
Interest income	250	2,985	463	2,416	5,651	877
Interest expense	(654)	(1,089)	(169)	(1,350)	(3,736)	(580)
Other income	220	733	114	1,794	866	134
Foreign exchange loss, net	(2,217)	(802)	(124)	(2,237)	(1,903)	(295)
Others, net	3	—	—	(12)	(53)	(8)
Loss before income tax	**(50,568)**	**(129,285)**	**(20,064)**	**(128,307)**	**(323,169)**	**(50,154)**
Income tax expense	—	—	—	—	—	—
Net loss	**(50,568)**	**(129,285)**	**(20,064)**	**(128,307)**	**(323,169)**	**(50,154)**
Accretion of convertible redeemable preferred shares to redemption value	(18,342)	—	—	(46,392)	(1,989)	(309)
Net loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders						
Other comprehensive loss	**(68,910)**	**(129,285)**	**(20,064)**	**(174,699)**	**(325,158)**	**(50,463)**
Foreign currency translation adjustments, net of nil tax	(5,455)	7,340	1,139	(1,957)	(3,798)	(589)
Total comprehensive loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	**(74,365)**	**(121,945)**	**(18,925)**	**(176,656)**	**(328,956)**	**(51,052)**
Weighted average number of ordinary shares used in per share calculation:						
—Basic	99,044,776	336,494,609	336,494,609	99,044,776	325,838,207	325,838,207
—Diluted	99,044,776	336,494,609	336,494,609	99,044,776	325,838,207	325,838,207
Net loss per share attributable to Gracell Biotechnologies Inc.'s ordinary shareholders						
—Basic	(0.70)	(0.38)	(0.06)	(1.76)	(1.00)	(0.15)
—Diluted	(0.70)	(0.38)	(0.06)	(1.76)	(1.00)	(0.15)