



科濟藥業控股有限公司

CARSGEN THERAPEUTICS HOLDINGS LIMITED

(Incorporated in the Cayman Islands with limited liability)

Stock Code : 2171.HK



2021
ANNUAL REPORT

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Corporate Information

BOARD OF DIRECTORS

Executive Directors

Dr. LI Zonghai
Dr. WANG Huamao

Non-executive Directors

Mr. GUO Bingsen
Mr. GUO Huaqing
Mr. XIE Ronggang
Ms. ZHAO Yachao

Independent Non-executive Directors

Dr. FAN Chunhai
Dr. YAN Guangmei
Mr. SO Tak Young

CORPORATE HEADQUARTERS

BLDG 12, No. 388 Yindu Road
Xuhui District
Shanghai
PRC

PRINCIPAL PLACE OF BUSINESS IN HONG KONG

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183 Queen's Road East
Hong Kong

REGISTERED OFFICE

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Grand Pavilion
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802 West Bay Road
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Cayman Islands

PRINCIPAL SHARE REGISTRAR AND TRANSFER OFFICE

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P.O. Box 1093, Boundary Hall
Cricket Square
Grand Cayman KY1-1102
Cayman Islands

LEGAL ADVISERS TO HONG KONG LAW

Davis Polk & Wardwell
18th Floor, The Hong Kong Club Building
3A Chater Road, Hong Kong

COMPANY SECRETARY

Mr. LUI Wing Yat Christopher

AUTHORIZED REPRESENTATIVES

Dr. LI Zonghai
Mr. LUI Wing Yat Christopher

AUDIT COMMITTEE

Mr. SO Tak Young (*Chairman*)
Dr. FAN Chunhai
Mr. GUO Huaqing

REMUNERATION COMMITTEE

Dr. FAN Chunhai (*Chairman*)
Dr. LI Zonghai
Dr. YAN Guangmei

NOMINATION AND CORPORATE GOVERNANCE COMMITTEE

Dr. LI Zonghai (*Chairman*)
Dr. FAN Chunhai
Dr. YAN Guangmei

HONG KONG SHARE REGISTRAR

Computershare Hong Kong Investor
Services Limited
Shops 1712-1716
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183 Queen's Road East
Wanchai
Hong Kong

STOCK CODE

02171

AUDITOR

PricewaterhouseCoopers
Certified Public Accountants
Registered Public Interest Entity Auditor
22/F, Prince's Building
Central
Hong Kong

COMPANY WEBSITE

www.carsgen.com

COMPLIANCE ADVISER

Guotai Junan Capital Limited
27/F., Low Block
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PRINCIPAL BANKER

Bank of Hangzhou Co., Ltd.
No. 46, Qingchun Road
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PRC

Chairman's Statement

Dear Shareholders,

On behalf of the Board of Directors of CARsgen, I am pleased to present the annual report of the Company for the year ended December 31, 2021.

CARsgen is a biopharmaceutical company with operations in China and the U.S. mainly focused on innovative CAR T-cell therapies for the treatment of hematologic malignancies and solid tumors. We have built an integrated cell therapy platform with in-house capabilities that span target discovery, antibody development, clinical trials, and commercial-scale manufacturing. We also have internally developed novel technologies and a product pipeline with global rights to address major challenges of CAR T-cell therapies, such as improving the safety profile, enhancing the efficacy against solid tumors, and reducing treatment costs.

Despite the challenges from COVID-19 pandemic, 2021 was a fruitful year for CARsgen, marked by important milestones achieved through the dedicated efforts. On June 18, 2021, CARsgen was successfully listed on the Hong Kong Stock Exchange, with approximately HK\$3,008 million raised, an important milestone for the development and growth of the Company. The successful IPO was a result of the dedicated efforts of CARsgen team to develop innovative CAR T-cell therapies for cancer patients worldwide and the continuous support and recognition we have been receiving from external partners. Behind the successful IPO listing are the significant advancements we have achieved with regards to clinical development of our pipeline products, technology platform innovation, manufacturing facility expansion, business development, particularly:

- CT053, an upgraded fully-human anti-BCMA CAR T-cell product candidate for the treatment of R/R MM, completed the patient enrollment of the pivotal Phase II clinical trial in China and entered the pivotal Phase 2 clinical trial in North America. As reported in the data update in the ASH Annual Meeting in December 2021, CT053 showed an ORR of 100%, a CR/sCR of 78.6% and favorable safety profile in the Phase I trial of LUMMICAR STUDY 1.
- CT041, a globally potential first-in-class anti-CLDN18.2 CAR T-cell product candidate for the treatment of CLDN18.2 positive solid tumors. We have initiated the confirmatory Phase II clinical trial in China and initiated the Phase 1b trial in North America. As reported in ESMO Congress in 2021, CT041 showed an ORR of 61.1%, a median PFS of 5.6 months, and a median OS of 9.5 months in patients with gastric/gastroesophageal junction cancer who had failed at least 2 prior lines of therapies at a dose of 2.5×10^8 , indicating significant breakthrough from existing therapies such as anti-PD-1 antibody. CT041 was granted PRIME Eligibility by the EMA, the first solid tumor CAR T-cell product with granted PRIME, and RMAT Designation by the FDA.
- In addition to the solid advancements of CT053, CT041, and other clinical-stage and pre-clinical pipeline product candidates, we continue to develop and optimize our innovative technology platforms and CAR T-cell products that can potentially address the challenges encountered by existing CAR T-cell therapies through 1) increasing efficacy against solid tumors 2) enhancing safety profile 3) expanding patient accessibility and 4) improving target availability. In particular, the Local Action Driven by Artificial Receptor (LADAR[®]) platform developed in CARsgen is a powerful tool in enabling the engineered immune cell therapies to precisely target cancer cells or deliver therapeutic proteins into disease sites.

Chairman's Statement

- We have made significant progresses in expanding our manufacturing capacities. We initiated and completed the construction of our manufacturing facility in RTP, Durham, North Carolina ("**RTP Manufacturing Facility**"), which subsequently successfully passed the official inspections and received the Certificate of Compliance from local authorities. Meanwhile, we are conducting technology transfer of CT053 and CT041 from manufacturing facility in Shanghai to the RTP Manufacturing Facility, advancing to the operation of clinical manufacturing. We believe the end-to-end manufacturing capabilities in-house in both China and the U.S. would significantly increase manufacturing capacities, reduce manufacturing costs, and shorten the vein-to-vein time for CAR T-cell treatment.

Building on these milestones, we will continue our endeavors to develop innovative product candidates for the treatment of cancer patients worldwide. In addition to tremendous efforts in the clinical development of CT053 and CT041 in China and global markets. We will also keep advancing our innovative technologies and other product candidates and further expanding our manufacturing capacities to support the clinical trials and future commercialization of our product candidates.

Looking forward, the management team and I are confident that CARsgen is well positioned to strengthen the leadership in CAR T-cell therapies globally, powered by our differentiated product candidates, innovative technology platforms, end-to-end manufacturing capacities in China and the U.S. and extensive IP protection.

On behalf of the Board of Directors, I would like to thank our employees and management team for their determination, hard work and outstanding contributions. I would also like to express my sincere gratitude to our shareholders and business partners for their long-term trust and continued support. Building on the achievements in 2021, we are embarking on an even more exciting journey into 2022, dedicated towards the realization of our vision to become a global biopharmaceutical leader that brings innovative and differentiated cell therapies to cancer patients worldwide and makes cancer curable.

Dr. LI Zonghai
Chairman,
Co-founder,
Chief Executive Officer and Chief Scientific Officer



Financial Highlights

	Year ended December 31,	
	2021 RMB'000	2020 RMB'000
Net loss	(4,744,423)	(1,064,049)
Net loss per share	(12.26)	(5.37)
Non-IFRS Measures		
Adjusted net loss ⁽¹⁾	(548,767)	(333,725)
Adjusted net loss per share ⁽¹⁾	(1.42)	(1.68)

	As at December 31,	
	2021 RMB'000	2020 RMB'000
Cash and cash equivalents	691,284	1,042,969
Terms deposits with original maturity between three and twelve months	2,315,654	–
Total	3,006,938	1,042,969

Our net loss was RMB4,744 million for the year ended December 31, 2021, representing an increase of RMB3,680 million from RMB1,064 million for the year ended December 31, 2020. The increase was primarily due to (i) the increase of fair value loss in financial instruments issued to investors (the “**Fair Value Loss**”), which totaled RMB4,156 million for the year ended December 31, 2021, representing an increase of RMB3,432 million from RMB724 million for the year ended December 31, 2020. Fair value loss related financial instruments were converted to ordinary shares upon the completion of the Company’s initial public offering on June 18, 2021 (the “**IPO**”), hence no loss would be recognized after the IPO; (ii) the listing fees of approximately RMB27 million (the “**Listing Fees**”) for the year ended December 31, 2021, representing an increase of RMB23 million from RMB4 million for the year ended December 31, 2020; (iii) the share-based compensation (together with the Fair Value Loss and the Listing Fees, collectively the “**Adjusted Items**”), which totaled RMB14 million for the year ended December 31, 2021, representing an increase of RMB12 million from RMB2 million for the year ended December 31, 2020; and (iv) higher research and development expenses and higher administrative expenses.

Our adjusted net loss^{Note (1)} was RMB549 million for the year ended December 31, 2021, representing an increase of RMB215 million from RMB334 million for the year ended December 31, 2020. The increase was primarily due to higher research and development expenses and higher administrative expenses.

Cash and cash equivalents and short-term investments were RMB3,007 million as of December 31, 2021, representing an increase of RMB1,964 million from RMB1,043 million as of December 31, 2020. The increase mostly resulted from proceeds received during the Company’s IPO.

Note (1) Adjusted net loss and adjusted net loss per share are non-IFRS measures. They exclude the impact of the Adjusted Items. For details of non-IFRS measures, please refer to “Non-IFRS Measures” subsection for details.

Business Highlights

On 18 June 2021, the Company was successfully listed on The Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”). During the Reporting Period, we have made significant advancements in the clinical development of our pipeline products, innovation of technology advancement, expansion of manufacturing facilities and establishment of external partnerships. Specifically, we made progress in the following areas:

CT053

CT053 is an autologous CAR T-cell product candidate against BCMA being developed for the treatment of relapsed/refractory multiple myeloma (R/R MM). We have completed patient enrollment in our pivotal Phase II trial in China. In addition, we have started our pivotal Phase 2 clinical trial in North America and treated our first patient in the pivotal Phase 2 trial in August 2021. As communicated with the U.S. FDA, we are adding outpatient administration of CT053 into our U.S. clinical investigations. We plan to submit the NDA to the NMPA in the first half of 2022 and plan to submit the BLA to the U.S. FDA in 2023. We also plan to conduct additional clinical trials to develop CT053 as an earlier line of treatment for multiple myeloma.

Additional data update from the Phase I/II study in China (LUMMICAR STUDY 1) and an integrated analysis in patients with R/R MM by high-risk factors have been available as posters at the 2021 American Society of Hematology (“**ASH**”) Annual Meeting in December 2021.

CT041

CT041 is an autologous CAR T-cell product candidate against the protein CLDN18.2 and has the potential to be first-in-class globally. CT041 targets the treatment of CLDN18.2 positive solid tumors with a primary focus on gastric/gastroesophageal junction cancer (GC/GEJ) and pancreatic cancer (PC). We have initiated the investigator-initiated trials, a Phase Ib clinical trial for advanced GC/GEJ and PC and a confirmatory Phase II clinical trial for advanced GC/GEJ in China, and initiated a Phase 1b clinical trial for advanced gastric or pancreatic adenocarcinoma in North America. We plan to submit an NDA to the NMPA in China in the first half of 2024 and also plan to initiate a Phase 2 clinical trial in the second half of 2022 in North America.

Additional data update from a China Investigator-Initiated Trial has been available as an oral presentation at the European Society for Medical Oncology Congress 2021 (“**ESMO Congress 2021**”) in September 2021.

CT011

CT011 is a CAR T-cell product candidate with proof-of-concept clinical data for the treatment of hepatocellular carcinoma (HCC) and has the potential to be the first-in class globally. We have completed patients enrollment of a Phase I trial in China.

AB011

AB011 is a humanized monoclonal antibody product candidate against CLDN18.2 being developed for the treatment of CLDN18.2 positive solid tumors. During the second quarter of 2021, we received supplemental application approval by CDE regarding the addition of a chemotherapy combination cohort with AB011 in Phase Ib, and we have subsequently initiated the combination cohort of AB011 with chemotherapy. We completed phase I monotherapy cohort enrollment and initiated combination with chemotherapy. We plan to consult with the NMPA in the second half of 2022 and to initiate the subsequent Phase II clinical trial.

DISCOVERY AND PRE-CLINICAL DEVELOPMENT

In addition to the existing technologies and clinical pipeline product candidates, which have shown promising efficacy and favorable safety profiles against hematologic malignancies and solid tumors, we continue to dedicate ourselves to advancing innovative CAR T technologies to address major challenges in the industry.

We are focusing on the following major research areas:

- (1) Increasing efficacy against solid tumors: developing innovative technologies, such as our CycloCAR® technology, to enhance efficacy of CAR T cells against solid tumors;
- (2) Enhancing safety profiles: developing innovative technologies to minimize safety concerns including CRS, neurotoxicity and on-target off-tumor toxicities;
- (3) Expanding patient accessibility: advancing our differentiated allogeneic THANK-uCAR® technology to reduce costs and increase affordability. THANK-uCAR® technology has the potential to overcome inefficient expansion and persistence associated with existing universal CAR T cells;
- (4) Improving target availability: exploring innovative technologies to enhance drug target availability and specificity of CAR T-cell therapy.

Technologies in these major research areas can be used to upgrade our existing product candidates as well as to generate future innovative pipeline product candidates. As of December 31, 2021, we had more than 300 patents of which more than 60 patents had been issued globally including China, the United States, Europe, and Japan. This is an increase of 31 issued patents and about 100 patent applications from the end of 2020. Our R&D activities would continue to generate substantial IP in our areas of expertise.

Manufacturing Capacity Expansion

We have established our in-house end-to-end clinical and commercial manufacturing capabilities for all three stages of CAR T manufacturing, including production of plasmids, lentiviral vectors and CAR T cells. With the clinical manufacturing facility in Xuhui, Shanghai and commercial GMP manufacturing facility in Jinshan, Shanghai ("**Jinshan Manufacturing Facility**"), we have been manufacturing CAR T cells in-house to support clinical trials in China and manufacturing the lentiviral vectors in-house to support clinical trials globally.

We have been expanding our manufacturing capacity in China and the U.S. to support both the clinical trials and the subsequent commercialization of our pipeline products. As of the Latest Practicable Date, we successfully passed the official facility inspections and received the Certificate of Compliance from the City-County Inspections Department of Durham for our RTP CGMP manufacturing facility ("**RTP Manufacturing Facility**") in Durham, North Carolina. The RTP Manufacturing Facility will provide CARsgen with additional manufacturing capacity of autologous CAR T-cell products for 700 patients annually. The RTP Manufacturing Facility will support the Company's ongoing clinical studies and early commercial launch in North America and Europe. CARsgen has started building a world-class CMC team for the RTP manufacturing facility operations. The RTP Manufacturing Facility project adopted an integrated project delivery approach that greatly shortens construction turnaround time and improves cost effectiveness.

Business Highlights

External License Agreement and Research Collaboration

CAFA THERAPEUTICS LIMITED, a subsidiary of CARsgen Therapeutics, has entered into a licensing agreement with HK inno.N Corporation (KOSDAQ: 195940) to develop and commercialize CT032 and CT053, for the potential treatment of various cancers in the Republic of Korea, with an upfront and additional milestone payments totaling up to USD50 million plus up to double-digit percentage royalties on net sales.

We also signed a new strategic agreement with Shanghai Cancer Institute for collaboration in oncology scientific and technologic research with the aim to enhance our understanding of oncology and technologies in CAR T-cell therapy and enrich our product pipeline.



Management Discussion and Analysis

1. OVERVIEW

CARsgen is a biopharmaceutical company with operations in China and the U.S. mainly focused on innovative CAR T-cell therapies for the treatment of hematologic malignancies and solid tumors. CARsgen has built an integrated cell therapy platform with in-house capabilities that span target discovery, antibody development, clinical trials, and commercial-scale manufacturing. CARsgen has internally developed novel technologies and a product pipeline with global rights to address major challenges of CAR T-cell therapies, such as improving the safety profile, enhancing the efficacy in treating solid tumors, and reducing treatment costs.

Our product pipeline includes an upgraded fully human BCMA CAR T (CT053), a global potential first-in-class Claudin18.2 CAR T (CT041) which is the only CLDN18.2-targeted CAR T-cell product candidate that is being studied in clinical trials with IND approvals, and a global potential first-in-class GPC3 CAR T (CT011). We have obtained eight IND clearances for CAR T-cell therapies in China, the United States, and Canada ranking the first among all CAR T-cell therapy companies in China. Our vision is to become a global biopharmaceutical leader that brings innovative and differentiated cell therapies to cancer patients worldwide and make cancer curable.

During the Reporting Period, we have made significant advancements in the areas of clinical development of our pipeline products, innovation of technology advancement, expansion of manufacturing facilities, and establishment of external partnerships. Specifically, we made progress in the following areas:

Rapid clinical development of our product pipeline in China and overseas

CT053

For CT053, an autologous CAR T-cell product candidate against BCMA being developed for the treatment of R/R MM we have completed patient enrollment in our pivotal Phase II trial in China (LUMMICAR STUDY 1). Phase I of LUMMICAR STUDY 1 showed no dose limiting toxicities (DLT), no treatment-related deaths, and no Grade 3 or higher events of cytokine release syndrome (CRS). No patient developed immune effector cell-associated neurotoxicity syndrome (ICANS). At the cut-off date of July 8, 2021, the objective response rate (ORR) was 100% (14/14). Of these 14 patients, 78.6% (11/14) achieved stringent complete responses (sCR) with minimal residual disease (MRD) 10^{-5} negative, and 9 patients reached sustained CR/sCR for more than 12 months. The 12-month progression-free survival (PFS) rate was 85.7% (12/14). The median duration of response (mDOR) and the median progression-free survival (mPFS) had not been reached. For the patients without EMD, the CR/sCR rate was 91.7% (11/12) and the 12-month PFS rate reached 100%.

In North America, we have initiated our Phase 2 CT053 trial, CT053 LUMMICAR STUDY 2, after receiving feedback from the U.S. FDA. As communicated with the U.S. FDA, we are adding outpatient administration of CT053 into our U.S. clinical investigations. We treated our first patient in the Phase 2 trial in August 2021.

As of August 27, 2021, 27 patients received CT053 infusion in the Phase 1b portion of LUMMICAR STUDY 2. There was no DLT or treatment related death. No grade 3 or higher CRS was observed. One (3.7%) transient Grade 3 immune effector cell-associated neurotoxicity syndrome (ICANS) occurred and it was fully resolved after steroid administration. The overall response rate was 96.3% (26/27). Duration of response, progression free survival and overall survival had not been reached.

Management Discussion and Analysis

CARsgen plans to submit the NDA to the NMPA in the first half of 2022 and plans to submit the BLA to the U.S. FDA in 2023. The Company also plans to conduct additional clinical trials to develop CT053 as an earlier line of treatment for multiple myeloma.

CT041

CT041 is an autologous CAR T-cell product candidate against the protein CLDN18.2 and has the potential to be first-in-class globally. CT041 targets the treatment of CLDN18.2 positive solid tumors with a primary focus on gastric/gastroesophageal junction cancer (GC/GEJ) and pancreatic cancer (PC). Leveraging our in-depth understanding in CAR T-cell therapy, as well as our integrated antibody platform, we were the first in the world to successfully identify, validate, and report CLDN18.2 as a solid tumor-associated antigen for the potential development of CAR T-cell therapies for solid tumors. To further address the challenges of CAR T-cell therapies in treating solid tumors, we have developed an innovative patent-protected preconditioning regimen, or the FNC regimen, before infusion of CT041, which features the addition of low-dose nab-paclitaxel to the conventional regimen using cyclophosphamide and fludarabine for lymphodepletion.

CT041 has demonstrated promising therapeutic efficacy and safety in the ongoing investigator-initiated trial in China for CLDN18.2 positive gastric cancer and pancreatic cancer. As of the latest data cut-off date of April 8, 2021, a total of 37 patients, including 28 patients with GC/GEJ, 5 with pancreatic cancer, and 4 with other types of digestive system tumors, received CT041 infusion. 18 GC/GEJ patients who had failed at least 2 prior lines of therapies were treated at a dose of 2.5×10^8 CAR T cells (recommended phase II dose). An ORR of 61.1%, DCR of 83.3%, median PFS of 5.6 months, median DOR of 6.4 months, and median OS of 9.5 months with a median follow-up time of 7.6 months were achieved. PFS, OS and follow up duration were calculated from CAR T-cell infusion date. CT041 also showed preliminary efficacy in five evaluable patients with pancreatic cancer who failed at least two prior lines of systemic treatment. CT041 was generally well-tolerated with no Grade 3 or higher CRS or neurotoxicity was reported (approximately 95% of patients experienced CRS, all of which were grade 1 or 2). No treatment-related death or ICANS was reported.

CT041 is the only CLDN18.2-targeted CAR T-cell product candidate globally that is being studied in clinical trials with IND/CTA approvals from the FDA, the NMPA, and Health Canada. We have initiated the investigator-initiated trials, a Phase Ib clinical trial for advanced GC/GEJ and PC and a confirmatory Phase II clinical trial for advanced GC/GEJ in China, and initiated a Phase 1b clinical trial for advanced gastric or pancreatic adenocarcinoma in North America. CARsgen plans to submit an NDA to the NMPA in China in the first half of 2024 and also plans to initiate a Phase 2 clinical trial in the second half of 2022 in North America and to submit the BLA to the U.S. FDA in 2024.

Management Discussion and Analysis

Other Candidates

We are also on track in progressing other pipeline product candidates including (i) CT011, an autologous CAR T-cell product candidate against GPC3 being developed for the treatment of HCC. We have completed the enrollment of the Phase I trial in China; (ii) CT032, an autologous CAR T-cell products candidate against CD19 being developed for the treatment of B cell Non-Hodgkin's lymphoma. We are conducting a Phase I/II clinical trial in China; (iii) AB011, a humanized monoclonal antibody product candidate against CLDN18.2 and being developed for the treatment of CLDN18.2 positive solid tumors. We received supplemental application approval by the CDE regarding the addition of chemotherapy combination cohort with AB011 in Phase Ib, and we have subsequently initiated the combination cohort of AB011 with chemotherapy. We completed phase I monotherapy cohort enrollment and initiated combination with chemotherapy; and (iv) the IND-enabling or pre-clinical stage product candidates including CT0180, CT0181, KJ-C2111 (CT0590), KJ-C1807 (CT048), KJ-C2112, KJ-C2113 and KJ-C2114. We continue to drive the development and expect to submit IND applications as planned.

Continuous Discovery and Technology Development

Despite the approved CAR T-cell products for the treatment of terminal line hematologic malignancies, there are still significant challenges, such as limited efficacies against solid tumors, undesirable safety concerns, and high manufacturing and treatment costs. We strive to explore and develop innovative technology platforms to address these challenges to generate better cell therapy products to global cancer patients. Our main focus includes:

- (1) Increasing efficacy against solid tumors: developing innovative technologies, such as our CycloCAR[®] technology, to enhance efficacies of CAR T cell against solid tumors. CycloCAR[®] is a next generation CAR T technology, which co-expresses cytokine IL-7 and chemokine CCL21 and potentially has greater clinical efficacy and reduced requirement for lymphodepletion conditioning;
- (2) Enhancing safety profile: developing innovative technologies to minimize safety concerns including CRS/neurotoxicity/on-target off-tumor toxicities;
- (3) Expanding patient accessibility: advancing our differentiated allogeneic THANK-uCAR[®] technology to reduce costs and increase affordability. THANK-uCAR[®] technology has the potential to overcome inefficient expansion and persistence associated with existing universal CAR T cells;
- (4) Improving target availability: exploring innovative technologies that can potentially enhance drug target availability and specificity of CAR T-cell therapy. We developed Local Action Driven by Artificial Receptor (LADAR[®]) technology, in which the intracellular transcription of the gene of interest is controlled by a chimeric regulatory antigen receptor. Through the LADAR[®] artificial receptor, the intracellular activity is only triggered when the extracellular domain is activated upon binding to specific antigen, making it possible to precisely control when and where immune cells act against cancer cells.

Management Discussion and Analysis

These technologies are currently being developed in-house with global rights and can be used alone or combined to upgrade our existing product candidates as well as to generate future innovative pipeline product candidates.

As of December 31, 2021, we had more than 300 patents of which more than 60 patents had been issued globally including China, the United States, Europe and Japan. This is an increase of 31 issued patents and about 100 patent applications from the end of 2020. Our R&D activities would continue to generate substantial IP in our areas of expertise.

Manufacturing Capacity Expansion

We have established our in-house end-to-end clinical and commercial manufacturing capabilities for all three stages of CAR T manufacturing, including production of plasmids, lentiviral vectors, and CAR T cells. With the clinical manufacturing facility in Xuhui, Shanghai and Jinshan Manufacturing Facility, we have been manufacturing CAR T cells in-house to support clinical trials in China and manufacturing the lentiviral vectors in-house to support clinical trials globally.

We have been expanding our manufacturing capacity in China and the U.S. to support both the clinical trials and the subsequent commercialization of our pipeline products. As of the Latest Practicable Date, we have made significant progress in the construction of RTP Manufacturing Facility in Durham, North Carolina. We successfully passed the official facility inspections and received the Certificate of Compliance from the City-County Inspections Department of Durham. We have commenced commissioning, qualification, and validation of RTP Manufacturing Facility including the consultation with the FDA. Concurrently, we have been executing the technology transfer of CT053 and CT041 manufacturing process and analytical procedures to RTP Manufacturing Facility, advancing to the clinical manufacturing operations. The RTP Manufacturing Facility, with a total gross floor area of approximately 3,300 sq.m, will provide additional manufacturing capacity of autologous CAR T-cell products for 700 patients annually, and it will support the Company's ongoing clinical studies and early commercial launch in North America and Europe.

External License Agreement and Research Collaboration

In addition to the internal research and development activities, we are also actively seeking extensive collaborations with external partners. CAFA THERAPEUTICS LIMITED, a subsidiary of CARsgen Therapeutics, has entered into a licensing agreement with HK inno.N Corporation (KOSDAQ: 195940), a fully-integrated pharmaceutical company, to develop and commercialize CT032 and CT053, targeting CD19 and BCMA respectively, for the potential treatment of various cancers in the Republic of Korea. Under the terms of the agreement, CARsgen is entitled to receive an upfront payment and additional milestone payments totaling up to USD50 million as well as up to double-digit percentage royalties on net sales in the Republic of Korea. The collaboration with HK inno.N Corporation showcases our commitment to establishing more external partnerships with leading pharmaceutical companies to maximize the application of our technology platform and the value of our product pipeline to benefit more cancer patients globally.

Management Discussion and Analysis

On July 31, 2021, we reached a new agreement with Shanghai Cancer Institute, Shanghai Jiao Tong University School of Medicine Affiliated Renji Hospital, for strategic collaboration in oncology research and technology development, following a previous agreement reached in 2015 between the two parties. This new agreement will accelerate the translation from early scientific research to clinical application for innovative cancer treatment options. This continued collaboration with Shanghai Cancer Institute will further enhance our understanding of technologies in CAR T-cell therapy and enrich our product pipeline.

Expansion and Retention of Talent

During the Reporting Period, we have expanded our team from about 337 employees as of December 31, 2020 to 573 employees as of December 31, 2021. We have also strengthened the leadership team. As of the Latest Practicable Date, we have hired Dr. Raffaele BAFFA as the Chief Medical Officer of the Company, responsible for overseeing the global clinical development strategies and operations for the Company's innovative pipeline product candidates. We have hired Mr. Richard John DALY as the President of CARsgen Therapeutics Corporation, a subsidiary of the Company in the U.S., and he will lead the CARsgen US team for the international business activities of CARsgen outside of China, including clinical development, CMC operation, business development, commercialization, investor relations and public relations. We have hired Dr. CHEN Baolu as Senior Vice President of CMC Operation, responsible for the establishment and implementation of global CMC strategies. We have hired Ms. JIANG Caihua as Senior Vice President of Quality, responsible for the establishment and implementation of global quality management system for CARsgen. We have hired Dr. ZHOU Guanjun as Vice President of Government Relations. Dr. Zhou is committed to monitoring policies and trends of biopharmaceutical industry and responsible for developing and strengthening relationships and communications with relevant government parties to support business development and strategic decisions for CARsgen in China.

Management Discussion and Analysis

2. BUSINESS REVIEW

Our product and Product Pipeline

Since our inception, we have adopted and executed a strategic business model of self-developing innovative and differentiated biopharmaceutical products with a focus on CAR T-cell therapies. Within our pipeline, our Core Product Candidate, CT053, is for the treatment of R/R MM, a form of hematologic malignancy, and is at the most advanced development stage among our product candidates in our pipeline. In addition, CT041, CT011, and AB011 in our pipeline, are for the treatment of solid tumors, and in confirmatory Phase II, Phase I, and Phase Ib clinical trials, respectively. The following chart summarizes our pipeline and the development status of each product candidate as of the Latest Practicable Date. Our product candidates are discovered and developed in-house, and we own the global rights to our product candidates. The clinical-stage product candidates are currently being developed for treating advanced stage cancers.

	Product Candidates	Target	Global Rights	Pre-clinical	Phase I	Pivotal***	
						Phase II/III	BLA/NDA
CAR T-cell therapies	CT053*	BCMA	Global**	R/R MM (China)			
				R/R MM (US, Canada)			
				R/R MM (IIT)			
	CT041	Claudin 18.2	Global	GC/GEJ (China)			
				GC/PC (US, Canada)			
				PC (China)			
				GC/GEJ and PC (IIT)			
	CT011	GPC3	Global	HCC (China)			
	CT032	CD19	Global**	B-NHL (China)			
	CT0180	GPC3	Global	HCC (IIT)			
	CT0181	GPC3	Global	HCC (IIT)			
	KJ-C2111 (CT0590)	BCMA	Global	R/R MM (IIT)			
KJ-C1807 (CT048)	Claudin 18.2	Global	GC/GEJ and PC				
KJ-C2112	EGFR/EGFRvIII	Global	Glioblastoma				
KJ-C2113	Mesothelin	Global	Solid tumor				
KJ-C2114	Undisclosed	Global	Solid tumor				
mAb	AB011	Claudin 18.2	Global	GC/PC (China)			

Notes:

* Core Product Candidate;

** Rights for the Republic of Korea market have been licensed out to HK Inno.N Corporation (KOSDAQ: 195940);

*** Phase II trials of some indications are pivotal studies;

R/R MM: relapsed/refractory multiple myeloma; GC: gastric cancer; PC: pancreatic cancer; B-cell non-Hodgkin lymphoma; GEJ: gastroesophageal junction cancer; HCC: hepatocellular carcinoma cancer.

Management Discussion and Analysis

Fully Human BCMA CAR T (CT053) – Our Core Product Candidate

CT053 is an upgraded fully human, autologous BCMA CAR T-cell product candidate for the treatment of R/R MM. It incorporates a CAR construct engineered by CARsgen that features a fully human BCMA-specific single-chain variable fragment with lower immunogenicity and increased stability, which reduces the self-activation of CAR T cells in the absence of tumor associated targets.

CARsgen has completed the patients enrollment of the pivotal Phase II trial patients in China (LUMMICAR STUDY 1) and plans to submit the NDA to the NMPA in the first half of 2022. CARsgen is conducting the pivotal Phase 2 trial in North America (LUMMICAR STUDY 2), and the Company plans to submit the BLA to the U.S. FDA in 2023. The Company also plans to conduct additional clinical trials to develop CT053 as an earlier line of treatment for multiple myeloma.

At the 2021 ASH Annual Meeting, the Company presented two posters with study results for CT053 (an autologous CAR T-cell product candidate against BCMA), which include (1) the sustainable efficacy and safety results from the Phase I/II study in China (LUMMICAR-1), and (2) an integrated analysis in patients with R/R MM by high-risk factors.

A total of 14 heavily pretreated patients received CT053 infusion in the Phase I LUMMICAR STUDY 1. No DLT, no treatment-related deaths, and no Grade 3 or higher events of CRS were observed. No patient developed ICANS. At the cut-off date of July 8, 2021, the ORR was 100% (14/14). Of these 14 patients, 78.6% (11/14) achieved sCR with MRD 10^{-5} negative, and 9 patients reached sustained CR/sCR for more than 12 months. 92.9% (13/14) of patients achieved at least very good partial responses (VGPR). The 12-month PFS rate was 85.7% (12/14). The mDOR and the mPFS had not been reached. For the patients without extramedullary disease (EMD), the CR/sCR rate was 91.7% (11/12) and the 12-month PFS rate reached 100%, which demonstrate better treatment trends.

Our Investigator initiated trials (IITs) were initiated in September 2017. A total of 24 heavily pretreated patients received CT053 BCMA CAR T-cell infusion. No treatment-related death and no Grade 3 or higher events of CRS were observed. One patient developed Grade 3 neurotoxicity (convulsion) which resolved quickly. The ORR and CR/sCR were 87.5% and 79.2%, respectively. As of June 30, 2021, with a median follow-up time of 14.8 months, the DOR and PFS were 21.8 months (95%CI, 9.2-NR) and 18.8 months (95%CI, 10.1-NR), respectively. The PFS rate at 24 months was 42.4%. Eight patients are still in remission and in long-term follow-up.

CT053 represents a promising treatment option for patients with R/R MM, including patients with high-risk disease, and it is generally well-tolerated. A total of 38 patients (IITs and LUMMICAR STUDY 1) received CT053 infusions. Of these, 31.6% of patients had EMD, 50.0% of patients had high-risk cytogenetics, and 28.9% of patients had ISS stage III disease. Based on the results of the analysis stratified by high-risk factors, the CR/sCR rate, mPFS, and mDOR were 58.3%, 9.3 months, and 9.2 months in patients with EMD, whereas the measures in patients without EMD were 88.5%, 25.0 months, and 24.0 months, respectively. The mPFS and mDOR in patients with high-risk cytogenetics were 15.6 months and 18.3 months, and were both 13.3 months in ISS III patients, while mPFS and mDOR had not been reached in patients without these two high-risk factors. These results suggest that the presence of the high-risk disease characteristics of EMD, high-risk cytogenetics, and ISS stage III at baseline might affect the clinical benefits. Although there were 50% of patients with high-risk disease at baseline, in the 13.9 months median follow-up time, the ORR was 92.1% (35/38), with 78.9% (30/38) of patients achieving CR/sCR and 86.8% (33/38) of patients achieving at least VGPR, and the mPFS and mDOR were 22.7 months and 24.0 months respectively.

Management Discussion and Analysis

In North America, we have initiated our Phase 2 CT053 trial of LUMMICAR STUDY 2. As communicated with the U.S. FDA, we are adding outpatient administration of CT053 into our U.S. clinical investigations. We treated our first patient in the Phase 2 trial in August 2021.

As of August 27, 2021, 27 patients received CT053 infusion in the Phase 1b portion of LUMMICAR STUDY 2. There was no DLT and no treatment related death. No Grade 3 or higher CRS was observed. One (3.7%) transient Grade 3 ICANS occurred and it fully resolved after steroid administration. The ORR was 96.3% (26/27). The mPFS, mDOR and mOS had not been reached.

Additional data from these clinical trials are planned to be disclosed in academic journals or conferences.

CARsgen has developed CT053 in-house with our integrated research and development platform. CT053 has received Regenerative Medicine Advanced Therapy (RMAT) and Orphan Drug designations for the treatment of R/R MM from the U.S. FDA in 2019, PRiority MEdicines (PRIME) eligibility and Orphan Medicinal Product designation for the treatment of R/R MM from the EMA in 2019 and 2020, respectively, and Breakthrough Therapy designation for the treatment of R/R MM from the NMPA in 2020.

We believe that CT053, the BCMA CAR T-cell product candidate with an upgraded, fully human CAR, has a promising efficacy profile and a favorable safety profile, as evidenced by the absence of Grade 3 or higher CRS and no treatment-related patient deaths in the investigator-initiated trials and the Phase I clinical trials.

WE MAY NOT BE ABLE TO ULTIMATELY MARKET CT053 SUCCESSFULLY.

Humanized CLDN18.2 CAR T (CT041)

CT041 is an autologous CAR T-cell product candidate against the protein CLDN18.2 and has the potential to be first-in-class globally. CT041 targets the treatment of CLDN18.2 positive solid tumors with a primary focus on gastric/gastroesophageal junction cancer and pancreatic cancer. CLDN18.2 is expressed in a range of different solid tumors, including gastric/gastroesophageal junction cancer, pancreatic, colorectal, lung, and ovarian cancers. Leveraging our in-depth understanding in CAR T-cell therapy, as well as our integrated antibody platform, we were the first in the world to successfully identify, validate, and report CLDN18.2 as a solid tumor-associated antigen for the potential development of CAR T-cell therapies for solid tumors in which CLDN18.2 is prevalently or highly expressed. To further address the challenges of CAR T-cell therapies in treating solid tumors, we have developed an innovative preconditioning regimen, or the FNC regimen, before infusion of CT041, which features the addition of low-dose nab-paclitaxel to the conventional regimen using cyclophosphamide and fludarabine for lymphodepletion.

CT041 is the only CLDN18.2-targeted CAR T-cell product candidate globally that is being studied in clinical trials with IND/CTA approvals from the FDA, the NMPA, and Health Canada. We have initiated the investigator-initiated trials, a Phase Ib clinical trial for advanced GC/GEJ and PC and a confirmatory Phase II clinical trial for advanced GC/GEJ in China, and initiated a Phase 1b clinical trial for advanced gastric or pancreatic adenocarcinoma in North America. CARsgen plans to submit an NDA to the NMPA in China in the first half of 2024 and also plans to initiate a Phase 2 clinical trial in the second half of 2022 in North America and to submit the BLA to the U.S. FDA in 2024.

Management Discussion and Analysis

CT041 has demonstrated promising therapeutic efficacy and safety in the ongoing investigator-initiated trial, which is led by Dr. Lin Shen at the Beijing Cancer Hospital.

At the European Society for Medical Oncology Congress 2021 (“**ESMO Congress 2021**”), we have orally presented updates on the investigator-initiated trial of CT041. As of April 8, 2021, 37 patients received CT041 infusion and completed at least 12 weeks of evaluation, including 28 cases of gastric/gastroesophageal junction cancer (GC/GEJ), 5 cases of pancreatic cancer (PC) and 4 cases of other types of digestive system tumors. Approximately 84% of patients had received at least 2 prior lines of therapies and the median number of metastatic organs was 3.

For the 28 patients with GC/GEJ, 67.9% of the patients had peritoneal metastases. 42.9% and 35.7% of the patients had been exposed to anti-PD-(L)1 antibody and multikinase inhibitor respectively.

Within the 28 patients with GC/GEJ, 18 received at least 2 prior lines of therapies. 18 GC/GEJ patients who had failed at least 2 prior lines of therapies (including 8 (44% of) patients had exposed to an anti-PD-(L)1 antibody) were treated at a dose of 2.5×10^8 (recommended phase II dose) CAR T cells and achieved an ORR of 61.1%, DCR of 83.3%, median PFS of 5.6 months, median DOR of 6.4 months, and median OS of 9.5 months with a median follow-up of 7.6 months. PFS, OS and follow up duration were calculated from CAR T-cell infusion date.

For the 28 patients with GC/GEJ, a subgroup analysis revealed that ORR could be maintained at 50% or above in patients with different baseline characteristics, such as expression level of CLDN18.2 and previous anti-PD-(L)1 antibody treatment. See the following table for details:

	Number of patients	ORR
CLDN18.2 expression		
High expression ($\geq 2+$, $\geq 70\%$)	19	57% (37.2, 75.5)
Medium expression ($\geq 2+$, $\geq 40\%$ and $< 70\%$)	7	58% (33.5, 79.7)
Low expression ($+$ or $< 40\%$)	2	50% (1.3, 98.7)
Previous anti-PD-(L)1 antibody treatment		
Unreceived	16	63% (35.4, 84.8)
Received	12	50% (21.1, 78.9)
Peritoneal Metastasis		
Yes	19	58% (33.5, 79.7)
No	9	56% (21.2, 86.3)
WHO Classification		
Signet ring cell carcinoma	12	58% (27.7, 84.8)
Others	15	60% (32.3, 83.7)
Lauren Classification		
Intestinal	10	70% (34.8, 93.3)
Diffused/Mixed	16	50% (24.7, 75.3)

CT041 also showed preliminary efficacy in five evaluable patients with pancreatic cancer who failed at least 2 prior lines of systemic treatment. Additional data from this clinical trial are planned to be disclosed in academic journals or conferences.

Management Discussion and Analysis

CT041 was generally well-tolerated with no Grade 3 or higher CRS and no neurotoxicity reported (approximately 95% of patients experienced CRS, all of which were grade 1 or 2). No treatment-related death and no ICANS were reported. The CT041 cells were observed to persist in the peripheral blood for eight weeks and up to six months and achieve T cell expansion up to several to tens of thousands of CAR copies in blood per microgram of genomic DNA.

In North America, we have initiated our Phase 1b trial of CT041-ST-02. We have treated the first patient in July 2021.

In 2020 and 2021, CT041 received Orphan Drug designation from the U.S. FDA for the treatment of GC/GEJ and Orphan Medicinal Product designation from the EMA for the treatment of advanced gastric cancer. In November 2021, CT041 was granted PRIME eligibility by the EMA for the treatment of advanced gastric cancer. In January 2022, CT041 was granted Regenerative Medicine Advanced Therapy (RMAT) Designation for the treatment of advanced gastric or gastroesophageal junction adenocarcinoma with CLDN18.2 positive tumors.

We believe CT041 has the potential to fulfill the significant unmet clinical needs for the treatment of gastric and pancreatic cancer and serve as a proof-of-concept for our breakthrough technology to apply CAR T modality to treating solid tumors.

WE MAY NOT BE ABLE TO ULTIMATELY MARKET CT041 SUCCESSFULLY.

Humanized GPC3 CAR T (CT011)

CT011 is a CAR T-cell product candidate with proof-of-concept clinical data for the treatment of HCC and has the potential to be the first-in class globally. Our co-founder, CEO and Chief Scientific Officer, Dr. Li Zonghai led the world's first successful effort in identifying, validating and reporting GPC3 as a tumor-associated target for the development of CAR T-cell therapies to treat HCC. Our investigator-initiated trial in China enrolled 13 patients with advanced GPC3+ HCC and demonstrated that CT011 therapy was generally tolerable in patients who have been heavily pretreated. The overall survival rates at 6 months, 1 year and 3 years were 50.3%, 42.0% and 10.5%, respectively, with a median overall survival of 278 days. We have completed enrollment of a Phase I trial in China.

Humanized CD19 CAR T (CT032)

CT032 is an autologous CAR T-cell product candidate against CD19 being developed for the treatment of B cell NHL. CT032 incorporates a humanized CD19-specific single-chain fragment variant, which we expect to reduce the toxicity of CT032 and reduce immunogenicity, as compared to currently commercialized CD19-specific CAR T-cell products which use murine anti-CD19 single chain variable fragment as the targeting moiety. We are conducting an open-label, single arm, Phase I/II trial in China to evaluate the safety and tolerability of CT032.

Management Discussion and Analysis

Anti-CLDN18.2 mAb (AB011)

AB011 is a humanized monoclonal antibody product candidate that targets CLDN18.2, which is a stomach-specific isoform of Claudin-18 and is highly expressed in gastric and pancreatic cancer cells. AB011 displayed strong in vitro antitumor activities against CLDN18.2 positive tumor cells in antibody-dependent cellular cytotoxicity (ADCC) assays and complement-dependent cytotoxicity (CDC) assays and showed potent in vivo antitumor activities when combined with oxaliplatin and 5-fluorouracil in CLDN18.2 positive gastric cancer mouse models. We obtained the second IND clearance in the world for a mAb targeting CLDN18.2. We are conducting a Phase I clinical trial of AB011 for the treatment of CLDN18.2 positive solid tumors in China to evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy of AB011 injection.

In the second quarter of 2021 we received supplemental application approval by the CDE regarding the addition of chemotherapy combination cohort with AB011 in Phase Ib, and we have subsequently initiated the combination cohort of AB011 with chemotherapy. We completed phase I monotherapy cohort enrollment and initiated combination with chemotherapy. In the monotherapy phase, we observed that one patient with advanced gastric cancer who had failed previous second-line chemotherapy achieved a CR. During the combination treatment phase, the first two patients with advanced gastric cancer were assessed to be in PR at week 6 after the first dose.

We plan to consult with the NMPA in the second half of 2022 and to initiate the subsequent Phase II clinical trial.

IND-Enabling or Pre-Clinical Stage Product Candidates

In addition to the above clinical-stage product candidates which are in IND trials, we have internally developed seven IND-enabling or pre-clinical stage product candidates as described below.

CT0180 is an autologous T cell product engineered to express a fusion protein of GPC3-targeted antibody fused T cell receptor (aTCR). It consists of a single-chain variable fragment (scFv) targeting GPC3 and a CD3 ϵ subunit, which can form a functional TCR complex with other TCR subunits (TCR α , TCR β , CD3 γ , CD3 δ and CD3 ζ) and redirect T cells to kill tumor cells in an MHC-independent manner. Our preclinical studies have shown that CT0180 could effectively recognize and kill GPC3-positive hepatocellular carcinoma cells and significantly inhibit HCC tumor growth in mouse xenograft models with reduced cytokine release compared to GPC3-CAR T cells in vitro and in vivo, which improve the safety and applicability of adoptive cell therapies. IIT trial has been initiated in China to evaluate the efficacy and safety of CT0180 in the treatment of hepatocellular carcinoma.

CT0181 is an autologous T cell product engineered with GPC3-targeted antibody fused T cell receptor co-expressing IL-7 cytokine. It consists of a single-chain variable fragment (scFv) targeting GPC3 and a CD3 ϵ subunit which can form a functional TCR complex with other TCR subunits (TCR α , TCR β , CD3 γ , CD3 δ and CD3 ζ) and redirect T cells to kill tumor cells in an MHC-independent manner. Co-expressed IL-7 via a 2A peptide is a cytokine that could enhance the proliferation and survival of T cells. Our preclinical studies have shown that CT0181 displays superior antitumor efficacy, T cell persistence, and immunological memory in solid tumors xenografts with low cytokine release compared to GPC3-CAR T cells. IIT trial has been initiated in China to evaluate the efficacy and safety of CT0181 in the treatment of hepatocellular carcinoma.

Management Discussion and Analysis

KJ-C2111 (CT0590) is an allogeneic CAR T-cell product candidate deploying our THANK-uCAR® technology that targets BCMA. We are developing KJ-C2111 for the treatment of R/R MM. We have initiated IIT trial to evaluate the efficacy and safety of CT0590 for the treatment of R/R MM.

KJ-C1807 (CT048) is a next-generation autologous CAR T-cell product candidate developed with our CycloCAR® technology. We anticipate that by co-expressing cytokine IL-7 and chemokine CCL21, KJ-C1807 potentially has a greater clinical efficacy and reduced requirement for lymphodepletion conditioning. KJ-C1807 targets CLDN18.2 and is being developed to treat patients with gastric/gastroesophageal junction cancer and pancreatic cancer.

KJ-C2112 is a next-generation autologous EGFR/EGFRvIII-bitargeted CAR T-cell product candidate harboring a humanized single-chain antibody with single specificity that binds to an epitope present on wild-type EGFR – and EGFRvIII-overexpressing tumor cells, but not on EGFR-expressing normal cells. KJ-C2112 is armored with a transcription factor. Pre-clinical studies have demonstrated the efficacy of KJ-C2112, such as its ability to suppress growth of EGFR-and/or EGFRvIII-overexpressing glioma xenografts in mice and prolong the survival of tumor-bearing mice. Therefore, KJ-C2112 may be a promising modality for the treatment of patients with EGFR/EGFRvIII-overexpressing glioblastoma. We plan to collaborate with an experienced reputable principal investigator and further study KJ-C2112 in an investigator-initiated trial.

KJ-C2113 is a next-generation autologous CAR T-cell product candidate developed with our CycloCAR® technology that targets mesothelin, a tumor differentiation antigen normally restricted to the body's mesothelial surfaces, but significantly overexpressed in a broad range of solid tumors. We are developing KJ-C2113 for the treatment of various types of solid tumors.

KJ-C2114 is an allogeneic CAR T-cell product candidate deploying our THANK-uCAR® technology with an undisclosed target for the treatment of certain solid tumors.

Discovery and Pre-clinical Research

We have established an integrated research and development platform covering the full CAR T development cycle including target discovery, antibody development, vector design, manufacturing, quality assurance, and quality control. Our integrated cell therapy platform is composed of target discovery, hybridoma and antibody humanization platform, fully human phage display antibody library platform, antibody identification platform, immune cell function evaluation platform, plasmid and lentiviral vector preparation platforms, cell therapy process development platform, analytical platforms with molecular, flow cytometry, biochemical, physical-chemical, and cell-based analytical capabilities, biological samples tests platform, clinical-scale and commercial-scale CAR T manufacturing platform, and platform for clinical studies. This platform enables us to efficiently and effectively advance a product candidate from early discovery to clinical trials and potentially to commercialization.

We continue to dedicate ourselves to advancing innovative CAR T technologies to address the major challenges of the industry.

Management Discussion and Analysis

To enhance the efficacy against solid tumors, we continue to develop next generation CAR T technologies, such as CycloCAR®. CycloCAR® is featured by co-expression of cytokines IL-7 and chemokine CCL21 in the CAR T cells to potentially improve clinical efficacy and reduce the requirement of lymphodepletion conditioning. Our preclinical studies have shown that IL-7 could enhance the proliferation and survival of CAR T cells and inhibit the apoptosis of CAR T cells, and CCL21 could drive infiltration of T cells and dendritic cells into tumor sites. The CycloCAR T cells could improve the therapeutic effects against solid tumors in mice when compared with conventional CAR T cells. Moreover, even without preconditioning chemotherapy, the CycloCAR T cells could potentially suppress the tumor growth with a significantly better efficacy than CAR T cells co-expressing IL-7 and CCL19 (7×19 CAR T, a previously reported design by other researchers). Taken together, our studies demonstrated that, independent of lymphodepletion chemotherapy, CycloCAR T cells exert potent antitumor effects which are facilitated by infiltration of T cells and dendritic cells into tumor tissues, increase in survival of CAR T cells, as well as the potential anti-angiogenesis effect. We are using CycloCAR® to develop CAR T-cell therapies against several different targets including CLDN18.2, GPC3 and mesothelin. We continue to explore potential combination approaches to boost the therapeutic effects of single agents and identify new targets and approaches to tackle new indications.

To minimize the safety concerns, we continue to develop innovative technologies that can help reduce the CRS, neurotoxicity and on-target off-tumor toxicities. We are able to leverage our own antibody platform, powered by a fully human phage display library and improved hybridoma technology, to identify and optimize antibody fragments with higher specificity for tumor targets and increased stability, which lead to reduced auto-activation of CAR T cells in the absence of tumor targets and controlled level of cytokine release. As a proof-of-concept of our antibody engineering capabilities, we have developed CT053, which had not induced Grade 3 or higher CRS in the investigator-initiated trials or in the Phase I clinical trials and allowed less administration of anti-IL-6 medication and other immunosuppressant medication as of the respective data cutoff date of the ongoing investigator initiated trials and clinical trials. We continue to explore other innovative technologies to improve the safety profiles of CAR T cells while maintaining or enhancing the anti-tumor effects.

To reduce the cost and increase the accessibility of CAR T-cell therapies, we continue to develop our differentiating allogeneic THANK-uCAR® technology. THANK-uCAR® is our proprietary technology to generate allogeneic CAR T cells with improved expansion and persistence by modifying donor-derived T cells. To minimize graft versus host disease (GvHD) and host versus graft response (HvGR) from allogeneic T cells, we disrupt the genomic loci encoding T cell receptor (TCR) and β 2 microglobulin (B2M) to eliminate surface expression of the TCR or the human leukocyte antigen (HLA), an approach that has been validated by previous research. However, NK cells attack T cells without HLA expression, which then limits the expansion and persistence of the allogeneic CAR T cells. To protect the allogeneic CAR T cells from the patient's NK cells, we arm the TCR/HLA⁻ CAR T cells with a CAR that recognizes NKG2A to eliminate the NKG2A positive NK cells and therefore resist the attack by NK cells. Our in vitro and in vivo studies demonstrated that the arming the TCR/HLA⁻ CAR T cells with anti-NKG2A CAR resulted in improved expansion in the presence of NK cells. We are developing allogeneic CAR T-cell product candidates using THANK-uCAR® technology, which we believe could potentially increase CAR T cell expansion, persistence and efficacy. We believe the successful application of THANK-uCAR® technology would significantly lower the cost of CAR T-cell therapy and eventually increase patient accessibility.

Management Discussion and Analysis

In the development of cancer therapies, the non-specific expression of tumor associated antigens poses a significant challenge, as these antigens are also expressed in normal tissues, leading to the on-target off-tumor toxicities. To resolve the challenge with target availability, we continue to explore innovative technologies to enhance drug target availability and therefore make undruggable targets druggable. We developed LADAR[®] technology, in which the intracellular transcription of the gene of interest is controlled by a chimeric regulatory antigen receptor. Through the LADAR[®] artificial receptor, the intracellular activity is only triggered when the extracellular domain is activated upon binding to specific antigen, making it possible to precisely control when and where immune cells act against cancer cells.

The LADAR-CAR circuits require both antigens for LADAR[®] and CAR recognition to kill target cells and thus reduce on-target off-tumor effects since these two antigens are not simultaneously expressed in normal tissues. In our in vitro studies, LADAR[®] system induced strong gene expression in response to antigen engagement and importantly, nearly no leakage expression in resting cells. LADAR-CAR T cells executed killing function only if both the antigens presented.

We are also working on other applications of LADAR[®] system, such as LADAR-cytokine circuits. We believe that the establishment of LADAR[®] system is the key step to develop the CAR T cells with powerful and precise killing of cancer.

To develop effective CAR T-cell products for more cancer types and further enhance the anti-tumor effect, we have been expanding our research to more promising oncology targets for cell therapies. In addition, leveraging our proprietary antibody platforms, we have successfully developed humanized or fully-human antibodies against these targets, such as GPRC5D, B7-H3, etc. These antibodies, together with our CAR-T technology platforms, will help further enhance the product pipeline.

Utilizing these technologies, we strive to further enrich our product pipeline and subsequently progress to these pipeline product candidates clinical and commercial stage.

As of December 31, 2021, we had more than 300 patents of which more than 60 patents had been issued globally including China, the United States, Europe and Japan. This status is an increase of 31 issued patents and about 100 patent applications from the end of 2020. Our R&D activities would continue to generate substantial IP in our areas of expertise.

Manufacturing

We have established in-house GMP-compliant manufacturing capabilities to support end-to-end CAR T manufacturing, including plasmids, lentiviral vectors and CAR T cells production. Our clinical manufacturing facility in Xuhui, Shanghai with a total gross floor area, or GFA, of approximately 3,000 sq.m. and an annual CAR T production capacity to support the CAR T-cell treatment of 200 patients has been used for clinical manufacturing of CAR T-cell products in supporting multiple clinical studies of our leading assets. Since establishment, our Xuhui facility has achieved over 95% manufacturing success rate for all product candidates.

We have also completed the construction of our commercial-scale manufacturing facility located in Jinshan, Shanghai with a total GFA of approximately 7,600 sq.m. and an estimated manufacturing capacity to support CAR T-cell treatment of up to 2,000 patients annually. The Jinshan Manufacturing Facility passed the on-site inspection conducted by the Shanghai Medical Products Administration, or the SHMPA, and obtained the first Manufacture License for Pharmaceutical Products (“**Manufacturing License**”) issued in China for CAR T-cell therapy.

Management Discussion and Analysis

With the clinical manufacturing facility in Xuhui, Shanghai and the commercial manufacturing facility in Jinshan, Shanghai, we can produce the lentiviral vectors and CAR T cells in-house to support clinical trials and CAR T cells commercialization in China. We also provide the lentiviral vectors to the clinical trials outside of China.

We have made significant progress in the construction of CARsgen RTP Manufacturing Facility in Durham, North Carolina. We successfully passed the official inspections and received the Certificate of Compliance from the City-County Inspections Department of Durham. We have commenced commissioning, qualification, and validation of RTP Manufacturing Facility including the consultation with the FDA. Meanwhile, we have been executing the technology transfer of CT053 and CT041 manufacturing process and analytical procedures to RTP Manufacturing Facility, advancing to the operations of clinical manufacturing.

The RTP Manufacturing Facility, with a total gross floor area of approximately 3,300 sq.m, will provide CARsgen with additional manufacturing capacity of autologous CAR T-cell products for 700 patients annually. The RTP Manufacturing Facility will support the Company's ongoing clinical studies and early commercial launch in North America and Europe. CARsgen has started building a world-class CMC team for the RTP manufacturing facility operations. The RTP Manufacturing Facility project adopted an integrated project delivery approach that greatly shortens construction turnaround time and improves cost effectiveness. This project has received the Job Development Investment Grant (JDIG) award and other investment incentives from North Carolina state, Durham County and Durham City.

To accelerate the clinical production at the RTP Manufacturing Facility, CARsgen Jinshan Manufacturing Facility in Shanghai, China will continue to provide the lentiviral vector used in manufacturing of CAR T-cell products for CT053 and CT041 clinical studies under active INDs cleared by the U.S. FDA. CARsgen has established sustainable and scalable GMP manufacturing capacity of lentiviral vectors. The large-scale production of lentiviral vector at Jinshan Manufacturing Facility could significantly reduce the manufacturing costs of CAR T-cell products.

By building end-to-end manufacturing capabilities in-house, we expect to significantly increase manufacturing sustainability, reduce manufacturing costs, and shorten the vein-to-vein time. In addition, we have an in-house GMP-compliant manufacturing facility capable of high yield production of lentiviral vectors. Our Jinshan, Shanghai facility has been allowed by the U.S. FDA to provide lentiviral vectors for manufacturing our CT041 and CT053 cell products in support of U.S. clinical trials. With large scale lentiviral vectors production, we could greatly reduce the CAR T manufacturing costs.

Commercialization

To better prepare for the commercialization of our innovative CAR T-cell products, we have started to formulate our marketing strategies in a staggered approach corresponding to the expected launch timeline of our product candidates. The staggered approach features stepwise expansion of our future marketing efforts. We have established a marketing team for the pre-launch activities of CT053 and CT041. For the China market, with NDA submission for CT053 expected in the first half of 2022, we intend to cover key Class III Grade A hospitals that are equipped to administer CT053 CAR T-cell therapy in their hematology department in tier one cities and selected tier two cities. We also plan to broaden our footprint into oncology departments as we approach the launch of CT041 and other solid tumor product candidates.

Management Discussion and Analysis

We aim to establish a centralized collaborative system for standard clinical management of CAR T-cell therapies by partnering with local key research and clinical centers, in order to achieve a whole-process management of patients treatment including medical evaluation, apheresis, pre-treatment, CAR T-cell infusion, post-infusion monitoring and long-term follow-up. We may also pursue a national CAR T consortia model by engaging with reputable medical centers and key opinion leaders to set up regional CAR T-cell treatment centers, as a mean to re-allocate the scarce medical resources from large cities to less-developed cities or regions and thereby provide access to patients who otherwise may not receive CAR T-cell treatment. In addition, in order to ensure continuous, efficient and cost-effective supplies of CAR T-cell products for commercial use, we aim to establish a standard validation process to expedite the establishment and certification of GMP-compliant CAR T manufacturing centers. We will also develop our commercial capabilities for overseas markets such as the United States and Europe.

Expansion and Retention of Talent

During the Reporting Period, we have expanded our team from about 337 employees as of December 31, 2020 to 573 employees as of December 31, 2021 of whom 64.6% are female. We have also strengthened the leadership team. As of the Latest Practicable Date, we have hired Dr. Raffaele BAFFA as the Chief Medical Officer of the Company, responsible for overseeing the global clinical development strategies and operations for the Company's innovative pipeline product candidates. We have hired Mr. Richard John DALY as the President of CARsgen Therapeutics Corporation, and he will lead the CARsgen US team for the international business activities of CARsgen outside of China, including clinical development, CMC operation, business development, commercialization, investor relations and public relations. We have hired Dr. CHEN Baolu as Senior Vice President of CMC Operation, responsible for the establishment and implementation of global CMC strategies. We have hired Ms. JIANG Caihua as Senior Vice President of Quality, responsible for the establishment and implementation of global quality management system for CARsgen. We have hired Dr. ZHOU Guanjun as Vice President of Government Relations. Dr. Zhou is committed to monitoring policies and trends of biopharmaceutical industry, and responsible for developing and strengthening relationships and communication with relevant government parties to support business development and strategic decisions for CARsgen China. Details of the biography of the senior management are set out in the Directors and Senior management section in this report.

Other Corporate Development

CAFA THERAPEUTICS LIMITED, a subsidiary of CARsgen Therapeutics, entered into a licensing agreement with HK inno.N Corporation (KOSDAQ: 195940), a fully-integrated pharmaceutical company, to develop and commercialize CT032 and CT053, targeting CD19 and BCMA respectively, for the potential treatment of various cancers in the Republic of Korea. Under the terms of the agreement, CARsgen will receive an upfront and additional milestone payments totaling up to USD50 million as well as up to double digit royalties on net sales in the Republic of Korea. This collaboration with HK inno.N Corporation (KOSDAQ: 195940) showcases our commitment to establishing more external partnerships with leading pharmaceutical companies to maximize the application of our technology platform and value of our product pipeline to benefit more cancer patients globally.

Management Discussion and Analysis

On July 31, 2021, we reached a new agreement with Shanghai Cancer Institute, Shanghai Jiao Tong University School of Medicine Affiliated Renji Hospital, for strategic collaboration in oncology research and technology development, following a previous agreement reached in 2015 between the two parties. This continued collaboration with Shanghai Cancer Institute will further enhance our understanding of oncology research and technologies in CAR T-cell therapy and enrich our product pipeline.

Impact of COVID-19

The COVID-19 outbreak since the end of 2019 has not caused termination of our clinical trials and has had a slight impact on our patient enrollment, patient visits and monitor's hospital visits. To minimize the impact of COVID-19, we conducted clinical trials at multiple institutions located in different areas, cities and countries. Although some delays have occurred due to lack of hospital staff and slight delays in responses from health authorities, there was no significant impact on the progress of clinical trials and interactions with health authorities. We do not expect the COVID-19 outbreak to have any material long-term impact on our clinical trials or our overall clinical development plans. Moreover, we continuously monitor and assess the impact of pandemic on the Company's U.S. operations and business activities outside China. We have noticed the manageable impacts of COVID-19 pandemic on the operations of the U.S. medical sites and the external vendors, which are involved in our clinical studies outside China. We may virtually monitor and audit some medical sites, CDMOs and CROs due to the temporary suspension of onsite visits by our partners. The procurement and delivery of materials, reagents and equipment that are used in the clinical manufacturing may be delayed or cancelled due to global supply chain constraints. Those uncertainties described above may slow down the progress of our clinical programs in the future. We have also noticed a potential impact of the COVID-19 pandemic on the construction, commissioning, qualification and validation of our U.S. CGMP manufacturing facility in Durham, North Carolina. The overall timeline of U.S. facility construction and commencement remains on track.

In 2021, the Company implemented a set of COVID-19 prevention and control measures, and there is no significant impact on our daily work and domestic travel for business. The measures undertaken include daily monitoring of the pandemic, tracking workforce health and travelling information, ensuring vaccination of the workforce, distributing personal protective equipment, frequent disinfection and good ventilation at workplace, and implementing strict visitor policies.

Although the pandemic remains ongoing, we believe the pandemic will not significantly impact our ability to continue our operations. While we cannot predict exactly how our operations will be affected, we do not expect to have any long-term impact on our business due to the COVID-19 outbreak.

Management Discussion and Analysis

Industry Overview

As a novel treatment modality, CAR T-cell therapy offers breakthrough efficacy and curative potential for cancer patients. The global CAR T-cell therapy market has been experiencing strong growth since the approval of the first CAR T-cell therapy in 2017. The global CAR T-cell therapy market is further driven by the increases in global cancer incidence, the approval of more CAR T-cell therapies in more cancer types and indications, the improvements in manufacturing technology and capacities, and the availability of CAR T-cell products in more markets. As of the Latest Practicable Date, there are six CAR T-cell products approved by U.S. FDA and two CAR T-cell products approved by NMPA in China. However, there are still significant unmet medical needs for the cancer patients worldwide, calling for more and better innovative CAR T-cell products, particularly for the treatment of solid tumors. With our pipeline products, including CT053 and CT041, and innovative technology platforms, including CycloCAR®, THANK-uCAR® and LADAR®, we are committed to developing the innovative therapies to fulfill these unmet medical needs.

Future and Outlook

With the mission of “making cancer curable”, we will continue to develop innovative product candidates for the treatment of cancer patients worldwide. Building on the milestones we have achieved, we will focus on rapid clinical development of CT053 and CT041 in both China and overseas. We will continue to advance the other product candidates in clinical and pre-clinical stages and to develop innovative CAR T technologies to further optimize the efficacy, safety and affordability of the CAR T-cell products. We will continue to expand our manufacturing capacity in China and the United States to support the clinical trials and future commercialization of our product candidates and to make CAR T-cell treatments more accessible and affordable. We will continue to establish additional external partnerships with leading research institutes and pharmaceutical companies on technology and product licenses as means to maximize the application of our technology platform and the value of our product pipeline, bringing more innovative cell therapy products to cancer patients worldwide and ultimately creating more value for our investors and the society.



3. FINANCIAL REVIEW

Overview

We have no products approved for commercial sale and have not generated any revenue from product sales. We have never been profitable and have incurred operating losses in every year since inception, with operating losses of RMB574 million and RMB327 million for the years ended December 31, 2021 and 2020, respectively. Substantially all of our operating losses resulted from research and development expenses and administrative expenses.

Loss for the years

Net loss was RMB4,744 million for the year ended December 31, 2021, representing an increase of RMB3,680 million from RMB1,064 million for year ended December 31, 2020. The increase was primarily due to (i) the increase of the Fair Value Loss, which totaled RMB4,156 million for the year ended December 31, 2021, representing an increase of RMB3,432 million from RMB724 million for the year ended December 31, 2020. Fair value loss related financial instruments were converted to ordinary shares upon the completion of the IPO, hence no loss would be recognized after the IPO; (ii) the Listing Fees of approximately RMB27 million for the year ended December 31, 2021, representing an increase of RMB23 million from RMB4 million for the year ended December 31, 2020; (iii) the share-based compensation, which totaled RMB14 million for the year ended December 31, 2021, representing an increase of RMB12 million from RMB2 million for the year ended December 31, 2020; and (iv) higher research and development expenses and higher administrative expenses.

Non-IFRS Measures

To supplement the Group's consolidated net loss and net loss per share which are presented in accordance with the IFRS, the Company has provided adjusted net loss and adjusted net loss per share as additional financial measures, which are not required by, or presented in accordance with, the IFRS.

Adjusted net loss for the periods and adjusted net loss per share for the periods represent the net loss and net loss per share respectively excluding the effect of certain non-cash items and/or one-time events, namely the fair value loss of the financial instrument issued to investors, the listing fee and share-based compensation. The terms adjusted net loss and adjusted net loss per share are not defined under the IFRS.

Management Discussion and Analysis

The table below sets forth a reconciliation of the loss to adjusted loss during the years indicated:

	Year ended December 31,	
	2021 RMB'000 (Audited)	2020 RMB'000 (Audited)
Loss for the years	(4,744,423)	(1,064,049)
Add:		
Fair value loss of financial instrument issued to investors	4,155,572	724,287
Listing fee	26,580	4,323
Share-based compensation	13,504	1,714
Adjusted net loss	(548,767)	(333,725)

	Year ended December 31,	
	2021 RMB'000 (Audited)	2020 RMB'000 (Audited)
Loss per share for the years	(12.26)	(5.37)
Add:		
Fair value loss of financial instrument issued to investors per share	10.74	3.66
Listing fee per share	0.07	0.02
Share-based compensation per share	0.03	0.01
Adjusted net loss per share	(1.42)	(1.68)

The Company believes that the adjusted non-IFRS measures are useful for understanding and assessing the underlying business performance and operating trends, and that the Company's management and investors may benefit from referring to these adjusted financial measures in assessing the Group's financial performance by eliminating the impact of certain unusual, non-recurring, non-cash and/or non-operating items that the Group does not consider indicative of the performance of the Group's core business. These non-IFRS measures, as the management of the Group believes, is widely accepted and adopted in the industry in which the Group is operating in. However, the presentation of these non-IFRS measures is not intended to be considered in isolation or as a substitute for the financial information prepared and presented in accordance with the IFRS. Shareholders of the Company and potential investors should not view the adjusted results on a stand-alone basis or as a substitute for results under IFRS. And these non-IFRS measures may not be comparable to similarly-titled measures represented by other companies.

Management Discussion and Analysis

Research and Development Expenses

	Year ended December 31,	
	2021 RMB'000 (Audited)	2020 RMB'000 (Audited)
Testing and clinical expenses	204,309	124,269
Employee benefit expenses	178,297	76,717
Research and development consumables	53,456	30,240
Depreciation of property, plant and equipment	28,155	25,490
Depreciation of right-of-use assets	16,193	7,459
Utilities	10,875	9,436
Amortization of intangible assets	5,321	5,494
Travelling and transportation expenses	2,982	1,668
Office expenses	776	–
Short term lease and low value lease expenses	691	719
Professional service fees	240	–
Other expenses	426	260
Total	501,721	281,752

Research and development expenses increased to RMB502 million for the year ended December 31, 2021, representing an increase of RMB220 million from RMB282 million for the year ended December 31, 2020, primarily due to increased head count and staff cost and expenses for testing and productions in support of our clinical trials.

Management Discussion and Analysis

Administrative Expenses

	Year ended December 31,	
	2021 RMB'000 (Audited)	2020 RMB'000 (Audited)
Employee benefit expenses	57,138	20,427
Listing expenses	26,580	4,323
Professional service fees	23,260	34,021
Office expenses	10,013	7,455
Auditors' remuneration	3,793	1,100
– audit service	3,585	600
– non-audit service	208	500
Depreciation of property, plant and equipment	1,492	1,302
Travelling and transportation expenses	799	405
Amortization of intangible assets	679	364
Depreciation of right-of-use assets	606	–
Utilities	308	75
Short term lease and low value lease expenses	100	–
Other expenses	1,063	7,421
Total	125,831	76,893

Administrative expenses increased to RMB126 million for the year ended December 31, 2021, representing an increase of RMB49 million from RMB77 million for the year ended December 31, 2020, primarily due to listing expenses incurred in relation to the Company's IPO and increased headcount and staff cost.

Management Discussion and Analysis

Details of employee benefit expenses and share-based payments included in the above administrative and research and development expenses are as below:

Employee benefit expenses

	Year ended December 31,	
	2021 RMB'000 (Audited)	2020 RMB'000 (Audited)
Wages and salaries	178,613	83,703
Pension costs	13,020	7,124
Share-based compensation	13,504	1,714
Other employee benefits	30,298	4,603
Total	235,435	97,144
Amount included in Research and Development Expenses	178,297	76,717
Amount included in Administrative Expenses	57,138	20,427

The increase of employee benefit expenses is mainly due to higher headcount and the related increase in staff salary and benefit costs. The larger increase of pension costs is due to social security relief policy of COVID-19 in 2020.

Share-based payments

Expenses for the share-based compensation have been charged to the consolidated statements of comprehensive loss as follows:

	Year ended December 31,	
	2021 RMB'000 (Audited)	2020 RMB'000 (Audited)
Administrative expenses	1,890	411
Research and development expenses	11,614	1,303
Total	13,504	1,714

Fair Value Loss of Financial Instruments Issued to Investors

The fair value loss of financial instruments issued to investors increase to RMB4,156 million for the year ended December 31, 2021, representing an increase of RMB3,432 million from RMB724 million for the year ended December 31, 2020, primarily due to the steeper increase in the fair value of the financial instruments leading up to our IPO. The financial instruments were converted to ordinary shares upon the Company's IPO in June 2021, hence no loss would be recognized after the IPO.

Management Discussion and Analysis

4. LIQUIDITY AND CAPITAL RESOURCES

Management monitors and maintains a level of cash and cash equivalents deemed adequate to finance our operations and mitigate the effects of fluctuations. In addition, management monitors our borrowings and, from time to time, evaluates operations to renew our borrowings upon expiry based on our actual business requirements. We rely on equity financing and debt financing as our major sources of liquidity.

The following table sets forth our cash flows for the periods indicated:

	Year ended December 31,	
	2021	2020
	RMB'000	RMB'000
	(Audited)	(Audited)
Net cash used in operating activities	(512,322)	(295,150)
Net cash used in investing activities	(2,471,321)	(6,897)
Net cash generated from financing activities	2,674,032	1,302,473
Net (decrease)/increase in cash and cash equivalents	(309,611)	1,000,426
Cash and cash equivalents at beginning of the period	1,042,969	96,476
Exchange loss on cash and cash equivalents	(42,074)	(53,933)
Cash and cash equivalents at end of the period	691,284	1,042,969

Net Cash Used in Operating Activities

During the Reporting Period, we incurred negative cash flows from operations, and substantially all of our operating cash outflows resulted from our research and development expenses and administrative expenses.

Our operating activities used RMB512 million and RMB295 million for the year ended December 31, 2021 and 2020, respectively. We are currently a pre-income company. We believe our pipeline products have promising global market potential in the future. We intend to continue investing in our research and development efforts and aim to obtain marketing approvals for our product candidates as soon as feasible. As we launch and commercialize our product candidates, we expect to generate operating income and improve our net operating cash outflow position.

Net Cash Used in Investing Activities

Our cash used in investing activities mainly reflects our cash used for investing in short term deposits and our purchase of property, plant and equipment. For the year ended December 31, 2021, our net cash used in investing activities was RMB2,471 million, which was primarily attributable to investment of term deposit and purchase of equipment. For the year ended December 31, 2020, our net cash used in investing activities was RMB7 million, which was primarily attributable to purchase of equipment.

Management Discussion and Analysis

Net Cash Generated from Financing Activities

During the Reporting Period, we derived our cash inflow from financing activities primarily from proceeds from the IPO, issuance of financial instruments to investors and bank borrowings.

For the year ended December 31, 2021, our net cash generated from financing activities was RMB2,674 million, primarily attributable to proceeds from our IPO of RMB2,576 million and net proceeds from bank borrowings of RMB146 million. For the year ended December 31, 2020, our net cash generated from financing activities was RMB1,302 million, which was primarily attributable to issuance of financial instruments to investors.

Cash and Cash Equivalents and Term Deposits with Original Maturity over Three Months

	As at December 31, 2021 RMB'000 (Audited)	As at December 31, 2020 RMB'000 (Audited)
Cash at banks		
– RMB	33,773	121,393
– USD	657,511	921,576
Subtotal	691,284	1,042,969
Term deposits with original maturity between three and twelve months – USD	2,315,654	–
Total	3,006,938	1,042,969

The Group's cash and cash equivalents and term deposits with original maturity between three and twelve months as at December 31, 2021 were RMB3,007 million, representing an increase of RMB1,964 million compared to RMB1,043 million as at December 31, 2020. The increase was primarily attributable to the net proceeds from the IPO.

Borrowing and Gearing Ratio

The Group's total borrowings, including interest-bearing borrowings, as at December 31, 2021 were RMB227 million, representing an increase of RMB147 million compared to RMB80 million as at December 31, 2020.

As at December 31, 2021 and December 31, 2020, the Group's bank borrowings of approximately RMB12 million and RMB16 million respectively are pledged by property, plant and equipment and right-of-use assets of the Group.

Management Discussion and Analysis

The fair values of the borrowings approximate their carrying amounts as the discounting impact is not significant.

As at December 31, 2021, the Group's unsecured borrowings are mature within six to twelve months with the interest rate ranging between 3.5000% – 5.5000% (2020: 3.5000% – 5.5000%)

As at December 31, 2021, the Group's secured borrowings is mature within three years with the interest rate of 5.2250% (2020: 5.2250%). The gearing ratio (calculated by dividing the sum of borrowings and lease liabilities by total equity) of the Group as at December 31, 2021 was 11.28%. Gearing ratio as at December 31, 2020 is not applicable as it would lead to a negative number.

Lease liabilities

The Group leases land use right and properties. Lease on land use right has been fully paid and lease on properties were measured at net present value of the lease payments to be paid during the lease terms.

Lease liabilities were discounted at incremental borrowings rates of the Group.

Our lease liabilities increased to RMB111 million as at December 31, 2021 from RMB20 million as at December 31, 2020, due to newly rented plant, offices and staff dormitories.

5. OTHER FINANCIAL INFORMATION

Significant Investments, Material Acquisitions and Disposals

As at December 31, 2021, we did not hold any significant investments. During the year ended December 31, 2021, we did not have material acquisitions or disposals of subsidiaries, associates and joint ventures.

Foreign Exchange Risk

We have transactional currency exposures. Certain of our bank balances, other receivables, and accruals and other payables are dominated in foreign currencies and are exposed to foreign currency risk. We currently do not have a foreign currency hedging policy. However, our management monitors foreign exchange exposure and will consider appropriate hedging measures in the future should the need arise.

Capital Expenditure

For the year ended December 31, 2021, the Group's total capital expenditure amounted to approximately RMB178 million, which was used in purchase of property, plant and equipment, and software.

Charge on Assets

As at December 31, 2021 and 2020, the Group's building with carrying values of RMB33 million and RMB35 million respectively were pledged for certain of the Group's borrowings.

As at December 31, 2021 and December 31, 2020, the Group's land use right with carrying values of RMB6.8 million and RMB6.9 million respectively was pledged as collateral for the Group's borrowings.

Management Discussion and Analysis

Contingent Liability

As at December 31, 2021, the Group did not have any material contingent liabilities.

Employees and Remuneration Policies

During the Reporting Period, we have expanded our team from about 337 employees as at December 31, 2020 to 573 employees as at December 31, 2021. As at December 31, 2021, we had a total of 573 employees, with 64.6% of them are female.

In compliance with the applicable labor laws, we enter into standard confidentiality and employment agreements with our key management and research staff. The contracts with our key personnel typically include a standard non-compete agreement that prohibits the employee from competing with us, directly or indirectly, during his or her employment and for up to two years after the termination of his or her employment. The agreements also typically include undertakings regarding assignment of inventions and discoveries made during the course of his or her employment.

During the Reporting Period and up to the Latest Practicable Date, we did not experience any strikes, labor disputes or industrial action which had a material effect on our business. We believe we have not experienced any significant difficulty in recruiting staff for our operations. We have established a labor union that represents employees with respect to the promulgation of bylaws and internal protocols in China.

Our employees' remuneration consists of salaries, bonuses, share-based incentive plans, social insurance contributions and other welfare payments. In accordance with applicable laws, we have made contributions to social insurance funds (including pension plan, unemployment insurance, work-related injury insurance, medical insurance and maternity insurance, as applicable) and housing funds for our employees. During the Reporting Period and up to the Latest Practicable Date, we had complied with all statutory social insurance fund obligations applicable to us under PRC & US laws in all material aspects, and housing fund obligations applicable to us under PRC laws.

To remain competitive in the labor market, we provide various incentives and benefits to our employees. We invest in continuing education and training programs, including internal and external training, for our management staff and other employees to upgrade their skills and knowledge. We also provide competitive salaries, project and stock incentive plans to our employees, especially key employees.

Future Investment Plans and Expected Funding

The Group will continue to expand its markets in the PRC and globally in order to tap its internal potential and maximize shareholders' interest. The Group will continue to grow through self-development, mergers and acquisitions, and other means. We will employ a combination of financing channels to finance capital expenditures, including but not limited to internal funds and bank loans. Currently, the bank credit lines available to the Group are adequate.

Directors and Senior Management

The biography details of the Directors and senior management are set out as follows:

EXECUTIVE DIRECTORS

Dr. Li Zonghai (李宗海), aged 48, was appointed as a Director in February 2018, and the Chief Executive Officer and the Chief Scientific Officer in February 2021. He was re-designated as an executive Director in February 2021.

Dr. Li has also held positions at CARsgen Therapeutics (Shanghai). He has been a director and the chief executive officer since October 2014, and the chief scientific officer since December 2017.

Dr. Li has approximately 20 years of work experience in the biopharmaceutical field. Prior to joining our Group, Dr. Li was a project manager at Guilin Pavay Gene Pharmaceutical Co., Ltd. (桂林華諾威基因藥業有限公司) from July 2000 to April 2002. Dr. Li worked at Shanghai Cancer Institute (上海市腫瘤研究所) from July 2005 to June 2018 and served as the leader of the biotherapy research team at the State Key Laboratory of Oncogenes and Related Genes of Shanghai Cancer Institute (上海市腫瘤研究所癌基因及相關基因國家重點實驗室) during such period. In light of the governmental policy to support and encourage scientific researchers to work in private technology companies conditional upon the requisite college or research institutes' approval, Dr. Li decided to establish our Group in October 2014 to conduct R&D work and the commercialization of cellular immunotherapy, while continuing to work at Shanghai Cancer Institute. The arrangement was ratified and approved by the Shanghai Cancer Institute in January 2016.

Dr. Li has dedicated himself to developing innovative treatment for the patients with cancer. One of his early career achievements is the identification of GE11, a peptide ligand of EGFR which has become a widely used unnatural peptide in antitumor study now. He is also the inventor of new technologies such as Hpd3cell, a new phage display technology; FR806, a new safety switch for T cell therapy; CycloCAR technology to increase the antitumor activities of chimeric antigen receptor (CAR) T cells. He has a leading role in the research on CAR T cell therapy against solid tumors by publishing the first paper of CAR T cell therapy against GPC3, Claudin 18.2 and EGFR/EGFRvIII worldwide. Dr. Li was a professor in Shanghai Cancer Institute, Renji Hospital affiliated to Shanghai Jiao Tong University School of Medicine (上海交通大學醫學院附屬仁濟醫院上海市腫瘤研究所) and a doctoral supervisor at Renji Hospital affiliated to Shanghai Jiao Tong University School of Medicine (上海交通大學醫學院附屬仁濟醫院).

Dr. Li obtained his bachelor's degree in preventive medicine and master's degree in pathology and pathogen biology from the Central South University (中南大學), formerly known as the Hunan Medical University (湖南醫科大學), the PRC, in June 1997 and July 2000 respectively. He obtained his Doctor of Philosophy degree in pathogen biology from Fudan University (復旦大學), the PRC, in June 2005. Dr. Li was awarded the Leading Talents of Shanghai City (上海市領軍人物) in 2018 and the Shanghai Youth Science and Technology Award (上海市青年科技傑出貢獻獎) in 2019.

Directors and Senior Management

Dr. WANG Huamao (王華茂), aged 45, was appointed as a Director in September 2018 and the Chief Operating Officer in February 2021. He was re-designated as an executive Director in February 2021.

Dr. Wang has also held positions at other members of our Group. He has been a director and the Chief Operating Officer of CARsgen Therapeutics (Shanghai) since October 2014, the general manager of CARsgen Pharmaceuticals since November 2017 and the general manager of CARsgen Diagnostics since November 2020.

Prior to joining our Group, Dr. Wang worked at Zhejiang Academy of Medical Sciences (浙江省醫學科學院) from July 2009 to January 2011, served as the deputy general manager of Shanghai Ruijin Biotechnology Co., Ltd. (上海銳勁生物技術有限公司) from January 2011 to June 2013, and the general manager of YIJE Biotech (Shanghai) Holding Limited (上海益傑生物技術有限公司) from July 2013 to October 2014.

Dr. Wang obtained his bachelor's degree in biochemistry from Sichuan University (四川大學), the PRC, in July 1999. He received his master's degree and Doctor of Philosophy degree in pathogenic organisms from Fudan University (復旦大學), the PRC, in June 2003 and June 2009, respectively.

NON-EXECUTIVE DIRECTORS

Mr. GUO Bingsen (郭炳森), aged 51, was appointed as a Director in September 2018 and re-designated as a non-executive Director in February 2021.

Mr. Guo had been a director of CARsgen Therapeutics (Shanghai) from April 2016 to April 2020.

Mr. Guo is an entrepreneur with expertise in plastic manufacturing industry. He cofounded Fujian Huian Xian Yide Plastic Co., Ltd. (福建惠安縣怡德塑膠有限公司) in March 1998 and acts as its director; established Xinsheng Precision Computer Mould (Fujian) Ltd. (鑫晟精密電腦模具(福建)有限公司) in April 2006 and acts as its executive director. In October 2009, Mr. Guo founded Hubei Xincheng Plastic Ltd. (湖北鑫晟塑膠有限公司). He co-founded Quanzhou Hongcheng Precision Plastic Mould Ltd. (泉州弘晟精密塑膠模具有限公司) in February 2017 and was appointed as a supervisor from February 2017 to April 2019. Mr. Guo was appointed as the vice president of the council of the Fifth Administrative Committee of Fujian Province Youth Commercial Association (福建省青年商會第五屆管委會理事會) in 2016.

Mr. Guo was awarded the 12th Fujian Province Outstanding Entrepreneur (第十二屆福建省優秀企業家) in 2008. He was nominated as one of the National Villages Young Entrepreneurial Leaders (全國農村青年創業致富帶頭人) in 2008.

Mr. Guo is an uncle of another non-executive Director, Mr. Guo Huaqing (郭華清).

Directors and Senior Management

Mr. GUO Huaqing (郭華清), aged 33, was appointed as a Director in September 2020 and re-designated as a non-executive Director in February 2021. Mr. Guo is primarily responsible for participating in formulating the corporate and business strategies of our Group. Since his appointment as a Director, Mr. Guo participated in the decision making of the Board in relation to important matters of our Company, including the Series C+ financing and the decision for the Listing on the Stock Exchange.

Mr. Guo served as a vice president at Quanzhou Jiatai Footwear Ltd. (泉州嘉泰鞋業有限公司) from September 2011 to August 2015, and as the general manager and legal representative at Fujian Dingwo Investment Management Ltd. (福建省鼎沃投資管理有限公司) from September 2015 to May 2020, during which he participated in equity investments projects. Mr. Guo has been an executive Director, the general manager and legal representative at Xiamen Runtang Tianyi Investment Management Ltd. (廈門潤唐天一投資管理有限公司) since June 2020 and has been responsible for investment management in the secondary market. With his experience in business administration and investment management, our Company believes that Mr. Guo can bring a unique perspective to the Board, in particular, in assisting our Company's business development and risk assessment of various investments.

Mr. Guo obtained his bachelor's degree in business administration from Jiageng College of Xiamen University (廈門大學嘉庚學院), the PRC, in July 2011.

Mr. Guo is a nephew of Mr. GUO Bingsen (郭炳森).

Mr. XIE Ronggang (謝榕剛), aged 35, was appointed as a Director in September 2020 and re-designated as a non-executive Director in February 2021.

Mr. Xie joined Shanghai Loyal Valley Investment Management Limited (上海正心谷投資管理有限公司) as a senior investment manager in October 2015, was promoted to a managing director in November 2016 and is currently a partner. Prior to joining Shanghai Loyal Valley Investment Management Limited, Mr. Xie served as an investment manager at Suzhou Kaifeng Zhengde Investment Management Co., Ltd (蘇州凱風正德投資管理有限公司) from June 2011 to June 2014, before he was appointed as an investment director between June 2014 and June 2015. Mr. Xie has been appointed as a director of Shanghai Allist Pharmaceuticals Co., Ltd. (上海艾力斯醫藥科技股份有限公司) (SSE: 688578), a non-executive director of Akeso, Inc. (康方生物科技(開曼)有限公司) (HKEX: 9926) and a non-executive director of InnoCare Pharma Limited (諾誠健華醫藥有限公司) (HKEX: 9969) since November 2019, August 2020 and March 2021, respectively.

Mr. Xie obtained his master's degree in biomedical engineering from Southeast University (東南大學), the PRC, in March 2011.

Directors and Senior Management

Ms. ZHAO Yachao (趙雅超), aged 40, was appointed as a Director in September 2018 and re-designated as a non-executive Director in February 2021.

Ms. Zhao has been working at BVCF Management Ltd. (百奧維達投資諮詢(上海)有限公司) since July 2007, previously as an investment manager and investment director, and currently the managing director.

Ms. Zhao completed her undergraduate studies and postgraduate studies in finance from Fudan University (復旦大學), the PRC, in July 2003 and June 2007, respectively.

INDEPENDENT NON-EXECUTIVE DIRECTORS

Dr. FAN Chunhai (樊春海), aged 48, was appointed as an independent non-executive Director effective as of the Listing Date.

Dr. Fan served as a researcher at the Shanghai Institute of Applied Physics, Chinese Academy of Sciences (中國科學院上海應用物理研究所), a distinguished researcher at the Chinese Academy of Sciences (中國科學院), the head of the Division of Physical Biology (物理生物學研究室) and the head of the Center of Bio-imaging, Shanghai Sychrotron Radiation Facility (上海光源生物成像中心) between 2004 and 2018. Dr. Fan has been a professor of the School of Chemistry and Chemical Engineering in Shanghai Jiao Tong University (上海交通大學化學化工學院) and the director of Shanghai Key Laboratory for Nucleic Acid Chemistry and Nanomedicine (上海市核酸化學與納米醫學重點實驗室) since 2018. He is also a K.C. Wong Chair Professor (王寬誠講席教授) of Shanghai Jiao Tong University (上海交通大學).

Dr. Fan obtained his bachelor's degree in biochemistry and doctorate degree in biochemistry and molecular biology from Nanjing University (南京大學), the PRC, in July 1996 and September 2000, respectively. In November 2019, Dr. Fan was elected as an academician of the Chinese Academy of Sciences (中國科學院).

Dr. YAN Guangmei (顏光美), aged 64, was appointed as an independent non-executive Director effective as of the Listing Date.

Dr. Yan began to teach at Sun Yat-sen University (中山大學) (previously known Sun Yat-sen University of Medical Sciences (中山醫科大學)) in August 1989. He was an assistant professor from August 1989 to July 1992 and was appointed as a professor from December 1996 to November 1999. Dr. Yan served as the vice president of the university from 2008 to 2017.

Directors and Senior Management

Dr. Yan has been an independent non-executive director of Medprin Regenerative Medical Technologies Co., Ltd. (廣州邁普再生醫學科技股份有限公司) (SZSE: 301033) since November 2018 and MGI Tech Co., Ltd. (深圳華大智造科技股份有限公司) since June 2020.

Dr. Yan obtained his bachelor's degree in medicine from the Central South University Xiangya School of Medicine (中南大學湘雅醫學院), formerly known as the Hunan Medical School (湖南醫學院), the PRC in December 1979 and completed a training course of the National College of Pharmacy Teaching (全國高等學校藥理學師資進修班) organized by the university in February 1982. Dr. Yan obtained his master's and doctorate degree in medicine from Sun Yat-sen University (中山大學), formerly known as Sun Yat-sen University of Medical Sciences (中山醫科大學), the PRC, in March 1985 and July 1989, respectively.

Mr. SO Tak Young (蘇德揚), aged 51, was appointed as an independent non-executive Director effective as of the Listing Date.

Mr. So has more than 20 years of experience in finance, accounting, investment and private equity businesses with global financial institutions and asset management companies. He started his career as an auditor with Ernst & Young, Hong Kong from February 1993 to December 1994. Mr. So served as a managing partner of FastLane Group in July 2012 and served as a partner of Prospere Capital Limited in January 2018. He served as an independent non-executive Director of Shanghai Henlius Biotech, Inc. (上海復宏漢霖生物技術股份有限公司) (HKEX: 2696) since September 2019.

Mr. So has previously served various positions, including vice president of global capital market/Asia treasury and vice president of financial controls of Bank of America, Hong Kong from January 1998 to March 2002, head of finance and operations of consumer and commercial banking in Hong Kong, head of asset and liability management of Greater China and chief financial officer of private client banking in Hong Kong of ABN AMRO Bank N.V., Hong Kong from March 2002 to January 2005, chief financial officer of Hamon Asset Management Limited, an affiliate of Bank of New York Mellon in February 2005, chief financial officer of Asia Pacific of asset management division for Deutsche Bank, Hong Kong from August 2007 to November 2011, and chief financial officer of PAG Capital in November 2011.

Mr. So received his bachelor of business degree and his master of business administration degree from the University of Technology in Sydney, Australia in April 1994 and September 1998, respectively. He is a fellow member of Certified Practising Accounting Australia since August 2011.



Directors and Senior Management

SENIOR MANAGEMENT

Dr. LI Zonghai (李宗海) and Dr. WANG Huamao (王華茂) are each an executive Director of our Company and also a member of our senior management team. For further details, please see “—Executive Director” for details of their biography.

Dr. Raffaele BAFFA, aged 62, joined the Group in April 2022 and is our Chief Medical Officer.

Dr. Baffa has rich experiences in pharmaceutical industry and research institutes, taking various leadership positions in multi-national corporations and biotech companies. Prior to joining our Group, Dr. Baffa served as Chief Medical Officer and Executive Vice President of Research & Development at Ziopharm Oncology (NASDAQ: ZIOP). Ziopharm Oncology was rebranded to Alaunos (NASDAQ: TCRT) in January, 2022. Prior to Ziopharm Oncology, Dr. Baffa was the Head of Research & Development and Chief Medical Officer in Medisix Therapeutics, a company focused on developing novel immune cell therapies. Dr. Baffa was the Vice President, Therapeutic Area Head of Oncology, Global Clinical Development for Shire Pharmaceuticals, and following the acquisition of the oncology division by Servier Pharmaceuticals, Dr. Baffa served as the Chief Medical Officer of Servier Pharmaceuticals. Dr. Baffa has also held leadership positions at Pfizer and Sanofi.

Dr. Baffa earned an M.D. from University of Padova, School of Medicine and a Ph.D. in biology and molecular pathology from University of Parma in Italy.

Mr. Richard John DALY, aged 61, joined the Group in January 2022 and is our President of CARsgen Therapeutics Corporation, a subsidiary of the Company in the United States.

Mr. Daly has approximately 30 years of experience in pharmaceutical industry, including leadership positions in multi-national corporations and biotech companies. Prior to joining our Group, Mr. Daly served as Chief Operating Officer of Beyond Spring, Inc. (NASDAQ: BYSI). From February 2016 to July 2018, Mr. Daly served as Chief Executive Officer, President and Chairman of Neuralstem, Inc. (NASDAQ: PALI). Mr. Daly served in AstraZeneca as the President of the U.S. Diabetes subsidiary (formerly BMS-AZ Diabetes Alliance). Prior to these positions, from 1998 to 2011, Mr. Daly served at Takeda and TAP Pharmaceuticals, a joint venture established between Takeda and Abbott Laboratories, holding several leadership positions, including the Executive Vice President at Takeda Pharmaceutical North America and the Senior Vice President of marketing at TAP Pharmaceuticals. Mr. Daly currently sits on the boards of directors of Catalyst Pharmaceuticals (NASDAQ: CPRX) and Opiant Pharmaceuticals (NASDAQ: OPNT).

Mr. Daly holds an MBA from Kellogg School of Management at Northwestern University and a Bachelor of Science degree from University of Notre Dame.

Directors and Senior Management

Dr. FAN Yong (范勇), aged 62, joined the Group in January 2020 and is our Senior Vice President, Global Regulatory Affairs.

Dr. Fan was a laboratory director at The Brooklyn Hospital Center from January 1995 to October 2000. In November 2000 Dr. Fan joined the New York Presbyterian Medical Center as the Lab Manager of the Stem Cell Processing Laboratory. In June 2002, she joined the Memorial Sloan-Kettering Cancer Center. Dr. Fan was a staff scientist at the National Institutes of Health from August 2004 to August 2007. She was a reviewer at the FDA from September 2007 to December 2017 during which she was responsible for reviewing IND applications, BLAs and medical devices.

Dr. Fan obtained her bachelor's degree in medicine from Beihua University (北華大學) (previously known as Jilin Medical College (吉林醫學院)) (equivalent to doctor of medicine in the United States) in the PRC in December 1982. Dr. Fan received FDA Outstanding Service Award and CBER Technical Excellence Award while working at the FDA.

Dr. HSU Leigh James, aged 51, joined our Group in June 2017 and is our Senior Vice President, Business Development.

Dr. Hsu has over 15 years of work experience in business management and strategic planning in the biotechnology industry. Prior to joining our Group, Dr. Hsu served as director of business development at Acadia Pharmaceuticals (NASDAQ: ACAD) and vice president of corporate development and strategy at Lpath, Inc. (merged with Apollo Endosurgery, Inc. in December 2016) between January 2005 and November 2016.

Dr. Hsu obtained his bachelor's degree in biochemistry and cell biology and his doctorate degree in molecular pathology from the University of California, San Diego in the United States, in June 1993 and September 1999, respectively. He received his master's degree in business administration from the University of California, Irvine in the United States, in June 2001.



Directors and Senior Management

Dr. JIA Jie (賈捷), aged 44, joined our Group in December 2016 and is our Vice President, Strategic Alliances and Operations.

Dr. Jia has served in CARsgen Therapeutics Corporation, our wholly-owned subsidiary incorporated in the United States since joining our Group, including as the Vice President, Business Development, responsible for overseeing the corporate operations of the Group in the United States, leading the strategic alliances and managing CMC operations from December 2016 to July 2017, as the Vice President, Strategic Alliances, responsible for overseeing the corporate operations in the United States, leading strategic alliances, managing CMC operations from July 2017 to December 2018, and as the Vice President, Strategic Alliances and Operations, responsible for overseeing the corporate operations in the United States, leading strategic alliances, managing CMC operations from January 2019 to present.

Dr. Jia obtained his bachelor's degree in biochemistry from Sichuan University (四川大學), the PRC, in July 1999 and his doctorate degree in biochemistry and molecular biology from Shanghai Institutes for Biological Sciences, Chinese Academy of Sciences (中國科學院上海生命科學研究院), the PRC, in August 2004. He has been a member of The North American Vascular Biology Organization and Sigma Xi since 2006 and 2008, respectively. In 2014, he joined The Nitric Oxide Society as a member. He became a member of American Association for the Advancement of Science in 2016. Dr. Jia joined the American Society of Clinical Oncology as an allied physician and doctoral scientist in 2017. He has been a member of the American Society of Hematology and a full member of the American Society of Quality since 2019.

Dr. MA Hong (馬洪), aged 51, joined our Group in August 2018 and is our Senior Vice President, Clinical Development.

Dr. Ma was the director of clinical operations at Endocyte, Inc. (NASDAQ: ECYT) (which is delisted on NASDAQ from 31 December 2018) from June 2012 to July 2014. He then worked as a temporary employee at Bellicum Pharmaceuticals, Inc. (NASDAQ: BLCM) from September 2014 to December 2014 and served as the director of clinical development from December 2014 to May 2016. Dr. Ma served as the senior medical director at Immatix US, Inc., a joint venture launched by Immatix Biotechnologies GmbH (NASDAQ: IMTX) and MD Anderson Cancer Center from May 2016 to August 2018.

Dr. Ma obtained his bachelor's degree in clinical medicine and his master's degree in cancer pathophysiology from Central South University (中南大學), formerly known as Hunan Medical University (湖南醫科大學), the PRC, in July 1994 and July 1997, respectively. He received his master's degree in business administration from University of Georgia, the United States, in May 2005. Dr. Ma has been elected as an Allied Physician/Doctoral Scientist of the American Society of Clinical Oncology since 2011. He has also been a member of the American Society of Hematology since 2016.

Directors and Senior Management

Dr. WANG Wei (汪薇), aged 47, joined our Group in June 2018 and is our Vice President.

Dr. Wang previously worked at Xiangya Hospital of Central South University (中南大學湘雅醫院). She also worked at Hangzhou MSD Pharmaceutical Co. Ltd. – Shanghai Branch (杭州默沙東製藥有限公司 – 上海分公司) from January 2007 to August 2011, where she was responsible for the medical affairs in the medical department. Dr. Wang then served at Beijing Novartis Pharma Co., Ltd. (北京諾華製藥有限公司) as a senior medical scientific expert from September 2011 to May 2012. Prior to joining our Group, Dr. Wang served as the associate safety risk lead and subsequently the clinical program lead at the China R&D center of Pfizer (China) Research and Development Co., Ltd. (輝瑞(中國)研究開發有限公司) from May 2012 to May 2018.

Dr. Wang obtained her bachelor's degree in clinical medicine from Central South University (中南大學), formerly known as Hunan Medical University (湖南醫科大學), the PRC, in June 1997. She obtained her master's degree in clinical medicine and doctorate degree in pediatrics from Central South University and Fudan University (復旦大學), the PRC, in June 2003 and July 2007, respectively.

Ms. XIE Lan, aged 49, joined the Group in March 2021 and is our Senior Vice President, Finance.

Prior to joining our Company, Ms. Xie served as the vice president, finance of Connect Biopharma (Shanghai) Co., Ltd. (康乃德生物醫藥(上海)有限公司), a subsidiary of Connect Biopharma Holdings Limited (NASDAQ: CNTB) from October 2020 to March 2021 during which she was responsible for U.S. listing, finance and tax related matters. Prior to this, Ms. Xie served as the chief financial officer of Sunshine Guojian Pharmaceuticals (Shanghai) Co., Ltd. (三生國健藥業(上海)股份有限公司) (SSE Sci-Tech Innovation Board: 688336) from April 2019 to May 2020 and she was the vice president and the chief financial officer (China region) of SciClone Pharmaceuticals (China) Co., Ltd. (賽生醫藥(中國)有限公司), a wholly-owned subsidiary of SciClone Pharmaceuticals Holdings Limited (賽生藥業控股有限公司) (HKEX: 6600) from August 2012 to September 2018. From November 2007 to July 2012, Ms. Xie served as the vice president, finance of Shanghai ChemPartner Co., Ltd. (上海睿智化學研究有限公司). Ms. Xie was a senior manager in PricewaterhouseCoopers Consultants, Shenzhen Co., Ltd. Shanghai Branch from August 2005 to November 2007 and was responsible for corporate mergers and acquisitions and financial due diligence related work.

Ms. Xie obtained her bachelor's degree in business administration in Boston University in May 1994. She has also earned a master of business administration degree (MBA) in INSEAD in July 2003.



Directors' Report

REPORT OF THE DIRECTORS

The Directors present their report and the audited consolidated financial statements (the “**Consolidated Financial Statements**”) of the Group for the Reporting Period.

GENERAL INFORMATION

The Company was incorporated in the Cayman Islands on February 9, 2018 as an exempted company with limited liability under the laws of the Cayman Islands. The Company's shares were listed on the Main Board of the Stock Exchange on June 18, 2021.

PRINCIPAL ACTIVITIES

CARsgen is a biopharmaceutical company with operations in China and the U.S., mainly focused on innovative CAR T-cell therapies for the treatment of hematologic malignancies and solid tumors. The Company has built an integrated cell therapy platform with in-house capabilities that span target discovery, antibody development, clinical trials, and commercial-scale manufacturing. CARsgen has internally developed novel technologies and a product pipeline with global rights to address major challenges of CAR T-cell therapies, such as improving the safety profile, enhancing the efficacy in treating solid tumors, and reducing treatment costs. There was no significant change in the nature of the Group's principal activities during the year and up to the Latest Practicable Date.

Particulars of the Company's principal subsidiaries as at December 31, 2021 are set out in Note 12 to the Consolidated Financial Statements.

BUSINESS REVIEW

A fair review of the business of the Group as well as a discussion and analysis of the Group's performance during the Reporting Period and the material factors underlying its financial performance and financial position as required by section 388(2) and Schedule 5 to the Companies Ordinance (Chapter 622 of the Laws of Hong Kong) (“**Companies Ordinance**”) can be found in the section headed “Management Discussion and Analysis” of this report.

RESULTS AND DIVIDEND

Details of the consolidated loss of the Group for the year and the Group's financial position as at December 31, 2021 are set out in the Consolidated Financial Statements and their accompanying notes on pages 141 to 216.

No dividend was paid or declared by the Company or other members of the Group during the Reporting Period.

FINANCIAL SUMMARY

Shares of the Company were listed on the Stock Exchange on June 18, 2021. A summary of the published results and of the assets, liabilities and equity of the Group for the last three financial years, as extracted from the published audited financial information and financial statements, is set out on page 217 of this report.

Directors' Report

ENVIRONMENTAL POLICIES AND PERFORMANCE

The Group is highly aware of the importance of environment protection and has not noted any material incompliance with all relevant laws and regulations in relation to its business including environmental protection, health and safety, workplace conditions, employment and the environment.

The Group has established detailed internal rules regarding environmental protection and adopted effective measures to achieve efficient use of resources, waste reduction and energy saving. For further details of the Group's environmental policies and performance, please refer to the Environmental, Social and Governance Report of the Company for the Reporting Period set out on pages 95 to 135, which has been prepared in accordance with Rule 13.91 and the Environmental, Social and Governance Reporting Guide contained in Appendix 27 of the Listing Rules.

PRINCIPAL RISKS AND UNCERTAINTIES

Risks Relating to Our Financial Position and Need for Additional Capital

- We have incurred significant net losses and net operating cash outflows since our inception, and we anticipate that we will continue to incur net losses and net operating cash outflows for the foreseeable future and may never become profitable;
- We have net operating cash outflow during the Reporting Period;
- We may need additional capital to meet our operating cash requirements, and financing may not be available on terms acceptable to us, or at all;
- We have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance. The risks involved in our business may cause potential investors to lose substantially all of their investment in our business;
- We may need to obtain additional financing to fund our operations, and if we are unable to obtain such financing, we may be unable to complete the development and commercialization of our primary drug candidates;
- Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

Risks Relating to Our Business

- We depend substantially on the success of our product candidates, all of which are in pre-clinical or clinical development. If we are unable to successfully complete clinical development, obtain regulatory approval and commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed;
- We operate in a rapidly changing industry and we face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do, or developing product candidates or treatments that are safer, more effective, more effectively marketed or cost less than ours, or receive regulatory approval or reach the market earlier. As a result, our product candidates may not achieve the sales we anticipate and could be rendered non-competitive or obsolete;
- Clinical development of biopharmaceutical products involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results;
- If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates;
- We may not be successful in our efforts to build or in-license a pipeline of new product candidates. If we fail to do so, our commercial opportunity will be limited;
- We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or have a greater likelihood of success.

Risks Relating to Extensive Government Regulation

- All material aspects of the research, development, manufacturing and commercialization of biopharmaceutical products are heavily regulated. Any failure to comply with existing regulations and industry standards, or any adverse actions by the NMPA or other comparable regulatory authorities against us, could negatively impact our reputation and our business, financial condition, results of operations and prospects;
- The regulatory approval processes of the NMPA and other comparable regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are ultimately unable to obtain, or experience delays in obtaining, regulatory approval for our product candidates, our business will be substantially harmed;
- Changes in government regulations or in practices relating to the pharmaceutical and biopharmaceutical industries, including healthcare reform in China, and compliance with new regulations may result in additional costs;
- Even if we are able to commercialize any approved product candidates, the products may become subject to unfavorable pricing regulations, or to unfavorable changes in national or third-party reimbursement practices, which could harm our business.

Directors' Report

Risks Relating to Manufacturing of Our Product Candidates

- Our product candidates are cell therapies. The manufacture of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to development or scaling-out of our manufacturing capabilities. If we encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

Risks Relating to Commercialization of Our Product Candidates

- The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small, and our projections regarding the size of the addressable market may be incorrect;
- We currently have a limited marketing and sales organization and have no experience as a company in launching and marketing products. If we are unable to establish marketing and sales capabilities to market and sell our product candidates, we may not be able to generate product revenue or commercialize future product candidates. We may not be able to effectively build and manage our sales network;
- Product liability claims or lawsuits could cause us to incur substantial liabilities, and our insurance coverage may be inadequate to protect us from all the liabilities we may incur;
- The increasing use of social media platforms presents new risks and challenges.

Risks Relating to Our Intellectual Property Rights

- If we or our licensors are unable to obtain and maintain adequate patent and other intellectual property protection for our product candidates and other intellectual property, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully develop and commercialize any of our product candidates or technologies may be adversely affected;
- If we determine that our intellectual property rights (including rights in-licensed from third parties) or other intangible assets are impaired, our results of operations and financial condition may be adversely affected;
- Even if we are able to obtain patent protection for our product candidates, the life of such protection, if any, is limited, and third parties could be able to circumvent our patents by developing similar or alternative products and technologies in a non-infringing manner, or develop and commercialize products and technologies similar or identical to ours and compete directly against us after the expiration of our patent rights, if any, and our ability to successfully commercialize any product or technology would be materially adversely affected.

For further details, please refer to the section headed "Risk Factors" in the Prospectus.

DIRECTORS

From the Listing Date to the Latest Practicable Date, the Board consists of the following Directors:

Executive Directors

Dr. LI Zonghai (*Chairman*)
Dr. WANG Huamao

Non-executive Directors

Mr. GUO Bingsen
Ms. ZHAO Yachao
Mr. XIE Ronggang
Mr. GUO Huaqing

Independent Non-executive Directors

Dr. FAN Chunhai
Dr. YAN Guangmei
Mr. SO Tak Young

In accordance with Article 16.19 of the Articles of Association of the Company, Dr. LI Zonghai, Dr. WANG Huamao and Mr. GUO Bingsen will retire from office by rotation at the forthcoming annual general meeting of the Company ("**AGM**") and, being eligible, will offer themselves for re-election.

DIRECTORS AND SENIOR MANAGEMENT'S BIOGRAPHIES

Biographical details of the Directors and senior management are set out in the section headed "Directors and Senior Management" of this report.

INDEPENDENCE OF INDEPENDENT NON-EXECUTIVE DIRECTORS

The Company has received from each of the independent non-executive Directors an annual confirmation in writing of his independence pursuant to Rule 3.13 of the Listing Rules. The Company considers that, during the Relevant Period and as at the Latest Practicable Date, all of the independent non-executive Directors are independent.

DIRECTORS' SERVICE CONTRACTS

For more information about the service contracts entered into by the Company, please see the Corporate Governance Report in this report for further details.

Directors' Report

EMOLUMENT POLICY AND DIRECTORS' REMUNERATION

Pursuant to Rule 3.25 of the Listing Rules and the Corporate Governance Code as set out in Appendix 14 to the Listing Rules, the Company has established the Remuneration Committee to formulate remuneration policies. The remuneration is determined and recommended based on the experience, qualification, position and seniority of each Director and senior management. As for the independent non-executive Directors, their remuneration is determined by the Board based on the recommendation from the Remuneration Committee. The Directors and the senior management are eligible participants of the applicable share incentive plans.

Details of the remuneration of the Directors and the five highest paid individuals are set out in Note 35 and Note 10 to the Consolidated Financial Statements of this report.

None of the Directors waived or agreed to waive any remuneration and there were no emoluments paid by the Group to any of the Directors or five highest paid individuals as an inducement to join, or upon joining the Group, or as compensation for loss of office.

The table below shows the emolument of senior management by band:

Emolument bands	Year ended December 31, 2021 (Number of Senior Management)
HKD1,500,001 to HKD2,000,000	1
HKD2,000,001 to HKD2,500,000	–
HKD2,500,001 to HKD3,000,000	3
HKD3,000,001 to HKD3,500,000	2
HKD3,500,001 to HKD4,000,000	–
HKD4,000,001 to HKD4,500,000	–
HKD4,500,001 to HKD5,000,000	–
HKD5,000,001 to HKD5,500,000	2
Total	8

PERMITTED INDEMNITY PROVISION AND DIRECTORS' AND OFFICERS' LIABILITY INSURANCE

A permitted indemnity provision (as defined in the Companies Ordinance (Chapter 622 of the Laws of Hong Kong)) in relation to the directors' and officers' liability insurance is currently in force and was in force during the Reporting Period. The Company has arranged appropriate directors' liability insurance coverage for the Directors of the Group since the Listing Date.

DIRECTORS' INTERESTS IN TRANSACTIONS, ARRANGEMENTS OR CONTRACTS

Save for the Contractual Arrangements as disclosed in this report, no Director nor an entity connected with a him/her had a material interest, whether directly or indirectly, in any transaction, arrangement or contract of significance to the business of the Group to which the Company or any of its subsidiaries was a party during the Reporting Period.

MANAGEMENT CONTRACTS

Save for the Directors' service contracts and appointment letters, no contract of significance concerning the management and administration of the whole or any substantial part of business of the Company or any of its subsidiaries was entered into or subsisted during the Reporting Period.

ARRANGEMENT FOR DIRECTORS TO ACQUIRE SHARES OR DEBENTURES

Save as disclosed in this report, at no time during the Reporting Period was the Company or any of its subsidiaries, the holding company, a party to any arrangement to enable a Director to acquire benefits by means of the acquisition of shares in, or debentures of, the Company or any other body corporate.

DIRECTORS' INTERESTS IN COMPETING BUSINESSES

During the Relevant Period and up to the Latest Practicable Date, none of the Directors or their respective close associates (as defined in the Listing Rules) is considered to have interests in businesses which compete or are likely to compete, either directly or indirectly, with the businesses of the Group pursuant to the Listing Rules.

DIRECTORS' AND CHIEF EXECUTIVES' INTERESTS IN SHARES AND UNDERLYING SHARES OF THE COMPANY AND ITS ASSOCIATED CORPORATIONS

Interests and short positions of our Directors in the share capital of the Company and its associated corporations

As at December 31, 2021, the interests or short positions of the Directors and chief executives' of the Company in the Shares, underlying Shares and debentures of the Company or any associated corporation (within the meaning of Part XV of the SFO), which (a) were required to be notified to the Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which he/she was taken or deemed to have under such provisions of the SFO); or (b) were required, pursuant to section 352 of the SFO, to be recorded in the register referred to therein; or (c) were required to be notified to the Company and the Stock Exchange pursuant to the Model Code, were as follows:

LONG POSITION IN THE SHARES OF THE COMPANY

Name of Director/Chief Executive	Capacity	Total number of Shares/ underlying Shares held	Approximate Percentage of Interest in the Company (Note 3)
Dr. LI Zonghai (Note 1) (Note 2)	Interest of controlled corporations and interest of party acting in concert	215,139,753/ Long position	37.91%
Mr. GUO Bingsen (Note 1) (Note 2)	Interest of controlled corporations and interest of party acting in concert	215,139,753/ Long position	37.91%
Dr. WANG Huamao (Note 1) (Note 2)	Interest of controlled corporations and interest of party acting in concert	215,139,753/ Long position	37.91%
Mr. GUO Huaqing (Note 1) (Note 2)	Interest of controlled corporations and interest of party acting in concert	215,139,753/ Long position	37.91%

Notes:

- As of December 31, 2021, YIJIE Biotech (BVI) held 198,139,536 Shares of our Company, representing 34.91% of interest of our Company. YIJIE Biotech (BVI) is owned as to 69.00%, 10.20%, 10.00%, 10.00% and 0.80% by CART Biotech, Redelle Holding, He Xi Holdings Limited, Candock Holdings Limited and Accure Biotech Limited (collectively, the "Intermediary Entities") respectively. The Intermediary Entities are wholly-owned by Dr. LI Zonghai, Mr. GUO Bingsen, Dr. WANG Huamao, Mr. GUO Huaqing and Mr. CHEN Haiou respectively.
- Dr. LI Zonghai, Mr. GUO Bingsen, Dr. WANG Huamao, Mr. GUO Huaqing, Mr. CHEN Haiou, the Intermediary Entities, Ms. YANG Xuehong, Yeed Holdings, Ms. GUO Xiaojing and Quanzhou Dingwo (LP) entered into the Concert Party Agreement on February 22, 2021 and each party is deemed to be interested in the Shares that the other parties are interested in under section 317 of the SFO. Each of Dr. LI Zonghai, Mr. GUO Bingsen, Dr. WANG Huamao, Mr. GUO Huaqing and Mr. CHEN Haiou, through the Intermediary Entities and YIJIE Biotech (BVI), are interested in 198,139,536 Shares of our Company, representing 34.91% of interest in our Company as at December 31, 2021. Ms. YANG Xuehong is interested in 8,888,888 Shares, representing 1.57% of interest in our Company through Yeed Holdings as at December 31, 2021. Ms. GUO Xiaojing is interested in 5,555,556 Shares, representing 0.98% of interest in our Company through Quanzhou Dingwo (LP) as of December 31, 2021. In addition, Mr. CHEN Haiou is entitled to receive up to 2,555,773 Shares pursuant to options granted to him, subject to the conditions (including vesting conditions) of those options. Therefore, Dr. LI Zonghai, Mr. GUO Bingsen, Dr. WANG Huamao, Mr. GUO Huaqing, Mr. CHEN Haiou, the Intermediary Entities, Ms. YANG Xuehong, Yeed Holdings, Ms. GUO Xiaojing and Quanzhou Dingwo (LP) are deemed to be interested in a total of 215,139,753 Shares, representing 37.91% of interest in our Company as at December 31, 2021.
- As at December 31, 2021, the total issued share capital of the Company was 567,537,086 Shares.

Directors' Report

SUBSTANTIAL SHAREHOLDERS' INTERESTS IN SHARES AND UNDERLYING SHARES OF THE COMPANY

Interests and short positions discloseable under Divisions 2 and 3 of Part XV of the SFO

As at December 31, 2021, the persons, other than the Directors or the chief executive of the Company, who had interests or short positions in the Shares and underlying Shares as recorded in the register of interests required to be kept by the Company pursuant to Section 336 of Part XV of the SFO are as follows:

LONG POSITION IN THE SHARES OF THE COMPANY

Name of Shareholders	Capacity	Number of securities/ Nature of Shares held	Approximate percentage of interest in the Company (Note 7)
CART Biotech (Note 1) (Note 2)	Interest of controlled corporations and interest of party acting in concert	215,139,753/ Long position	37.91%
Redelle Holding (Note 1) (Note 2)	Interest of controlled corporations and interest of party acting in concert	215,139,753/ Long position	37.91%
He Xi Holdings (Note 1) (Note 2)	Interest of controlled corporations and interest of party acting in concert	215,139,753/ Long position	37.91%
CANDOCK Holdings (Note 1) (Note 2)	Interest of controlled corporations and interest of party acting in concert	215,139,753/ Long position	37.91%
Mr. CHEN Haiou (Note 1) (Note 2)	Interest of controlled corporations and interest of party acting in concert	215,139,753/ Long position	37.91%
Accure Biotech (Note 1) (Note 2)	Interest of controlled corporations and interest of party acting in concert	215,139,753/ Long position	37.91%
Ms. YANG Xuehong (Note 2) (Note 3)	Interest of controlled corporations and interest of party acting in concert	215,139,753/ Long position	37.91%
Yeed Holdings (Note 2) (Note 3)	Interest of controlled corporations and interest of party acting in concert	215,139,753/ Long position	37.91%
Ms. GUO Xiaojing (Note 2) (Note 4)	Interest of controlled corporations and interest of party acting in concert	215,139,753/ Long position	37.91%

Directors' Report

Name of Shareholders	Capacity	Number of securities/ Nature of Shares held	Approximate percentage of interest in the Company (Note 7)
Quanzhou Dingwo (LP) (Note 2) (Note 4)	Beneficial interest and interest of party acting in concert	215,139,753/ Long position	37.91%
YIJIE Biotech (BVI) (Note 1)	Beneficial interest and interest of party acting in concert	215,139,753/ Long position	37.91%
GIC Private Limited (Note 5)	Interest in controlled corporation	64,339,150 Long position	11.34%
		6,500,000 Short position	1.15%
GIC Special Investments Private Limited (Note 5)	Interest in controlled corporation	64,339,150 Long position	11.34%
		6,500,000 Short position	1.15%
GIC (Ventures) Pte. Ltd. (Note 5)	Interest in controlled corporation	64,339,150 Long position	11.34%
		6,500,000 Short position	1.15%
Mr. YANG Zhi (Note 5)	Interest in controlled corporation	39,894,706/ Long position	7.03%
		6,500,000 Short position	1.15%
BVCF Realization Fund GP, Ltd. (Note 5)	Interest in controlled corporation	39,894,706/ Long position	7.03%
		6,500,000 Short position	1.15%
Prowell Ventures Pte Ltd (Note 5)	Interest in controlled corporation	39,894,706/ Long position	7.03%
		6,500,000 Short position	1.15%
BVCF Realization Fund, L.P. (Note 5)	Interest in controlled corporation	39,894,706/ Long position	7.03%
		6,500,000 Short position	1.15%

Directors' Report

Name of Shareholders	Capacity	Number of securities/ Nature of Shares held	Approximate percentage of interest in the Company (Note 7)
Applied Biomaterial Ltd. (Note 5)	Interest in controlled corporation	39,894,706/ Long position	7.03%
China Medmaterial (Note 5)	Beneficial interest	39,894,706/ Long position	7.03%
Mr. YU Youqiang (Note 6)	Interest in controlled corporation	28,385,012/ Long position	5.00%
Zhejiang Jolly Pharmaceutical Co., Ltd. (Note 6)	Interest in controlled corporation	28,385,012/ Long position	5.00%
Zhejiang Jolly Healthcare Investment Management Limited (Note 6)	Interest in controlled corporation	28,385,012/ Long position	5.00%
Zhejiang Zuoli Innovation Medical Investment Management Co., Ltd. (Note 6)	Beneficial interest	28,385,012/ Long position	5.00%

Notes:

- (1) YIJIE Biotech (BVI) holds 198,139,536 Shares of our Company, representing 34.91% of interest of our Company as at December 31, 2021. YIJIE Biotech (BVI) is owned as to 69.00%, 10.20%, 10.00%, 10.00% and 0.80% by the Intermediary Entities respectively. The Intermediary Entities are wholly-owned by Dr. LI Zonghai, Mr. GUO Bingsen, Dr. WANG Huamao, Mr. GUO Huaqing and Mr. CHEN Haiou respectively.
- (2) Dr. LI Zonghai, Mr. GUO Bingsen, Dr. WANG Huamao, Mr. GUO Huaqing, Mr. CHEN Haiou, the Intermediary Entities, Ms. YANG Xuehong, Yeed Holdings, Ms. GUO Xiaojing and Quanzhou Dingwo (LP) entered into the Concert Party Agreement on February 22, 2021 and each party is deemed to be interested in the Shares that the other parties are interested in under section 317 of the SFO. Each of Dr. LI Zonghai, Mr. GUO Bingsen, Dr. WANG Huamao, Mr. GUO Huaqing and Mr. CHEN Haiou, through the Intermediary Entities and YIJIE Biotech (BVI), are interested in 198,139,536 Shares of our Company, representing 34.91% of interest in our Company as at December 31, 2021. Ms. YANG Xuehong is interested in 8,888,888 Shares, representing 1.57% of interest in our Company through Yeed Holdings as at December 31, 2021. Ms. GUO Xiaojing is interested in 5,555,556 Shares, representing 0.98% of interest in our Company through Quanzhou Dingwo (LP) as of December 31, 2021. In addition, Mr. CHEN Haiou is entitled to receive up to 2,555,773 Shares pursuant to options granted to him, subject to the conditions (including vesting conditions) of those options. Therefore, Dr. LI Zonghai, Mr. GUO Bingsen, Dr. WANG Huamao, Mr. GUO Huaqing, Mr. CHEN Haiou, the Intermediary Entities, Ms. YANG Xuehong, Yeed Holdings, Ms. GUO Xiaojing and Quanzhou Dingwo (LP) are deemed to be interested in a total of 215,139,753 Shares, representing 37.91% of interest in our Company as at December 31, 2021.
- (3) Yeed Holdings holds 8,888,888 Shares in our Company, representing 1.57% of interest in our Company as at December 31, 2021. Yeed Holdings is wholly-owned by Ms. YANG Xuehong, the wife of our non-executive Director, Mr. GUO Bingsen.
- (4) Quanzhou Dingwo (LP) holds 5,555,556 Shares in our Company, representing 0.98% of interest in our Company as at December 31, 2021. The general partner of Quanzhou Dingwo (LP) is Ms. GUO Xiaojing, the daughter of our non-executive Director, Mr. GUO Bingsen.

- (5) China Medmaterial Limited is wholly-owned by Applied Biomaterial Ltd., which is in turn wholly-owned by BVCF Realization Fund, L.P.. The general partner of BVCF Realization Fund, L.P. is BVCF Realization Fund GP, Ltd., a company wholly-owned by Mr. YANG Zhi (楊志). Prowell Ventures Pte. Ltd., a company wholly-owned by GIC (Ventures) Pte. Ltd., which is in turn wholly-owned by the Minister for Finance of the Government of Singapore, owns more than one-third interest in BVCF Realization Fund, L.P. GIC (Ventures) Pte. Ltd. is wholly-owned by GIC Special Investments Private Limited, which is in turn wholly-owned by GIC Private Limited. On the other hand, Loyal Valley Capital Advantage Fund II LP holds 24,444,444 Shares in the Company. Loyal Valley Capital Advantage Fund II LP is wholly-owned by Highbury Investment Pte Ltd, which is in turn wholly-owned by GIC (Ventures) Pte. Ltd.. Accordingly, each of GIC Private Limited, GIC Special Investments Private Limited and GIC (Ventures) Pte. Ltd. is deemed to be interested in a total of 64,339,150 Shares in the Company.
- (6) Zhejiang Zuoli Innovation Medical Investment Management Co., Ltd. ("**Jolly Innovation**") is a limited liability company incorporated under the laws of the PRC. Jolly Innovation is owned as to 92.50% by Zhejiang Jolly Healthcare Investment Management Limited, which is wholly-owned by Zhejiang Jolly Pharmaceutical Co., Ltd. (浙江佐力藥業股份有限公司) ("**Jolly Pharmaceutical**"), a high-tech pharmaceutical company combining R&D, production and commercialization. Jolly Pharmaceutical is listed on the Shenzhen Stock Exchange (stock code: 300181). The controlling shareholder of Jolly Pharmaceutical is Mr. YU Youqiang (俞有強), an Independent Third Party.
- (7) As at December 31, 2021, the total issued share capital of the Company was 567,537,086 Shares.

Save as disclosed above and to the best knowledge of the Directors, as at the Latest Practicable Date, the Company is not aware of any other person (other than the Directors or the chief executive of the Company) who had an interest or short position in the Shares or underlying Shares as recorded in the register required to be kept by the Company pursuant to Section 336 of the SFO.

CONTROLLING SHAREHOLDER'S INTERESTS IN SIGNIFICANT CONTRACTS

Save as disclosed in this report, at no time during the Reporting Period had the Company or any of its subsidiaries, and any of the controlling shareholders (as defined in the Listing Rules) of the Company or any of their subsidiaries (as the case may be) entered into any contract of significance or any contract of significance for the provision of services by any such controlling shareholders or their subsidiaries (as the case may be) to the Company or any of its subsidiaries.

SHARE INCENTIVIZATION SCHEMES

We have adopted three share incentive schemes, collectively referred to as Share Incentive Schemes.

2019 EQUITY INCENTIVE SCHEME

Our Company adopted the 2019 Equity Incentive Plan on January 22, 2019. The purpose of the 2019 Equity Incentive Plan is to attract, motivate, retain and reward certain employees, Directors, and certain other eligible persons of our Group.

On May 11, 2021, our Company allotted and issued 12,497,947 Shares to Carfa Unity Limited and 7,125,575 Shares to Carfe Unity Limited, both of which are wholly-owned by the 2019 Equity Incentive Plan Trustee. Such Shares are to be held in trust by the 2019 Equity Incentive Plan Trustee to facilitate the transfer of Shares to the grantees upon vesting of the relevant Share Options and Share Awards.

As of December 31, 2021, pursuant to the 2019 Equity Incentive Plan, we had granted to Directors, executives and employees of the Group outstanding options to subscribe for 19,926,841 Shares, representing approximately 3.51% of the total issued share capital of our Company as of December 31, 2021. As at the Latest Practicable Date, the total number of securities available for issue under the 2019 Equity Incentive Plan is 5,653,377, representing approximately 0.99% of the total issued share capital of our Company.

Directors' Report

Movement of the options, which were granted under the 2019 Equity Incentive Plan, during the Relevant Period is as follows:

Name of Grantee	As at the Listing Date	Number of options during the Relevant Period				As at December 31, 2021	Date of grant of share options	Exercise Period	Vesting Period	Exercise price US\$
		Granted during the Relevant Period	Exercised during the Relevant Period	Cancelled during the Relevant Period	Lapsed during the Relevant Period					
1. Connected Person										
Mr. CHEN Haiou	2,539,773	0	0	0	0	2,539,773	December 28, 2020	December 28, 2020 - December 27, 2028	March 31, 2017 - March 30, 2020	0.04
2. Other Grantees										
Mr. LIU Rongxi	166,667	0	0	0	0	166,667	December 28, 2020	December 28, 2020 - December 27, 2028	Four years from the vesting commencement date stipulated in relevant grant letters	0
3. Employees										
	17,666,035	0	254,187	191,447	0	17,220,401	December 28, 2020	December 28, 2020 - December 27, 2028	Three or four years from the vesting commencement date stipulated in relevant grant letters	0-1.40
Total:	20,372,475	0	254,187	191,447	0	19,926,841				

Directors' Report

The weighted average closing price of the Company's shares immediately before the dates on which the options were exercised during the Relevant Period is approximately HK\$32.36.

On July 22, 2021, 16,000 RSUs were granted to a connected grantee, representing 16,000 underlying Shares, and approximately 0.0028% of the issued share capital of the Company as of December 31, 2021. On August 23, 2021, an aggregate of 1,600,867 RSUs were granted to a total of 115 RSU grantees (including 6 senior management and 109 other employees), representing 1,600,867 underlying Shares, and approximately 0.28% of the issued share capital of the Company.

Movement of the RSUs, which were granted under the 2019 Equity Incentive Plan, during the Relevant Period is as follows:

Name of Grantee	As at the Listing Date	Number of underlying Shares during the Relevant Period				As at December 31, 2021	Date of grant of RSUs	Vesting Period
		Granted during the Relevant Period	Vested during the Relevant Period	Cancelled during the Relevant Period	Lapsed during the Relevant Period			
1. Connected Person								
Mr. CHEN Haiou	0	16,000	0	0	0	16,000	July 22, 2021	July 22, 2022-July 21, 2025
2. Employees								
	0	1,600,867	10,656	37,254	0	1,552,957	July 22, 2021	July 22, 2022-July 21, 2025
Total:	0	1,616,867	10,656	37,254	0	1,568,957		

POST-IPO RSU SCHEME

Our Company adopted the Post-IPO RSU Scheme on April 30, 2021. The purpose of the Post-IPO RSU Scheme is to align the interests of the eligible persons with those of our Group through ownership of Shares to encourage and retain them to make contributions to the long-term growth and profits of our Group.

Directors' Report

As of December 31, 2021, no RSU had been granted or agreed to be granted under the Post-IPO RSU Scheme.

POST-IPO SHARE OPTION SCHEME

Our Company adopted the Post-IPO Share Option Scheme on April 30, 2021. The purpose of the Post-IPO Share Option Scheme is to reward employees for their past contribution to the success of the Company and to provide incentives to them to further contribute to the Company.

As of December 31, 2021, a total of 730,578 options were outstanding under the Post-IPO Share Option Scheme and all options thereunder have not been exercised and lapsed, 6,081 options have been cancelled. As at the Latest Practicable Date, the maximum number of securities available for issue under the Post-IPO Share Option Scheme is 45,297,617, representing approximately 7.95% of the total issued share capital of our Company.

Set out below are details of movements of the outstanding Options granted under the Post-IPO Share Option Scheme throughout the Relevant Period.

Name of Grantee	As at the Listing Date	Number of options during the Relevant Period				As at December 31, 2021	Date of grant of share options	Exercise Period	Vesting Period	Exercise price HK\$
		Granted during the Relevant Period	Exercised during the Relevant Period	Cancelled during the Relevant Period	Lapsed during the Relevant Period					
Employees	0	730,578	0	6,081	0	724,491	July 22, 2021 ^{Note}	The Options may be exercised during the period from the date of vesting to the 10th anniversary of the grant date.	July 22, 2022- July 21, 2025	HK\$31.00 per Share
Total:	0	730,578	0	6,081	0	724,491				

Note: The closing price per ordinary share of the Company is HK\$30.04 on July 21, 2021, being the business day immediately before July 22, 2021.

For further details of the Share Incentive Schemes, including but not limited to fair value of options granted under the Share Incentive Schemes, please refer to Note 24 to the Consolidated Financial Statements.

SUMMARY OF THE SHARE INCENTIVE SCHEMES

The principal terms and details of the Share Incentive Schemes are set out below:

Details	2019 Equity Incentive Plan	Post-IPO RSU Scheme	Post-IPO Share Option Scheme
1. Purpose	to secure and retain the services of eligible participants, to provide incentives for such persons to exert maximum efforts for the success of our Company and our affiliates, and to provide a means by which such eligible recipients may be given an opportunity to benefit from increases in value of the Shares through the granting of the Share Awards to align the interests of the eligible persons with those of our Group through ownership of Shares to encourage and retain them to make contributions to the long-term growth and profits of our Group.	to align the interests of the eligible persons with those of our Group through ownership of Shares to encourage and retain them to make contributions to the long-term growth and profits of our Group.	to reward employees for their past contribution to the success of the Company and to provide incentives to them to further contribute to the Company.

Directors' Report

Details	2019 Equity Incentive Plan	Post-IPO RSU Scheme	Post-IPO Share Option Scheme
2. Eligible Participants	<p>Eligible persons include any person employed by our Company or our affiliates, any director of our Company or any of its subsidiaries, any person, including an advisor, who is (i) engaged by our Company or our affiliates to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of our affiliates and is compensated for such services.</p>	<p>Any individual, being an employee, director (including executive Directors, non-executive Directors and independent non-executive Directors) or officer, consultant, advisor, distributor, contractor, customer, supplier, agent, business partner, joint venture business partner or service provider of any member of the Group or any affiliate (an “Eligible Person” and, collectively “Eligible Persons”) who the Board or its delegate(s) considers, in its sole discretion, to have contributed or will contribute to the Group is eligible to receive an award granted by the Board, by way of RSUs, which may vest in the form of Award Shares or the actual selling price of the Award Shares of RSUs in cash in accordance with the Post-IPO RSU Scheme. However, no individual who is resident in a place where the grant, acceptance or vesting of an Award pursuant to the Post-IPO RSU Scheme is not permitted under the laws and regulations of such place or where, in the view of the Board or its delegate(s), compliance with applicable laws and regulations in such place makes it necessary or expedient to exclude such individual, shall be entitled to participate in the Post-IPO RSU Scheme.</p>	<p>Any individual, being an employee, director or officer of any member of our Group who the Board may in its absolute discretion select to grant an Option to subscribe for such number of Shares as the Board may determine at the Subscription Price.</p>



Details	2019 Equity Incentive Plan	Post-IPO RSU Scheme	Post-IPO Share Option Scheme
3. Maximum number of Shares that can be awarded	Subject to capitalization adjustments, the aggregate number of Shares that may be issued pursuant to Share Awards shall not exceed 27,519,380 Shares.	The aggregate number of Shares underlying all grants made pursuant to the Post-IPO RSU Scheme (excluding Award which have been forfeited in accordance with the Post-IPO RSU Scheme) will not exceed 5% of the issued share capital of the Company as of the date of approval of the Post-IPO RSU Scheme without shareholders' approval, being 22,648,808 Shares.	The maximum number of Shares in respect of which Options may be granted under the Post-IPO Share Option Scheme when aggregated with the maximum number of Shares in respect of which Options may be granted under any other option scheme over Shares shall not exceed 10% of the issued share capital of the Company as of the date of approval of the Post-IPO Share Option Scheme (or of the refreshing of the 10% limit) by the shareholders of the Company, being 45,297,617 Shares. Options lapsed in accordance with the terms of the Post-IPO Share Option Scheme shall not be counted for the purpose of calculating the 10% limit. Within the aforesaid 10% limit (or alternatively subject to the approval of shareholders of the Company in general meeting), the maximum number of Shares to be issued upon exercise of all outstanding Options under this Post-IPO Share Option Scheme may be increased by increments as determined by the Board, provided that the total number of Shares to be issued upon exercise of all outstanding Options under the Post-IPO Share Option Scheme and all other schemes of the Company granted and yet to be exercised does not exceed 30% of all the Shares in issue from time to time. No Option may be granted under the Post-IPO Share Option Scheme if this will result in the limit being exceeded.

Directors' Report

Details	2019 Equity Incentive Plan	Post-IPO RSU Scheme	Post-IPO Share Option Scheme
4. Maximum entitlement of each participant under the scheme	N/A	Save as prescribed in the scheme or as otherwise restricted by the Listing Rules, for any 12-month period, the aggregate number of Shares granted to any Selected Participant shall not exceed 1% of the total number of the issued Shares at the relevant time, without Shareholders' approval.	Except with the approval of Shareholders in general meeting, no Option may be granted to any one person such that the total number of Shares issued and to be issued upon exercise of Options and any other option over the Shares (including exercised, cancelled and outstanding options) granted and to be granted to such person in any 12-month period up to the date of the latest grant exceeds one per cent of the Shares in issue from time to time.
5. Vesting	The total number of Shares subject to a Share Option may vest and therefore become exercisable in periodic installments that may or may not be equal. The Share Option may be subject to such other terms and conditions on the time or times when it may or may not be exercised (which may be based on the satisfaction of performance goals or other criteria) as the Board may deem appropriate. The vesting provisions of each Share Option may vary.	<p>The Board or its delegate(s) may from time to time while the Post-IPO RSU Scheme is in force and subject to all applicable laws, determine such vesting criteria and conditions or periods for the Award to be vested.</p> <p>Within a reasonable time period as agreed between the RSU Trustee and the Board from time to time prior to any Vesting Date, the Board or its delegate(s) will send a vesting notice to the relevant selected participant and instruct the RSU Trustee the extent to which the Award Shares held in the trust shall be transferred and released from the trust to the selected participant. Subject to the receipt of the vesting notice and notification from the Board or its delegate(s), the RSU Trustee will transfer and release the relevant Award in the manner as determined by the Board or its delegate(s).</p>	Subject as provided in the Post-IPO Share Option Scheme and any conditions specified by the Board, an Option may, subject to the terms and conditions upon which such option is granted, be exercised in whole or in part by the grantee giving notice in writing to our Company in such form as the Board may from time to time determine stating that the option is thereby exercised and the number of Shares in respect of which it is exercised.

Details	2019 Equity Incentive Plan	Post-IPO RSU Scheme	Post-IPO Share Option Scheme
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If, in the absolute discretion of the Board or its delegate(s), it is not practicable for the selected participant to receive the Award in Shares, solely due to legal or regulatory restrictions with respect to the selected participant's ability to receive the Award in Shares or the RSU Trustee's ability to give effect to any such transfer to the selected participant, the Board or its delegate(s) will direct and procure the RSU Trustee to sell, on-market at the prevailing market price, the number of RSUs so vested in the form of Award Shares in respect of the selected participant and pay the selected participant the proceeds arising from such sale based on the actual selling price of the Award Shares following vesting of such RSUs in cash as set out in the vesting notice.

If there is an event of change in control of our Company by way of a merger, a privatization of our Company by way of a scheme or by way of an offer, the Board or the committee of the Board or person(s) to which the Board has delegated its authority shall at their sole discretion determine whether the Vesting Dates of any Awards will be accelerated to an earlier date.

Directors' Report

Details	2019 Equity Incentive Plan	Post-IPO RSU Scheme	Post-IPO Share Option Scheme
6. Duration	<p>No Share Option shall be exercisable after the expiration of eight years from the date of its grant or such shorter period specified in a share award agreement.</p> <p>As at December 31, 2021, the remaining life of the 2019 Equity Incentive Plan was approximately five years.</p>	<p>The Post-IPO RSU Scheme shall terminate on the earlier of:</p> <ul style="list-style-type: none"> (i) the end of the period of ten years commencing on the Listing Date except in respect of any non-vested RSUs granted hereunder prior to the expiration of the Post-IPO RSU Scheme, for the purpose of giving effect to the vesting in the form of Award Shares of such RSUs or otherwise as may be required in accordance with the provisions of the Post-IPO RSU Scheme; and (ii) such date of early termination as determined by the Board provided that such termination shall not affect any subsisting rights of any selected participant under the rules of the Post-IPO RSU Scheme, provided further that for the avoidance of doubt, the change in the subsisting rights of a selected participant in this paragraph refers solely to any change in the rights in respect of the RSUs already granted to a selected participant. <p>As at December 31, 2021, the remaining life of the Post-IPO RSU Scheme was approximately nine years and eight months.</p>	<p>The Post-IPO Share Option Scheme shall be valid and effective for a period of 10 years commencing on the date when the Post-IPO Share Option Scheme becomes unconditional, after which period no further Options will be granted by the provisions of the Post-IPO Share Option Scheme, but the provisions of this Post-IPO Share Option Scheme shall remain in full force and effect to the extent necessary to give effect to the exercise of any Options granted prior thereto or otherwise as may be required in accordance with the provisions of the Post-IPO Share Option Scheme.</p> <p>As at December 31, 2021, the remaining life of the Post-IPO Share Option Scheme was approximately nine years and eight months.</p>

Directors' Report

Details	2019 Equity Incentive Plan	Post-IPO RSU Scheme	Post-IPO Share Option Scheme
7. Exercise price	The exercise price (or strike price) of each Share Option shall be determined in good faith by the Administrator and as set forth in a share award agreement. The consideration, if any, to be paid by the participant upon delivery of each Share subject to the restricted share unit award will be determined by the Board at the time of grant of such award.	N/A	<p>The amount payable for each Share to be subscribed for under an option in the event of the option being exercised shall be determined by the Board at its absolute discretion, but shall be not less than the greater of:</p> <ul style="list-style-type: none"> (i) the closing price of a Share as stated in the daily quotations sheet issued by the Stock Exchange on the date of grant; (ii) the average closing price of our Shares as stated in the daily quotations sheets issued by the Stock Exchange for the five business days immediately preceding the date of grant; and (iii) the nominal value of a Share on the date of grant.
8. Option Period	No share option shall be exercisable after the expiration of eight years from the date of its grant or such shorter period specified in a share award agreement.	N/A	The period during which the option can be exercised as set forth in the relevant offer letters in accordance with the plan.

Directors' Report

Details	2019 Equity Incentive Plan	Post-IPO RSU Scheme	Post-IPO Share Option Scheme
9. Others	<p>Right of Repurchase</p> <p>The terms of any repurchase right shall be specified in a share award agreement. The repurchase price for vested and unvested Shares shall both be determined in good faith by the Board.</p>	<p>Issue of Shares and/or transfer of funds to the RSU Trustee</p> <p>Our Company shall, as soon as reasonably practicable and no later than 30 business days from the Grant Date, (i) issue and allot Shares to the RSU Trustee and/ or (ii) transfer to the RSU Trustee the necessary funds and instruct the RSU Trustee to acquire Shares through on-market transactions at the prevailing market price, so as to satisfy the Awards.</p> <p>Our Company shall not issue or allot Award Shares nor instruct the RSU Trustee to acquire Shares through on-market transactions at the prevailing market price, where such action (as applicable) is prohibited under the Listing Rules, the Securities and Futures Ordinance or other applicable laws from time to time. Where such a prohibition causes the prescribed timing imposed by the Post-IPO RSU Scheme Rules or the trust deed to be missed, such prescribed timing shall be treated as extended until as soon as reasonably practicable after the first Business Day on which the prohibition no longer prevents the relevant action.</p>	<p>Performance target</p> <p>The Post-IPO Share Option Scheme does not set out any performance targets that must be achieved before the options may be exercised. However, subject to the provisions of the Listing Rules, the Board may in its absolute discretion specify such event, time limit or conditions (if any) as it thinks fit including, without limitation, conditions as to performance criteria to be satisfied and/or the Company and/or the Group which must be satisfied before an Option can be exercised, provided such terms and conditions shall not be inconsistent with any other terms and conditions of the Post-IPO Share Option Scheme.</p>



CONTINUING CONNECTED TRANSACTIONS AND RELATED PARTY TRANSACTIONS

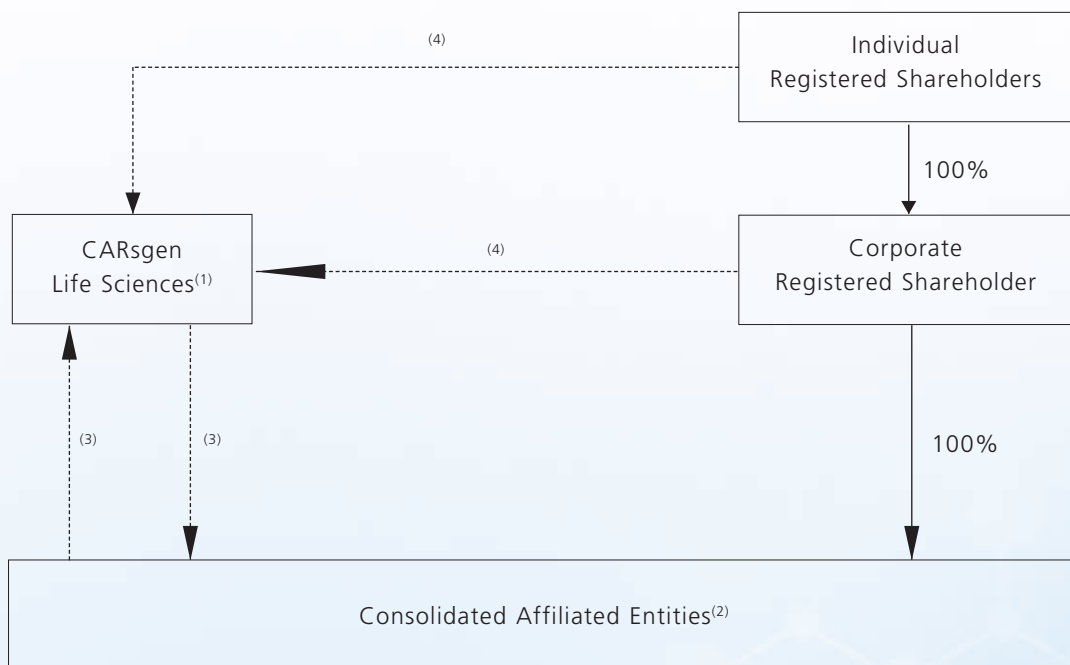
Contractual Arrangement

The Group entered into a series of Contractual Arrangements which would constitute non-exempt continuing connected transactions pursuant to Chapter 14A of the Listing Rules.

Background

In order to comply with the PRC laws and regulations and maintain effective control over all of our operations, we, through our wholly-owned subsidiary, CARsgen Life Sciences entered into the Contractual Arrangements with CARsgen Therapeutics (Shanghai), the Corporate Registered Shareholder (i.e. the shareholder of CARsgen Therapeutics (Shanghai)) and the Individual Registered Shareholders (i.e. the shareholders of the Corporate Registered Shareholder), pursuant to which CARsgen Life Sciences acquired effective control over the finance and operations of our Consolidated Affiliated Entities and is entitled to all the economic benefits derived from their operations.

The following simplified diagram illustrates the flow of economic benefits from our Consolidated Affiliated Entities to our Group stipulated under the Contractual Arrangements:



"———" Denotes legal and beneficial ownership in the equity interest

"- - - - -" Denotes the Contractual Arrangements

Directors' Report

Note:

- (1) CARsgen Life Sciences is wholly-owned by CARsgen Pharma Holdings Limited, which is in turn wholly-owned by our Company.
- (2) Our Consolidated Affiliated Entities include CARsgen Therapeutics (Shanghai) and CARsgen Pharmaceuticals. CARsgen Pharmaceuticals is wholly-owned by CARsgen Therapeutics (Shanghai), which is in turn wholly-owned by the Corporate Registered Shareholder, which is in turn owned by the Individual Registered Shareholders, namely as to 69% by Dr. Li, 10.2% by Mr. GUO Bingsen (郭炳森), 10% by Dr. WANG Huamao, 10% by Mr. GUO Huaqing (郭华清) and 0.8% by Mr. CHEN Haiou.
- (3) CARsgen Life Sciences provides technology consultation services in exchange for service fees from CARsgen Therapeutics (Shanghai). See sub-section headed "Exclusive Business Cooperation Agreements" below.
- (4) The Corporate Registered Shareholder executed the Corporate Exclusive Option Agreement (as defined below) in favour of CARsgen Life Sciences for the acquisition of 100% equity interests and/or assets in CARsgen Therapeutics (Shanghai). See sub-section headed "Exclusive Option Agreements". The Individual Registered Shareholders in turn executed the Individual Exclusive Option Agreement (as defined below) in favour of CARsgen Life Sciences for the acquisition of 100% equity interests and/or assets in the Corporate Registered Shareholder.

The Corporate Registered Shareholder pledged as first charge all of its equity interests in CARsgen Therapeutics (Shanghai) to CARsgen Life Sciences as security for its and CARsgen Therapeutics (Shanghai)'s performance under the Exclusive Business Cooperation Agreements (as defined below), the Corporate Exclusive Option Agreement (as defined below), the Corporate Share Pledge Agreement (as defined below) and the Corporate Powers of Attorney (as defined below), as applicable. The Individual Registered Shareholders in turn pledged as first charge all of their respective equity interests in the Corporate Registered Shareholder to CARsgen Life Sciences as security for their respective performance and the performance of the Corporate Registered Shareholder and CARsgen Therapeutics (Shanghai) under the Exclusive Business Cooperation Agreement, Exclusive Option Agreements, Powers of Attorney, Share Pledge Agreements (as applicable). See subsection headed "Share Pledge Agreements."

The Corporate Registered Shareholder executed the Corporate Powers of Attorney in favour of CARsgen Life Sciences. The Individual Registered Shareholders in turn executed the Powers of Attorney in favour of CARsgen Life Sciences in respect of their respective rights as shareholders of the Corporate Registered Shareholder.

Summary of Contractual Arrangements

Exclusive Business Cooperation Agreements

CARsgen Life Sciences and CARsgen Therapeutics (Shanghai) entered into the exclusive business cooperation agreements on April 18, 2018 and the amended and restated exclusive business cooperation agreements on February 2, 2021 (collectively, the "**Exclusive Business Cooperation Agreements**"), pursuant to which CARsgen Therapeutics (Shanghai) agreed to engage CARsgen Life Sciences as its exclusive provider of technology consultation, technical services and other related services, including but not limited to (i) technological support in relation to product development and testing, (ii) design, develop, update and maintenance service in relation to technology system, (iii) technological support in relation to research and development activities, (iv) technological consultation service (including but not limited to viability testing, technology prediction, investigation into specific technologies and producing analytical valuation reports), (v) personnel training services, (vi) onsite personnel supervision; and (vii) other related services requested by CARsgen Therapeutics (Shanghai) from time to time to the extent permitted under PRC law.

Pursuant to the Exclusive Business Cooperation Agreements, the service fee shall be paid annually to CARsgen Life Sciences. The annual service fees shall be reasonably determined by CARsgen Life Sciences based on certain factors, including, among other things, the complexity and difficulty of such services, time and commitment required to provide such services, actual service scope and the market value of comparable service.

The Exclusive Business Cooperation Agreements are for an initial term of 10 years and is automatically extended upon expiry for a term provided by CARsgen Life Sciences in writing unless terminated by CARsgen Life Sciences in the same manner, or otherwise terminated pursuant to the terms of the Exclusive Business Cooperation Agreements.

Powers of Attorney

CARsgen Life Sciences and CARsgen Therapeutics (Shanghai) entered into the powers of attorney with the Corporate Registered Shareholder and other related parties on April 18, 2018 and the amended and restated powers of attorney on February 2, 2021 with Corporate Registered Shareholder (the "**Corporate Powers of Attorney**") pursuant to which the Corporate Registered Shareholder irrevocably and exclusively granted CARsgen Life Sciences or its designee(s) (being the directors of the offshore parent company CARsgen Life Sciences and liquidators and other successors replacing such directors) the power to exercise all rights of the shareholders as set out in the then valid articles of association of CARsgen Therapeutics (Shanghai) and relevant laws and regulations.

The Corporate Powers of Attorney shall remain effective from the date of signing until the Corporate Registered Shareholder (including its successor(s)) ceases to be the shareholder of CARsgen Therapeutics (Shanghai) or otherwise terminated pursuant to the terms of the Corporate Powers of Attorney.

On the other hand, CARsgen Life Sciences also entered into the powers of attorney (the "**Individual Powers of Attorney**", and together with the Corporate Powers of Attorney, the "**Powers of Attorney**") on February 2, 2021 with the Individual Registered Shareholders, pursuant to which the Individual Registered Shareholders irrevocably and exclusively granted CARsgen Life Sciences or its designee(s) (being the directors of the offshore parent company of CARsgen Life Sciences and liquidators and other successors replacing such directors) the power to exercise all rights of the shareholders as set out in the then valid articles of association of the Corporate Registered Shareholder on similar terms as the Corporate Powers of Attorney.

Exclusive Option Agreements

CARsgen Life Sciences and CARsgen Therapeutics (Shanghai) entered into an exclusive option agreement with the Corporate Registered Shareholder and other related parties on April 18, 2018 and an amended and restated exclusive option agreement on February 2, 2021 (collectively the "**Corporate Exclusive Option Agreement**") with the Corporate Registered Shareholder, pursuant to which CARsgen Life Sciences (or a third party designated by it, the "designee") will be granted an irrevocable and exclusive right to acquire 100% of the equity interest in and/or assets of CARsgen Therapeutics (Shanghai), in whole or in part at the sole and absolute discretion of CARsgen Life Sciences, to the extent permitted under the PRC laws and regulations.

On the other hand, CARsgen Life Sciences also entered into an exclusive option agreement on February 2, 2021 (the "**Individual Exclusive Option Agreement**", and together with the Corporate Exclusive Option Agreement, the "**Exclusive Option Agreements**") with the Individual Registered Shareholders pursuant to which CARsgen Life Sciences will be granted an irrevocable and exclusive right to acquire 100% of the equity interest in and/or assets of the Corporate Registered Shareholder, in whole or in part at the sole and absolute discretion of CARsgen Life Sciences to the extent permitted under the PRC laws and regulations, on similar terms as the Corporate Exclusive Option Agreement.

The Exclusive Option Agreements shall remain effective for 10 years from the date of signing and shall extend at the election of CARsgen Life Sciences, except until (1) all of the equity interest in and the assets of CARsgen Therapeutics (Shanghai) have been transferred to CARsgen Life Sciences or its designees and (2) CARsgen Life Sciences could conduct the business operated by CARsgen Therapeutics (Shanghai) legally.

Directors' Report

Share Pledge Agreements

CARsgen Life Sciences and CARsgen Therapeutics (Shanghai) entered into the share pledge agreement with the Corporate Registered Shareholder and other related parties on April 18, 2018 and the amended and restated share pledge agreement (the "**Corporate Share Pledge Agreement**") on February 2, 2021 with the Corporate Registered Shareholder, pursuant to which the Corporate Registered Shareholder agreed to pledge all of its equity interest in CARsgen Therapeutics (Shanghai) to CARsgen Life Sciences to secure performance of its and CARsgen Therapeutics (Shanghai)'s obligations under the Corporate Exclusive Business Cooperation Agreement, the Corporate Exclusive Options Agreement, the Corporate Share Pledge Agreement and the Corporate Powers of Attorney (as applicable).

On the other hand, CARsgen Life Sciences entered into the share pledge agreement (the "**Individual Share Pledge Agreement**", and together with the Corporate Share Pledge Agreement, the "**Share Pledge Agreements**") on February 2, 2021 with the Individual Registered Shareholders, pursuant to which the Individual Registered Shareholders agreed to pledge all of their respective equity interests in the Corporate Registered Shareholder to CARsgen Life Sciences to secure performance their respective performance and the performance of the Corporate Registered Shareholder and CARsgen Therapeutics (Shanghai) under the Exclusive Business Cooperation Agreement, Exclusive Option Agreements, Powers of Attorney, Share Pledge Agreements (as applicable), on similar terms as the Corporate Share Pledge Agreement. As of the Latest Practicable Date, we have registered the share pledges under the Individual Share Pledge Agreements with the relevant PRC governmental authority in accordance with PRC laws and regulations.

Spouse Undertakings

Each of the spouses of the Individual Registered Shareholders (as applicable) has executed an undertaking (collectively, the "**Spouse Undertakings**"), to the effect that (i) she acknowledges and consents to the execution of the Contractual Arrangements by the relevant Individual Registered Shareholder and acknowledges that she does not have any equity interest or rights with respect to the Contractual Arrangements; (ii) she undertakes not interfere with the performance of the Contractual Arrangements nor to make any assertions in connection with the equity interest of the Corporate Registered Shareholder held by the respective Individual Registered Shareholder; (iii) she has not participated and will not participate in the management of the Corporate Registered Shareholder and will not make any assertions in connection with the equity interest and assets of the Corporate Registered Shareholder; and (iv) in the event that she obtains any interests in the Corporate Registered Shareholder, she shall be bound by the Contractual Arrangements shall execute all necessary documents to comply with the Contractual Arrangements.

Reasons for Adoption of Contractual Arrangements

Foreign investment activities in the PRC are mainly governed by the Industry Guidelines on Encouraged Foreign Investment (2020) 《鼓勵外商投資產業目錄(2020年版)》 and the Special Administrative Measures (Negative List) for the Access of Foreign Investment (2020) 《外商投資准入特別管理措施(負面清單)(2020年版)》 (collectively, the “**Relevant PRC Regulations**”) promulgated jointly by the MOFCOM and the NDRC, pursuant to which the industries listed therein are divided into four categories in terms of foreign investment, namely, “encouraged”, “permitted”, “prohibited” and “restricted”. According to the Relevant PRC Regulations, foreign investment is prohibited in the development and application of human stem cells and genes diagnosis and treatment technologies.

Our Group engages in discovering, developing and commercializing innovative cell therapies for the treatment of hematological malignancies and solid tumors (the “**Relevant Business**”), which involves the development and application of gene therapeutic technologies and products, and therefore falls into the scope of the “prohibited” category of the Relevant PRC Regulations. In order to comply with the PRC laws and regulations and maintain effective control over the Relevant Business, our Group entered into the Contractual Arrangements with CARsgen Therapeutics (Shanghai), the Corporate Registered Shareholder (i.e. the shareholder of CARsgen Therapeutics (Shanghai)) and the Individual Registered Shareholders (i.e. the shareholders of the Corporate Registered Shareholder). Our Directors (including the independent non-executive Directors) are of the view that the Contractual Arrangements and the transactions contemplated therein are fundamental to our Group’s legal structure and business.

Risks Relating to the Contractual Arrangements

There are certain risks that are associated with the Contractual Arrangements, including:

- If the PRC government finds that the agreements that establish the structure for operating our business in China do not comply with PRC laws and regulations, or if these regulations or their interpretations change in the future, we could be subject to severe consequences and the relinquishment of our interests in the Consolidated Affiliated Entities.
- There is substantial uncertainty with respect to the interpretation and implementation of the newly enacted Foreign Investment Law and how it may impact the viability of our current corporate structure, corporate governance and business operations.
- Our Contractual Arrangements may not be as effective in providing operational control as direct ownership, and the Registered Shareholders and the Consolidated Affiliated Entities may fail to perform their obligations under our Contractual Arrangements.

Directors' Report

- We may lose the ability to use the permits and licenses held by the Consolidated Affiliated Entities that are important to the operation of our business if the Consolidated Affiliated Entities declares bankruptcy or becomes subject to a dissolution or liquidation proceeding.
- Our Contractual Arrangements may be subject to scrutiny by the PRC tax authorities and additional taxes may be imposed. A finding that we owe additional taxes could substantially reduce our consolidated net income and the value of your Shares.
- The Registered Shareholders of CARsgen Therapeutics (Shanghai) may potentially have a conflict of interest with us, and they may breach their contracts with us or cause such contracts to be amended in a manner contrary to our interests.
- Certain of the terms of the Contractual Arrangements may not be enforceable under PRC laws.
- If we exercise the option to acquire equity ownership of CARsgen Therapeutics (Shanghai) and/or the Corporate Registered Shareholder, the ownership transfer may subject us to certain limitations and substantial costs.

Our Group has adopted measures to ensure the effective operation of our Group's businesses with the implementation of the Contractual Arrangements and our compliance with the Contractual Arrangements, including:

- major issues arising from the implementation and compliance with the Contractual Arrangements or any regulatory enquiries from government authorities will be submitted to our Board, if necessary, for review and discussion on an occurrence basis;
- our independent non-executive Directors will review the overall performance of and compliance with the Contractual Arrangements annually;
- our Company will disclose the arrangements in place and compliance with the Contractual Arrangements in our annual reports; and
- our Company will engage external legal advisors or other professional advisors, if necessary, to assist the Board in reviewing the implementation of the Contractual Arrangements.

Material Change

As of the Latest Practicable Date, there were no material changes in the Contractual Arrangements and/or the circumstances under which the Contractual Arrangements were adopted.

Unwinding of the Contractual Arrangements

As of the Latest Practicable Date, there has not been any unwinding of any Contractual Arrangements, nor has there been any failure to unwind any Contractual Arrangements when the restrictions that led to the adoption of the Contractual Arrangements are removed.

Waiver from the Stock Exchange

In relation to the Contractual Arrangements, we have applied to the Stock Exchange for, and the Stock Exchange has granted, a waiver from strict compliance with (i) the announcement, circular and independent shareholders' approval requirements under Chapter 14A of the Listing Rules in respect of the transactions contemplated under the Contractual Arrangements pursuant to Rule 14A.105 of the Listing Rules, (ii) the requirement of setting an annual cap for the transactions under the Contractual Arrangements under Rule 14A.53 of the Listing Rules, and (iii) the requirement of limiting the term of the Contractual Arrangements to three years or less under Rule 14A.52 of the Listing Rules, for so long as the Shares are listed on the Stock Exchange subject however to the following conditions:

- (a) no change without independent non-executive Directors' approval;
- (b) no change without independent shareholders' approval;
- (c) the Contractual Arrangements shall continue to enable our Group to receive the entire economic benefits derived by CARsgen Therapeutics (Shanghai);
- (d) on the basis that the Contractual Arrangements provide an acceptable framework for the relationship between our Company and its subsidiaries in which our Company has direct shareholding, on the one hand, and CARsgen Therapeutics (Shanghai), on the other hand, that framework may be renewed and/or reproduced upon the expiry of the existing arrangements or in relation to any existing or new wholly foreign owned enterprise or operating company (including branch company) engaging in the same business as that of our Group which the Group might wish to establish when justified by business expediency, without obtaining the approval of the shareholders, on substantially the same terms and conditions as the existing Contractual Arrangements; and
- (e) our Group will disclose details relating to the Contractual Arrangements on an on-going basis.

For details, please refer to the section "Connected Transactions" in the Prospectus.

Directors' Report

Confirmation from Independent Non-executive Directors

Our independent non-executive Directors have reviewed the Contractual Arrangements and confirmed that:

- (i) no transaction has been carried out during Relevant Period, which have not been entered into in accordance with the relevant provisions of the Contractual Arrangements;
- (ii) no dividends or other distributions have been made by the Consolidated Affiliated Entities to the holders of its equity interests which are not otherwise subsequently assigned or transferred to our Group, which is confirmed by the auditor of the Company;
- (iii) no new contract has been entered into, renewed or reproduced between our Group and the Consolidated Affiliated Entities during the Relevant Period; and
- (iv) the Contractual Arrangements had been entered into in the ordinary and usual course of business of our Group, and are on normal commercial terms and are fair and reasonable so far as our Group is concerned, and in the interest of our Company and its shareholders as a whole.

Further, the Consolidated Affiliated Entities undertakes that, for so long as the Shares are listed on the Hong Kong Stock Exchange, the Consolidated Affiliated Entities will provide our Group's management and our auditor with full access to its relevant records for the purpose of procedures to be carried out by our auditor on the connected transactions. For the year ended December 31, 2021, the net loss of CARsgen Therapeutics is approximately RMB0.26 million, and as at December 31, 2021, the total assets of CARsgen Therapeutics is approximately RMB0.36 million.

Confirmations from Company's Independent Auditor

The auditor of the Company confirmed that based on the foregoing, in respect of the disclosed continuing connected transactions (a) nothing has come to their attention that causes them to believe that the disclosed continuing connected transactions have not been approved by the Directors; (b) nothing has come to their attention that causes them to believe that the transactions were not entered into, in all material respects, in accordance with the relevant agreements governing such transactions; and (c) with respect of the disclosed continuing connected transactions with CARsgen Therapeutics (Shanghai) under the Contractual Arrangements, nothing has come to their attention that causes them to believe that dividends or other distributions have been made by CARsgen Therapeutics (Shanghai) to the holders of the equity interests of CARsgen Therapeutics (Shanghai) are not otherwise subsequently assigned or transferred to the Group.

RELATED PARTY TRANSACTIONS

Details of the related party transactions carried out in the normal course of business are set out in note 34 to the Consolidated Financial Statements. Save as disclosed above, none of these related party transactions constitutes a connected transaction or continuing connected transaction as defined under the Listing Rules, and the Company has complied with the disclosure requirements under Chapter 14A of the Listing Rules and disclosed in this annual report.

RETIREMENT BENEFITS SCHEME

Carsgen Therapeutics (Shanghai)'s full-time employees in the PRC, including some of our named executive officers, participate in a government mandated defined contribution plan, pursuant to which pension benefits, medical care, an employee housing fund and other welfare benefits are provided to employees. Chinese labor regulations require that our PRC subsidiaries make contributions to the government for these benefits based on percentages of the employees' salaries which are capped at 300 percent of the average local wage.

For employees in the United States, CARsgen Therapeutics Corporation (Employer) is helping to make saving for retirement under our 401(k) Plan easier by offering an Employer safe harbor matching contribution, which is another defined contribution plan of the Group. Employee's combined elective contributions and Roth 401(k) contributions are subject to a calendar year limit even though the Plan Year may not be the calendar year. The limit for the 2021 calendar year is US\$19,500. The limit for catch-up contributions for the 2021 calendar year is US\$6,500. Employer will be matching both employee's pre-tax and/or Roth elective contributions, dollar for dollar, up to 6% of employee's eligible pay. This contribution is called a safe harbor matching contribution. This contribution will be made on behalf of all eligible employees. Employer may choose to revoke or suspend the safe harbor contribution during the year. If this occurs, employee will be given 30 days advance notice of the suspension and employee will be given an opportunity to change employee's elective contribution rate.

Details of the pension obligations of the Company are set out in Note 10 to the Consolidated Financial Statements in this report. During the Reporting Period, there was no forfeiture of contributions under the defined contribution plans of the Group, and there were no forfeited contributions had been used by the Group to reduce the existing level of contributions.

PROPERTY, PLANT AND EQUIPMENT

Details of the movements in the property, plant and equipment of the Group during the Reporting Period are set out in Note 15 to the Consolidated Financial Statements.

SHARE CAPITAL

Details of the movements in share capital of the Company during the Reporting Period are set out in note 23 to the Consolidated Financial Statements of this report.

DISTRIBUTABLE RESERVES

The Company may pay dividends out of the share premium account, retained earnings and any other reserves provided that immediately following the payment of such dividends, the Company will be in a position to pay off its debts as and when they fall due in the ordinary course of business.

As of December 31, 2021, the Company did not have any distributable reserves.

Details of the movements in the reserves of the Company during the year ended December 31, 2021 are set out in the consolidated statement of changes in equity and Note 36 to the consolidated financial statements.

Directors' Report

USE OF PROCEEDS FROM THE GLOBAL OFFERING

The Company's Shares were listed on the Stock Exchange on June 18, 2021 with a total of 94,747,000 offer shares issued and the net proceeds raised from the Global Offering were approximately HK\$3,008 million. The net proceeds from the Listing (adjusted on a pro rata basis based on the actual net proceeds) have been and will be utilized in accordance with the purposes set out in the Prospectus. There was no change in the intended use of net proceeds as previously disclosed in the Prospectus as follows:

- approximately HK\$902.4 million (US\$115.7 million) (or approximately 30% of the net proceeds) to fund further development of our Core Product Candidate, BCMA CAR-T (CT053)
- approximately HK\$932.5 million (US\$119.6 million) (or approximately 31% of the net proceeds) to fund ongoing and planned research and development of our other pipeline product candidates
- approximately HK\$601.6 million (US\$77.2 million) (or approximately 20% of the net proceeds) for developing full-scale manufacturing and commercialization capabilities
- approximately HK\$300.8 million (US\$38.6 million) (or approximately 10% of the net proceeds) for continued upgrading of CAR-T technologies and early-stage research and development activities
- approximately HK\$270.7 million (US\$34.7 million) (or approximately 9% of the net proceeds) will be used for our working capital and other general corporate purposes.

The net proceeds from the Global Offering have been utilized in accordance with the purposes set out in the Prospectus. The table below sets out the applications of the net proceeds and actual usage up to December 31, 2021:

Use of proceeds		Planned allocation of Net Proceeds (HKD million)	Planned allocation of Net Proceeds (RMB million)	Utilized amount (as at December 31, 2021) (RMB million)	Remaining amount (as at December 31, 2021) (RMB million)
Further development of our Core Product Candidate, BCMA CAR-T (CT053)	30%	902.4	737.8	86.8	651.0
Ongoing and planned research and development of our other pipeline product candidates	31%	932.5	762.4	143.4	619.0
Developing full-scale manufacturing and commercialization capabilities	20%	601.6	491.9	138.5	353.4
Upgrading of CAR-T technologies and early-stage research and development activities	10%	300.8	245.9	19.0	226.9
Working capital and other general corporate purposes	9%	270.7	221.3	–	221.3
Total	100%	3,008.0	2,459.3	387.7	2,071.6

The unutilized amount of net proceeds is expected to be used by 2023.

Saved as disclosed above, we did not have any other issuance of shares for the period from the Listing Date up to the Latest Practicable Date.

SUFFICIENCY OF PUBLIC FLOAT

Based on the information that is publicly available to the Company and within the knowledge of the Directors, the Company had maintained the prescribed public float under Rule 8.08 of the Listing Rules during the Relevant Period and as at the Latest Practicable Date.

PURCHASE, SALE OR REDEMPTION OF THE COMPANY'S LISTED SECURITIES

During the Relevant Period, neither the Company nor any of its subsidiaries had purchased, sold or redeemed the Company's listed securities.

PRE-EMPTIVE RIGHTS

There is no provision for pre-emptive rights under the articles of association of the Company or the laws of the Cayman Islands which would oblige the Company to offer new shares on a pro-rata basis to its existing shareholders.

TAX RELIEF AND EXEMPTION

During the Reporting Period and as at the Latest Practicable Date, the Directors are not aware of any tax relief and exemption available to the shareholders by reason of their holding of the Company's securities.

BANK BORROWINGS AND OTHER BORROWINGS

Details of the bank borrowings of the Group as at December 31, 2021 are set out in Note 27 to the Consolidated Financial Statements.

Save as disclosed above, we did not have any material mortgages, charges, debentures, loan capital, debt securities, loans, unutilized banking facilities, bank overdrafts or other similar indebtedness, liabilities under acceptances (other than normal trade bills), acceptance credits, which are either guaranteed, unguaranteed, secured or unsecured, or guarantees.

KEY PERFORMANCE INDICATORS

Details of the key performance indicators of the Group as at December 31, 2021 are set out to the Management Discussion & Analysis.

CHARITABLE CONTRIBUTIONS

During the Reporting Period, the Group did not make charitable contributions.

Directors' Report

MAJOR CUSTOMERS AND SUPPLIERS

The Group values long-standing relationships with its suppliers, customers, medical experts, and other business associates are key to the Group's success. The Group aims at delivering high quality products to its potential customers and developing mutual trust and enhancing communication and commitment between the Group and its suppliers to maintain sustainable growth. For more information, please refer to the "Environmental, Social and Governance Report" as part of this report.

During the year ended December 31, 2021, the Group had only one customer and derived substantially all of its revenues from license fee income. For further details, please see Note 6 to the Consolidated Financial Statements of this report.

Purchases attributable to the Group's five largest suppliers and the largest supplier accounted for 39.33% and 19.11%, respectively, of the Group's total purchases for the Reporting Period.

None of the Directors or any of their close associates (as defined in the Listing Rules) or any shareholders of the Company (whom, to the best knowledge and belief of the Directors, own more than 5% of the Company's total issued share capital) had any beneficial interest in the Group's five largest suppliers and the single customer for the Reporting Period.

CONTINUING DISCLOSURE OBLIGATIONS PURSUANT TO THE LISTING RULES

Save as disclosed in the annual report, the Company does not have any disclosure obligations under Rule 13.20, 13.21 and 13.22 of the Listing Rules.

COMPLIANCE WITH THE RELEVANT LAWS AND REGULATIONS

The Group has compliance policies and procedures in place to ensure adherence to applicable laws, rules and regulations, in particular, those that have a significant impact on it. The Group would seek professional legal advice from its legal advisers to ensure that transactions and business to be performed by the Group are in compliance with the applicable laws and regulations. During the Reporting Period and up to the Latest Practicable Date, the Group was not aware of any non-compliance with the laws, regulations and regulatory requirements of the places where the Group operates in all material respects, including the requirements under the Companies Ordinance, the Listing Rules, the SFO and the Corporate Governance Code for, among other things, the disclosure of information and corporate governance.

RELATIONSHIPS WITH THE GROUP'S EMPLOYEES

The Group believes that employees are important and valuable assets. The Group will provide trainings for employees to enhance their knowledge in corporate values and culture and to implement them thoroughly. Meanwhile, the Group encourages staff on continuous learnings by sponsoring recognized development trainings. The Group also aims to provide competitive and attractive remuneration packages to retain its employees. Management reviews annually the remuneration package offered to the employees of the Group. Meanwhile, for the purpose of providing incentives and rewards to eligible participants who have contributed to the success of the Group's operations, the Company has adopted 2019 Equity Incentive Plan, Post-IPO Share Option Scheme and Post-IPO RSU Scheme. Details of such schemes are set out in the sub-sections headed "Share Incentivization Schemes" in this report. For more information, please refer to the "Environmental, Social and Governance Report" as part of this report.

MATERIAL LITIGATION

The Company was not involved in any material litigation or arbitration for the year ended December 31, 2021. The Directors are also not aware of any material litigation or claims that are pending or threatened against the Group for the year ended December 31, 2021.

SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

Save as disclosed in this report, as at the Latest Practicable Date, the Group has no significant events occurred after the Reporting Period which require additional disclosures or adjustments.

CORPORATE GOVERNANCE

Particulars of the Company's corporate governance practices are set out in the section headed "Corporate Governance Report" of this report.

EQUITY-LINK AGREEMENT

Save as disclosed in this report, the Company had not entered into any equity-linked agreement for the year ended 31 December 2021, nor did any equity-linked agreement subsist as at 31 December 2021.

REVIEW BY AUDIT COMMITTEE

The Audit Committee currently comprises two independent non-executive Directors, namely, Mr. SO Tak Young and Dr. FAN Chunhai, and one non-executive Director, namely Mr. GUO Huaqing. The Audit Committee has reviewed the audited Consolidated Financial Statements for the year ended December 31, 2021 with the management and the auditor of the Company. The Audit Committee considered that the annual results are in compliance with the applicable accounting standards, laws and regulations, and the Company has made appropriate disclosures thereof. The Audit Committee has also discussed matters with respect to the accounting policies and practices adopted by the Company and internal control with senior management of the Company.

INDEPENDENT AUDITOR

The Consolidated Financial Statements for the Reporting Period have been audited by PricewaterhouseCoopers who will retire and, being eligible, offer itself for re-appointment at the forthcoming AGM. Having been approved by the Board upon the Audit Committee's recommendation, a resolution for the re-appointment of PricewaterhouseCoopers as the Independent Auditor for the ensuing year will be put to the forthcoming AGM for shareholder's approval.

Since the Listing Date, the auditor of the Company has not changed.

Corporate Governance Report

The Board hereby presents to the shareholders the corporate governance report for the year ended December 31, 2021 (the “**Corporate Governance Report**”).

CORPORATE GOVERNANCE PRACTICES

The Company recognizes the importance of good corporate governance for enhancing the management of the Company as well as preserving the interests of the shareholders as a whole. The Company has adopted corporate governance practices based on the principles and code provisions as set out in the CG Code as contained in Appendix 14 to the Listing Rules as its own code of corporate governance practices.

The Board is of the view that during the Relevant Period, the Company has complied with all the applicable code provisions as set out in the CG Code, except for code provision C.2.1 described in the paragraph headed “C. Directors’ Responsibilities, Delegation and Board Proceedings – C.2 Chairman and Chief Executive”, and C.5.1. The Board will continue to review and monitor the code of corporate governance practices of the Company with an aim to maintaining a high standard of corporate governance.

Pursuant to code provision C.5.1, the Board should meet regularly and board meetings should be held at least four times a year at approximately quarterly intervals. There are approximately six months from the Listing Date to December 31, 2021, so board meetings should be held at least two times during the Relevant Period. In view of the simplicity of the Group’s businesses, we only convened one board meeting during the Relevant Period, on which the interim results of the Group for the six months ended June 30, 2021 were reviewed and discussed by the Directors. Together with the circulation of written materials to keep the Board informed throughout the Relevant Period, sufficient measures had been taken to ensure that there was efficient communication among the Directors, including the independent non-executive Directors.

MODEL CODE FOR SECURITIES TRANSACTIONS

The Company has adopted the Model Code set out in Appendix 10 to the Listing Rules as its code of conduct regarding dealings in the securities of the Company by the Directors and the Group’s senior management who, because of his/her office or employment, is likely to possess inside information in relation to the Group or the Company’s securities. Specific enquiries have been made to all Directors and the Directors have confirmed that they have complied with the Model Code throughout the Relevant Period.

The Company’s employees, who are likely to be in possession of inside information of the Company, have also been subject to the Model Code for securities transactions. No incident of non-compliance of the Model Code by the employees was noted by the Company for the Relevant Period.

BOARD OF DIRECTORS

Responsibilities

The Board is responsible for the overall leadership of the Group, oversees the Group's strategic decisions and monitors business and performance. The Board has delegated the authority and responsibility for day-to-day management and operation of the Group to the senior management of the Group. To oversee particular aspects of the Company's affairs, the Board has established three Board committees including the audit committee (the "**Audit Committee**"), the remuneration committee (the "**Remuneration Committee**") and the nomination and corporate governance committee (the "**Nomination and Corporate Governance Committee**") (collectively the "**Board Committees**"). The Board has delegated to the Board Committees responsibilities as set out in their respective terms of reference.

All Directors have carried out duties in good faith and in compliance with applicable laws and regulations, and have acted in the interests of the Company and the shareholders at all times.

All Directors have full and timely access to all the information of the Company as well as the services and advice from the company secretary and senior management. The Directors may, upon request, seek independent professional advice in appropriate circumstances, at the Company's expenses for discharging their duties to the Company.

The Company has arranged appropriate liability insurance in respect of legal action against the Directors. The insurance coverage will be reviewed on an annual basis.

Responsibility, Accountabilities and Contributions of the Board and Management

The Board should assume responsibility for leadership and control of the Company and is collectively responsible for directing and supervising the Company's affairs. The Board directly, and indirectly through its committees, leads and provides direction to the management by laying down strategies and overseeing their implementation, monitors the Group's operational and financial performance, and ensures that sound internal control and risk management systems are in place.

All Directors, including independent non-executive Directors, have brought a wide spectrum of valuable business experience, knowledge and professionalism to the Board for its efficient and effective functioning. The independent non-executive Directors are responsible for ensuring a high standard of regulatory reporting of the Company and providing a balance in the Board for bringing effective independent judgement on corporate actions and operations.

The Board reserves for its decisions on all major matters relating to policy matters, strategies and budgets, internal control and risk management, material transactions (in particular those that may involve conflict of interests), financial information, appointment of directors and other significant operational matters of the Company. Responsibilities relating to implementing decisions of the Board, directing and coordinating the daily operation and management of the Company are delegated to the management.

The Board has clearly set out the circumstances under which the management should report to and obtain prior approval from the Board before making decisions or entering into any commitments on behalf of the Company. The Board regularly reviews the above said circumstances and ensures they remain appropriate.

The Company has arranged appropriate liability insurance in respect of legal action against the Directors. The insurance coverage will be reviewed on an annual basis.

Corporate Governance Report

Continuous Professional Development of Directors

The Company believes education and training are important for maintaining an effective Board. Every Director has received formal and comprehensive trainings to ensure appropriate understanding of the business and operations of the Company and full awareness of Director's responsibilities and obligations under the Listing Rules and relevant statutory requirements.

The Company arranges continuous professional development trainings to Directors to ensure Directors keep abreast of regulatory developments and changes in order to effectively perform their responsibilities and to ensure that their contribution to the Board remains informed and relevant. Directors also regularly meet with the senior management team to understand the Group's businesses, governance policies and regulatory environment. All Directors are also encouraged to attend relevant training courses.

The Directors pursued continuous professional development to comply with C.1.4 of the CG Code and relevant details are summarised as follows:

Name of Director	Participated in continuous professional development*
Executive Directors	
Dr. LI Zonghai (<i>Chairman</i>)	√
Dr. WANG Huamao	√
Non-executive Directors	
Mr. GUO Bingsen	√
Ms. ZHAO Yachao	√
Mr. XIE Ronggang	√
Mr. GUO Huaqing	√
Independent Non-executive Directors	
Dr. FAN Chunhai	√
Dr. YAN Guangmei	√
Mr. SO Tak Young	√

* During the Reporting Period, our Company arranged trainings for the Directors related to updates and changes in regulatory requirements, business and market environment in a variety of ways from time to time.

Corporate Governance Report

Chairman and Chief Executive Officer

We do not have separate Chairman of the Board and Chief Executive Officer (“**CEO**”) and Dr. LI Zonghai (“**Dr. Li**”), the Chairman of our Board and CEO, currently performs these two roles. Our Board believes that, in view of his experience, personal profile and his roles in our Company as mentioned above, Dr. Li is the Director best suited to identify strategic opportunities and focus of the Board due to his extensive understanding of our business as our CEO. Our Board also believes that the combined role of Chairman of the Board and CEO can promote the effective execution of strategic initiatives and facilitate the flow of information between management and the Board. Our Board will continue to review and consider splitting the roles of Chairman of the Board and the CEO at a time when it is appropriate by taking into account the circumstances of our Group as a whole.

Composition

As at the Latest Practicable Date, the Board is comprised of nine Directors, with two executive Directors, four non-executive Directors and three independent non-executive Director. During the Relevant Period, there is no change to the composition of the Board. A list of Directors and their respective biographies are set out on pages 36 to 40 of this report. Save as disclosed in this report, to the best knowledge of the Company, there are no financial, business, family, or other material relationship among members of the Board.

The Board’s composition is in compliance with the requirement under Rule 3.10A of the Listing Rules that the number of independent non-executive Director must represent at least one-third of the Board. The Board believes that the balance between the executive Directors and the non-executive Directors is reasonable and adequate to provide sufficient checks and balances that safeguard the interests of the shareholders and the Group.

The Board values the importance of professional judgment and advice provided by non-executive Directors to safeguard the interests of the shareholders. The non-executive Directors contribute diversified qualifications and experience to the Group by expressing their views in professional, constructive and informed manner, and actively participate in Board and committee meetings and to bring professional judgment and advice on issues relating to the Group’s strategies, policies, performance, accountability, resources, key appointments, standards of conduct, conflicts of interests and management process, with the shareholders’ interests being the utmost important factor. The non-executive Directors also exercise their professional judgment and utilise their expertise to scrutinise the Company’s performance in achieving agreed corporate goals, and monitor performance reporting.

Further, in compliance with Rule 3.10 of the Listing Rules, one of the Company’s independent non-executive Director (namely Mr. So Tak Young) has the appropriate professional qualifications of accounting or related financial management expertise, and provide valuable advice from time to time to the Board. The Company has also received from each independent non-executive Director an annual confirmation of his independence and the Nomination Committee has conducted an annual review and considers that all independent non-executive Director are independent, taking into account of the independence guidelines set out in Rule 3.13 of the Listing Rules in the context of the length of service of each independent non-executive Director.

As part of the Company’s corporate governance practice to provide transparency to the investor community and in compliance with the Listing Rules and the CG Code, the independent non-executive Director are clearly identified in all corporate communications containing the names of the Directors. In addition, an up-to-date list of Directors identifying the independent non-executive Director and the roles and functions of the Directors is maintained on the Company’s website and the Stock Exchange’s website.

Corporate Governance Report

Appointments and Re-election of Directors

Each of our executive Directors and non-executive Directors has entered into a service contract with us under which the initial term of their service contracts shall be three years commencing from the date of their appointment until terminated in accordance with the terms and conditions of the service contract or by either party giving to the other not less than one month's prior notice. Pursuant to the service contracts entered into with us, none of our executive Directors and non-executive Directors will receive any remuneration as director's fee.

Each of our independent non-executive Directors has entered into an appointment letter with us effective from the Listing Date. The initial term of their appointment letters shall commence from the date of their appointment for a period of three years or until the third annual general meeting of our Company after the Listing Date, whichever is earlier (subject always to re-election as and when required under the Articles of Association) until terminated in accordance with the terms and conditions of the appointment letter or by either party giving to the other not less than one month's prior notice in writing.

None of the Directors has entered into a service contract which is not determinable by the Group within one year without payment of compensation (other than statutory compensation).

In accordance with the Articles of Association, all Directors are subject to retirement by rotation at least once every three years and any new Director appointed to fill a casual vacancy shall submit himself for re-election by the shareholders at the first general meeting of the Company after appointment and new Directors appointed as an addition to the Board shall submit himself for re-election by the shareholders at the next following general meeting of the Company after appointment.

The procedures and process of appointment, re-election and removal of Directors are set out in the Articles of Association. The Nomination Committee is responsible for reviewing the Board composition and making recommendations to the Board on the appointment or re-election of Directors and succession planning for Directors.



Corporate Governance Report

Board Meetings

As the Shares of the Company have only been listed since June 18, 2021, the Board has met only one time during the Relevant Period. The attendance of each Director at Board and committee meetings of the Company, whether in person or by means of electronic communication, is detailed in the table below:

Name of Directors	Attendance/No. of Meetings held during the Relevant Period			
	Board	Audit Committee	Remuneration Committee	Nomination and Corporate Governance Committee
Executive Directors				
Dr. LI Zonghai	1/1	N/A	N/A	N/A
Dr. WANG Huamao	1/1	N/A	N/A	N/A
Non-executive Directors				
Mr. GUO Bingsen	1/1	N/A	N/A	N/A
Ms. ZHAO Yachao	1/1	N/A	N/A	N/A
Mr. XIE Ronggang	1/1	N/A	N/A	N/A
Mr. GUO Huaqing	1/1	1/1	N/A	N/A
Independent Non-executive Directors				
Dr. FAN Chunhai	1/1	1/1	N/A	N/A
Dr. YAN Guangmei	1/1	N/A	N/A	N/A
Mr. SO Tak Young	1/1	1/1	N/A	N/A

At the Board meeting held during the Relevant Period, the Board discussed a wide range of matters, including interim results announcement and Auditors' remuneration, etc.

The Chairman of the Board held one meeting with the independent non-executive Directors during the Relevant Period without the presence of other Directors.

No annual general meeting was held during the Relevant Period.

BOARD COMMITTEES

The Company has established the following committees under the Board of Directors: an Audit Committee, a Remuneration Committee and a Nomination and Corporate Governance Committee. The committees operate in accordance with terms of reference established by our Board of Directors.

Corporate Governance Report

Audit Committee

Our Company has established the Audit Committee with written terms of reference in compliance with Rule 3.21 of the Listing Rules and the Corporate Governance Code. The Audit Committee consists of two independent non-executive Directors, namely Mr. SO Tak Young and Dr. FAN Chunhai, and one non-executive Director, namely Mr. GUO Huaqing. Mr. SO Tak Young, being the chairman of the Audit Committee, holds the appropriate professional qualifications as required under Rules 3.10(2) and 3.21 of the Listing Rules. The primary duties of the Audit Committee are to assist the Board by providing an independent view of the effectiveness of the financial reporting process, internal control and risk management systems of our Group, overseeing the audit process and performing other duties and responsibilities assigned by our Board of Directors.

During the Relevant Period, the Audit Committee scheduled one meeting, during which matters such as financial reporting, operational and compliance controls, effectiveness of the risk management and internal control systems and internal audit function were discussed.

The attendance records of the members of the Audit Committee are as follows:

Name of Members of the Audit Committee	Attendance
Mr. SO Tak Young	1/1
Dr. FAN Chunhai	1/1
Mr. GUO Huaqing	1/1

Remuneration Committee

Our Company has established the Remuneration Committee with written terms of reference in compliance with Rule 3.25 of the Listing Rules and the Corporate Governance Code. The Remuneration Committee consists of two independent non-executive Directors, namely, Dr. YAN Guangmei and Dr. FAN Chunhai, and one executive Director, namely Dr. Li. Dr. FAN Chunhai is the chairman of the Remuneration Committee. The primary duties of the Remuneration Committee include, without limitation, making recommendations to the Board of Directors on our policy and structure for the remuneration of all Directors and senior management and on the establishment of a formal and transparent procedure for developing the policy on such remuneration and determining the specific remuneration packages of all Directors and senior management.

During the Relevant Period, no meeting of the Remuneration Committee was held.

Corporate Governance Report

Nomination and Corporate Governance Committee

Our Company has established the Nomination and Corporate Governance Committee with written terms of reference in compliance with the Corporate Governance Code. The Nomination and Corporate Governance Committee consists of two independent non-executive Directors, namely Dr. YAN Guangmei and Dr. FAN Chunhai, and one executive Director, namely, Dr. Li. Dr. Li is the chairman of the Nomination and Corporate Governance Committee. The primary duties of the Nomination and Corporate Governance Committee include, without limitation, reviewing the structure, size and composition of the Board of Directors, assessing the independence of the independent non-executive Directors, making recommendations to the Board of Directors on matters relating to the appointment of Directors, developing, reviewing and assessing the adequacy of our Company's policies and practices on corporate governance and reviewing our Company's compliance with the Corporate Governance Code and disclosure in the corporate governance report.

During the Relevant Period, no meeting of the Nomination and Corporate Governance Committee was held.

DIVERSITY

The Board has adopted a board diversity policy which sets out the objective and approach to achieve and maintain diversity of our Board in order to enhance the effectiveness of our Board. Pursuant to the board diversity policy, we seek to achieve board diversity through the consideration of a number of factors, including but not limited to professional experience, skills, knowledge, gender, age, nationality, cultural and education background, ethnicity and length of service. Nevertheless, in recognizing the particular importance of gender diversity, our Company confirms that our Nomination Committee will, within three years from the Listing Date, identify and recommend one female candidate to our Board for consideration on her appointment as Director of our Company.

We are also committed to adopting a similar approach to promote diversity within the management (including but not limited to the senior management) of our Company to enhance the effectiveness of corporate governance of our Company as a whole.

Nomination and Corporate Governance Committee will review the board diversity policy from time to time to ensure its continued effectiveness.

Corporate Governance Report

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We recognize that risk management is critical to the success of our business operation. Key operational risks faced by us include changes in general market conditions and the regulatory environment of the PRC, the United States and global biologics market, our ability to develop, manufacture and commercialize our product candidates, and our ability to compete with other pharmaceutical companies operating in the same markets as ours. See “Risk Factors” in the Prospectus for a discussion of various risks and uncertainties we face. We also face various market risks. In particular, we are exposed to foreign exchange, cash flow and fair value interest rate, credit and liquidity risks that arise in the normal course of our business.

We have adopted a series of risk management policies which set out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an ongoing basis. Our senior management, and ultimately our Directors, supervise the implementation of our risk management policies. Risks identified by management will be analyzed on the basis of likelihood and impact, and will be properly followed up and mitigated and rectified by our Group and reported to our Directors.

The following key principles outline our approach to risk management:

- Our Audit Committee will oversee and manage the overall risks associated with our business operation, including (i) reviewing and approving our risk management policies to ensure that it is consistent with our corporate objectives; (ii) monitoring the most significant risks associated with our business operation and our management’s handling of such risks; (iii) reviewing our corporate risk and (iv) monitoring and ensuring the appropriate application of our risk management framework across our Group.
- Our management team will be responsible for (i) formulating and updating our risk management policy and targets; (ii) reviewing and approving major risk management issues of our Group; (iii) promulgating risk management measures; (iv) providing guidance on our risk management approach to the relevant departments in our Group; (v) reviewing the relevant departments’ reporting on key risks and providing feedback; (vi) supervising the implementation of our risk management measures by the relevant departments; (vii) ensuring that the appropriate structure, processes and competencies are in place across our Group; and (viii) reporting to our Audit Committee on our material risks.
- The relevant departments, including but not limited to the finance department, the legal department and the human resources department, are responsible for developing and implementing our risk management policy and carrying out our day-to-day risk management practice, such as assessing risks on key business operations, advising risk responses and optimizing risk management policies. In order to standardize risk management across our Group and set a common level of transparency and risk management performance, the relevant departments will (i) gather information about the risks relating to their operation or function; (ii) conduct risk assessments, which include the identification, prioritization, measurement and categorization of all key risks that could potentially affect their objectives; (iii) continuously monitor the key risks relating to their operation or function; (iv) implement appropriate risk responses where necessary; and (v) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

Corporate Governance Report

Internal Control

Our Board is responsible for establishing and ensuring effective internal controls to safeguard our Shareholder's investment at all times. Our internal control policies set out a framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an ongoing basis.

Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- We have adopted various measures and procedures regarding each aspect of our business operation, such as protection of intellectual property, environmental protection, and occupational health and safety. For example, we maintain a list of positions that require a certificate to undertake and require that the corresponding personnel to participate in trainings and pass the necessary assessment to obtain the certificate before they are allowed to commence their work. We provide periodic trainings on these measures and procedures to our employees as part of our employee training programs. From time to time, we are inspected for our compliance with environmental, health and safety laws and regulations by authorities such as the Public Security Bureau and the Health Commission. As of the Latest Practicable Date, we had not been subject to any administrative penalties in connection with environmental, health and safety matters.
- Our Directors (who are responsible for monitoring the corporate governance of our Group), with help from our legal advisors, will also periodically review our compliance status with all relevant laws and regulations after the Listing. We have established an Audit Committee in connection with the Listing, which (i) makes recommendations to our Directors on the appointment and removal of external auditors; and (ii) reviews the financial information and renders advice in respect of financial reporting as well as oversee internal control procedures of our Group.
- We have engaged Guotai Junan Capital Limited as our compliance advisor to provide advice to our Directors and management team until the end of the first fiscal year after the Listing regarding matters relating to the Listing Rules. Our compliance advisor is expected to, upon our consultation, provide advice and guidance in respect of compliance with the applicable laws and the Listing Rules including various requirements of directors' duties and internal control in a timely fashion.
- We have engaged a PRC law firm to advise us on and keep us abreast of PRC laws and regulations after the Listing. We will continue to arrange various trainings sessions to be provided by external legal advisors from time to time when necessary, and/or any appropriate accredited institution to update our Directors, senior management and relevant employees on the latest PRC laws and regulations.

Corporate Governance Report

- We have established procedures to protect the confidentiality of clinical trial data. We clearly define the scope of the personnel who can access data generated from clinical trials and the information about the enrolled participants. Access to such data has been strictly limited to the authorized personnel according to the GCP and relevant regulations. We have also implemented measures to secure patients' privacy. For example, we only use anonymized code as a basis for patient identification. We require external parties and internal employees involved in clinical trials to comply with confidentiality requirements. Data are to be used only for the intended use, as agreed by the patients and consistent with the Informed Consent Form, or the ICF. We will obtain consent from patients for use of genetic materials or if any use of data falls outside the scope of the previously signed ICF. With regard to the use of genetic materials, our biological sample analysis laboratory has formulated standard procedures and strictly follow such procedures for the storage, use and destruction of biological samples of the clinical trial participants. In addition, our clinical operations team has standardized procedures for handling human genetic materials in compliance with the relevant laws and regulations, such as the HGR Regulation.
- We have developed the policy on information disclosure management which provide a general guide to the Directors, senior management and relevant employees of the Company in handling and dissemination of confidential information, monitoring information disclosure and responding to enquiries. Control procedures have been implemented to ensure that unauthorized access and use of inside information are strictly prohibited. The Board is aware of its obligations to announce any inside information in accordance with the Listing Rules.
- Our compliance policies are standard for our industry and apply to all of our employees. We have established and maintained strict anti-corruption and anti-bribery policies, which sets forth our internal policies and procedures with regard to business entertainment, provision of gifts and financial reimbursement. We also require all of our employees to attend the trainings on the anti-corruption and anti-bribery polices. In addition, we will periodically review and update the policies and provide trainings to our employees on such updates. We will also ensure that our commercialization team complies with applicable promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations and limitations on industry-sponsored scientific and educational activities. Moreover, we have formulated an anti-corruption and anti-bribery integrity agreement which we require our suppliers, including CROs to execute before we enter into business relationship. All of these compliance policies can be readily applied to our future in-house sales and marketing team.
- We have complied with the Corporate Governance Code, except for the deviation from the code provisions C.2.1 and C.5.1 of the Corporate Governance Code. We have established three board committees, namely, the Audit Committee, the Nomination and Corporate Governance Committee and the Remuneration Committee, with respective terms of reference in compliance with the Corporate Governance Code.
- Our Directors believe that compliance creates value for us and dedicate to cultivating a compliance culture among all of our employees. To ensure such compliance culture is embedded into everyday workflow and set the expectations for individual behavior across the organization, we regularly conduct internal compliance checks and inspections, adopt strict accountability internally and conduct compliance training.

During the Relevant Period, we have regularly reviewed and enhanced our internal control system. We believe that our Directors and senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with risk management and internal control matters.

Investment Risk Management

We engage in short-term investments with surplus cash on hand. Our primary objective for short-term investments is to preserve principal and increase fund-using efficiency and liquidity as well. Our finance department, under the supervision of our Vice President of Finance, is responsible for managing our short-term investment activities. Before making a proposal to invest in wealth management products, our financial department must assess our cash flow and operational needs and capital expenditures.

We operate under a Board approved investment policy which governs the investment of our funds and is reviewed from time to time by our Board. We will make its investment decisions on a case-by-case basis after thoroughly considering a number of factors, including but not limited to macroeconomic environment, general market conditions and the expected profit or potential loss of the investment. Under the Company's investment policy, we are prohibited from investing in high risk products and the proposed investment must not interfere with its business operation or capital expenditure. As of the Latest Practicable Date, the Company's investment decisions did not deviate from its investment policy.

Our portfolio to date have been required to hold only instruments with an effective final maturity of 6 months or less, with effective final maturity being defined either as the obligation of the issuer to repay principal and interest or the discretionary ability of investor to put the security back in advance to the issuer. The initial target range for the average maturity of our portfolio is 6 months.

We believe that our internal investment policies and the related risk management mechanism are adequate. We may make investments that meet the above criteria after consultation and approval by our Board where we believe it is prudent to do so.

Effectiveness of Risk Management and Internal Control

The Board acknowledges that it is its responsibility to ensure that the Company establishes and maintains sound risk management and internal control systems within the Group and to review the effectiveness of the systems. Such systems are designed to manage and mitigate risks inherent in the Group's business faced by the Group to an acceptable level, but not to eliminate the risk of failure to achieve business objectives, and can only provide reasonable assurance against material misstatement, loss or fraud.

The Audit Committee, on behalf of the Board, continuously reviews the risk management and internal control systems. The review process comprises, among other things, meetings with management of business groups, internal audit team, and the external auditors, reviewing the relevant work reports and information of key performance indicators, and discussing the major risks with the senior management of the Company. The Board has reviewed the risk management and internal control system of the Group for the year ended December 31, 2021, which covers financial operational, compliance procedural and risk management functions, and considers them efficient and adequate.

In addition, the Board believes that the Company's accounting and financial reporting functions have been performed by staff of the appropriate qualifications and experience and that such staff receives appropriate and sufficient training and development. Based on the audit report of the Audit Committee, the Board also believes that sufficient resources have been obtained for the Company's internal audit function and that its staff qualifications and experience, training programs and budgets are sufficient.

Corporate Governance Report

SHAREHOLDERS

The Company strives to provide ready, equal, regular and timely disclosure of information that is material to the investor community. Therefore, the Company works to maintain effective and on-going communication with shareholders so that they, along with prospective investors, can exercise their rights in an informed manner based on a good understanding of the Group's operations, businesses and financial information. The Company also encourages shareholders' active participation in annual general meetings and other general meetings or other proper means. To safeguard shareholders' interests and rights, a separate resolution will be proposed for each issue at general meetings, including the election of individual Directors. All resolutions put forward at general meetings will be voted by poll pursuant to the Listing Rules and poll results will be posted on the websites of the Company and the Stock Exchange in a timely manner after each general meeting. To promote effective communication, the Company maintains a website at www.carsgen.com, where information and updates on the Company's business developments and operations, financial information, corporate governance practices and other information are available for public access.

A summary of the disclosure of interests of the substantial shareholders of the Company is set out on pages 52 to 55 of this report.

Convening of Extraordinary General Meeting

Any one or more members holding as of date of deposit of the requisition not less than one-tenth of the paid-up capital of the Company carrying the right of voting at general meetings of the Company shall at all times have the right, by written requisition, to require an extraordinary general meeting of the Company to be called by the Board for the matter specified in such requisition. A written requisition shall be deposited at Level 54, Hopewell Centre, 183 Queen's Road East, Hong Kong. If within 21 days of such deposit the Board fails to proceed to convene such meeting to be held within a further 21 days, the requisitionist(s) themselves or any of them representing more than one-half of the total voting rights of all of them, may do so in the same manner, and all reasonable expenses incurred by the requisitionist(s) as a result of the failure of the Board shall be reimbursed to the requisitionist(s) by the Company.

Putting Forward Proposals at General Meetings

There are no provisions in the Articles of Association or in the Companies Law of the Cayman Islands for putting forward proposals or new resolutions by shareholders at general meetings. Shareholders who wish to move forward a resolution may request the Company to convene a general meeting in accordance with the procedures mentioned above.

Enquiries to the Board

Shareholders who intend to put forward their enquiries about the Company to the Board could send written enquiries to the Company. The Company will not normally deal with verbal or anonymous enquiries.

Corporate Governance Report

Shareholders may send their enquiries or requests as mentioned above to the following:

Address: 1F, Building 2,
No. 466 Yindu Road
Xuhui District
Shanghai
the PRC
(For the attention of the Board of Directors)

Email: IR@carsgen.com

COMPANY SECRETARY

Mr. LUI Wing Yat Christopher has been appointed as the Company Secretary on February 23, 2021 and has taken no less than 15 hours of relevant professional training during 2021 and has complied with Rule 3.29 of the Listing Rules in relation to the professional training requirements. The primary contact person of Mr. LUI Wing Yat Christopher at the Company is Mr. Chen Haiou who is our executive vice president.

DIRECTORS' RESPONSIBILITY IN RESPECT OF THE FINANCIAL STATEMENTS

The Directors acknowledge their responsibility for preparing the financial statements of the Company for the year ended December 31, 2021, and are not aware of any material uncertainties relating to events or conditions that may cast significant doubt upon the Company's ability to continue as a going concern.

The statement of the Auditors about their reporting responsibilities on the financial statements is set out in the section headed "Independent Auditor's Report".

AUDITOR'S RESPONSIBILITY AND REMUNERATION

The Company appointed PricewaterhouseCoopers ("PwC") as the external auditor for the year ended December 31, 2021. A statement by PwC about their reporting responsibilities for the financial statements is included in the Independent Auditors' Report on pages 136 to 217.

The remuneration for the audit and non-audit services provided by the Auditor to the Group during the year ended December 31, 2021 was approximately as follows:

Type of Services	Amount (RMB'000)
Audit and audit related services	3,585
Non-audit services	208
Total	3,793

Note: Non-audit services are related to the 2021 ESG report.

Corporate Governance Report

CHANGE IN CONSTITUTIONAL DOCUMENTS

The Company's constitutional documents consist of its Amended and Restated Memorandum of Association (the "**Memorandum**") and the Amended and Restated Articles of Association (the "**Articles**"). The Memorandum and Articles of the Company have been amended and restated with effect from the Listing Date, and are available on the respective websites of the Stock Exchange and the Company.

Save as disclosed above, there is no other change in constitutional documents of the Company during the Relevant Period.

DIVIDEND POLICIES

The Company has adopted a policy on payment of dividends pursuant to code provision F.1.1 of the CG Code taking into consideration of various elements including but not limited to, among other things, the Company's profitability, operation and development plans, external financing environment, costs of capital, the Company's cash flows and other factors that the Directors may consider relevant. The policy sets out the factors in consideration, procedures, methods and intervals of the payment of dividends with an objective to provide the shareholders with continuing, stable and reasonable returns on investment while maintaining the Company's business operation and achieving its long-term development goal. Distribution of any interim or final dividends will be formulated by the Board, and will be subject to shareholders' approval.

As at December 31, 2021, no arrangement was reached pursuant to which the Shareholders waived or agreed to waive their dividends.



Environmental, Social and Governance Report

ABOUT THE REPORT

CARsgen Therapeutics Holdings Limited (“**the Company**” or “**CARsgen Therapeutics**”, stock code: 2171) has issued the 2021 Environmental, Social and Governance Report (“**ESG Report**”) as the Company’s first ESG report to introduce its management and performance concerning environmental protection, social responsibilities and corporate governance to stockholders.

REPORTING SCOPE

Unless otherwise stated, the Report covers CARsgen Therapeutics Holdings Limited, CARsgen Therapeutics Co., Ltd. (“**CARsgen Therapeutics (Shanghai)**”), CARsgen Pharmaceuticals Co., Ltd., CARsgen Life Sciences Co., Ltd. and CARsgen Diagnostics Co., Ltd. (jointly referred to as “**the Group**” or “**We**”). The period covered is from 1 January 2021 to 31 December 2021, and some content may trace back to previous years or extend to future years.

REPORTING STANDARDS

The Report is prepared in compliance with the requirements of Appendix 27 *Environmental, Social and Governance Reporting Guide* to the Main Board Listing Rules (“**Listing Rules**”) of Stock Exchange of Hong Kong Limited (“**HKEX**”).

REPORTING PRINCIPLES

“Materiality”: The ESG Report includes communication with stakeholders and materiality assessment in the preparation process as the basis for determination of important ESG topics.

“Quantitative”: The ESG Report adopts quantitative information to disclose the key performance indicators (“**KPI**”) on environmental and social levels accompanied by a narrative, explaining its purposes and impacts.

“Balance”: The ESG Report provides an unbiased picture of our ESG performance in compliance with the “Balance” principle.

“Consistency”: The ESG Report is the Company’s first ESG Report, and we will adopt consistent statistical methods in the subsequent years to allow for meaningful comparison in the future.

REPORT AVAILABILITY

The Report is released in both print and online versions. The online version is available for view or download on the HKEX news website (<http://www.hkexnews.hk>) and the Company’s official website (<http://www.CARsgen.com>).

Environmental, Social and Governance Report

CORPORATE HONORS

- **May 2019** Dr. Li Zonghai was granted Shanghai Youth Science and Technology Outstanding Contribution Award

Silver award of the Shanghai Excellent Invention Trial
- **August 2019** “Most Innovative Asian-pacific Companies of 2019” from Clarivate
- **December 2019** Dr. Li Zonghai was granted “Shanghai May 1st Labor Medal”
- **May 2020** CT041 autologous CAR T-cell therapy was granted “Top Ten Drug Innovation Pioneering Award of the Year” from Securities Times
- **April 2021** The second prize of Yangtze River Delta High-value Patent Competition
- **October 2021** “Worker Pioneer in Shanghai” Award

Golden Horse Award of 2021 China’s Biopharmaceutical Innovation Billboard
- **December 2021** Gelonghui – Most Innovative IPO of 2021

First Prize of Cancer Diagnosis and Treatment Conference

Sina Med – “Company with the Most Investment Value” Award

Healthcare Manager – “China’s Top 100 Innovative Pharmaceutical Companies” Award



The certificate of the “Shanghai Youth Science and Technology Outstanding Contribution Award”



The certificate of the “Top Ten Drug Innovation Pioneering Award of the Year”



The certificate of the “Second Prize Yangtze River Delta High-value Patent Competition”

Environmental, Social and Governance Report

1. ESG MANAGEMENT

1.1. Governance structure

As a biochemical company with a vision of “Making Cancer Curable”, we are highly aware of performing corporate social responsibilities to create more value for stakeholders and the society. We integrate the concept of sustainable development into our operations, striving for more scientific corporate ESG governance, thus improving our environmental and social performance.

Since officially listed on HKEX in June 2021, the Company has adopted and applied related regulations on ESG governance in the Listing Rules. We have defined the ESG governance functions of the Board of Directors. In addition to assessing and developing ESG management policies and strategies, as well as overseeing ESG issues, the Board of Directors is fully responsible for the Company’s ESG strategies and reporting, regularly reviewing ESG-related issues, ESG-related goals and progress, and approving annual ESG report. Meanwhile, in order to further implement top-down governance approach of ESG issues, we have set up ESG working groups, which plan and implement the Company’s ESG management policies, put ESG policies into practice and report to the Board of Directors about ESG working progress. In the future, we plan to further improve ESG management mechanism and continuously enhance our ESG performance.

1.2. Stakeholder communication

We firmly believe that the effective participation of the stakeholders is of great importance to our long-term development. Our stakeholders mainly include shareholders, investors, the government and regulators, suppliers, partners, employees, customers, patients, industry associations, communities and the public. We actively communicate with the stakeholders through diversified channels to timely learn about and proactively respond to their demands and expectations, and to understand their opinions and advices to our ESG strategies and performance.

Stakeholders	Demands and expectations	Communication methods
Shareholders and investors	Return on investment Information disclosure Risk control	Annual reports, financial statements and announcements Company’s website Meetings, road shows and investor summits
Government administration	Operation compliance Tax payment in accordance with laws Making contribution to the society	Government research Thematic meeting of the government administration Written reports Industry forums
Potential customers/subjects	Product quality and safety Product R&D and innovation Rights & interests Protection Privacy protection	Customers’ feedbacks Communication and discussion Survey on customer satisfaction

Environmental, Social and Governance Report

Stakeholders	Demands and expectations	Communication methods
Suppliers/partners	Supplier management Justice and fairness Win-win cooperation Anti-corruption	Business communication Regular meetings Field visits Assessment and evaluation
Employees	Training and development Well-established remuneration and benefits mechanism Equal opportunities and diversification Occupational health and safety	Labor union Internal meetings Performance assessment Team building
Industry associations	Communication and cooperation Fair competition Industry empowerment	Industry alliance Seminars and exchange conferences Project cooperation
Community and the public	Community care Social public benefit activities participation Environmental protection	Company's website Daily communication Public services Social media

1.3. Materiality assessment

In order to identify key areas of ESG practice, we have appointed third-party professional organizations to conduct materiality assessment to determine the materiality of ESG topics to the Company's business development and the stakeholders, and used the assessment results as important references for ESG management strategies and ESG reporting. During the reporting period, we conducted interviews on various ESG topics, assessed their importance and confirmed their impacts.

Step 1 Identify ESG topics

Based on the requirements of the *ESG Guide* and taking the Company's actual business and industry characteristics into account, we have identified 17 ESG-related topics to which the stakeholders paid attention through a series of analysis, and confirmed that these topics already covered our ESG practice during the reporting period;

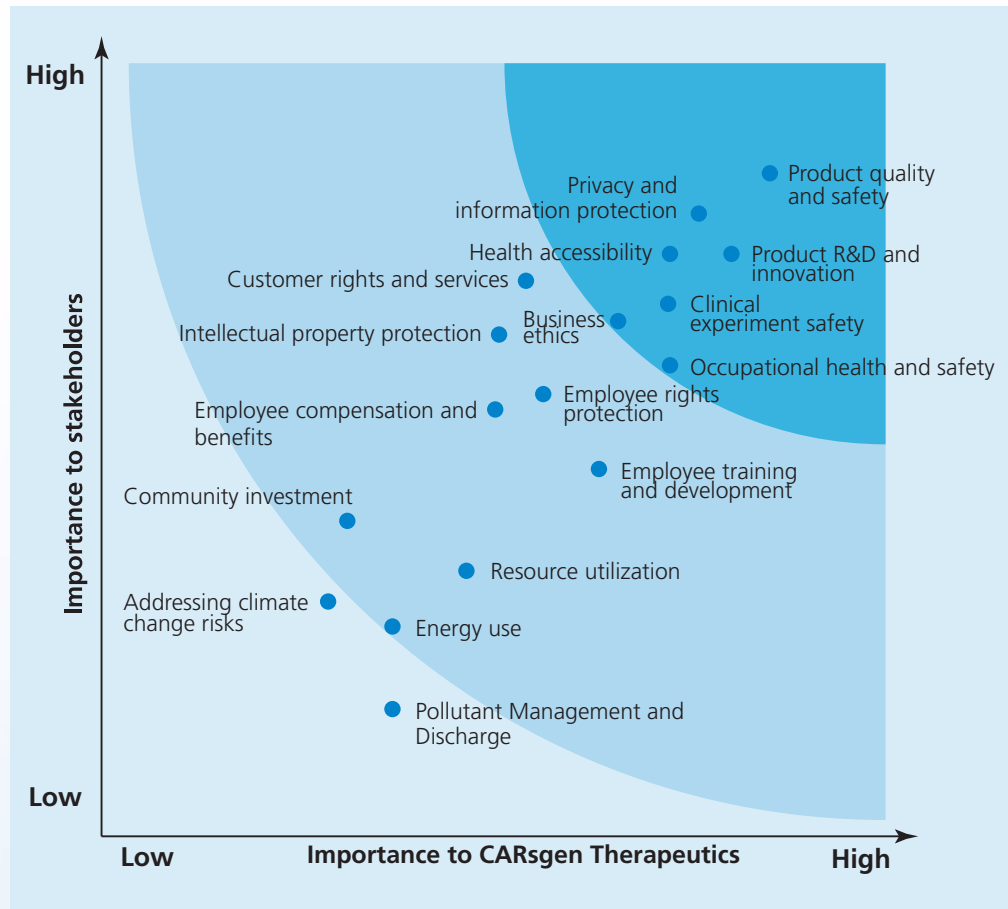
Step 2 Determine the materiality

We have assessed and adjusted the topics from the aspects of "importance to CARsgen Therapeutics" and "importance on stakeholders" through internal interviews and discussions as well as seeking external opinions, and generated materiality assessment matrix based on the survey results to set the priority of the ESG topics;

Environmental, Social and Governance Report

Step 3 Verify assessment results

The Board of Directors and senior management of the Company have reviewed and confirmed the assessment results. 7 topics of high importance to the Company have been identified, including product quality and safety, privacy and information protection, product R&D and innovation, health accessibility and clinical experiment safety. We will respond to the topics of high importance in corresponding chapters of the Report in order to address the concerns of all stakeholders.



Materiality assessment results of CARsgen Therapeutics

Environmental, Social and Governance Report

2. PATIENTS FIRST AND R&D INNOVATION

With the corporate vision of “Making Cancer Curable”, we focus on innovative ¹CAR T-cell therapies for the treatment of hematological malignancies and solid tumors, make progress together with our partners, dedicate ourselves to providing innovative and differentiated cell therapies as well as high-quality reliable CAR T-cell products for cancer patients around the world by means of leading R&D capabilities, advanced automation technology, process schemes with advantages, as well as well-established quality control capability.

2.1. Product R&D

2.1.1. R&D and innovation

We are committed to our mission of “becoming a global biopharmaceutical leader that brings innovative and differentiated cell therapies to cancer patients worldwide and making cancer curable.”, and build up a comprehensive cell-treating platform covering target discovery, antibody development, clinical experiments and commercial-scale manufacturing. We have continuously developed novel technologies over years and now we have a product pipeline with global rights to address major challenges of CAR T-cell therapies, and help improve the safety profile, enhance the efficacy in treating solid tumors and reduce treatment costs.

Case: Solid tumor CAR T-Cell Product – CT401

CT041 is a globally potential pioneering CLDN18.2-targeted CAR T-candidate product independently developed by CARsgen Therapeutics. It received the product qualification recognition for orphan medicines by USA FDA in 2020, and is used to treat gastric/gastroesophageal junction cancer. Since September 2021 when CT041 firstly showed up on the ESMO Congress, CT041 has won the qualification for EMA PRIME, becoming the first solid tumor CAR T-cell product being included in the PRIME plan around the world.

As of the end of the reporting period, CT041 was the only registered CLDN18.2-targeted CAR T-cell immunotherapy globally that is being studied in clinical trials with US FDA approvals and IND approvals from the National Medical Products Administration.

¹ CAR-T: Chimeric Antigen Receptor T-Cell Immunotherapy.

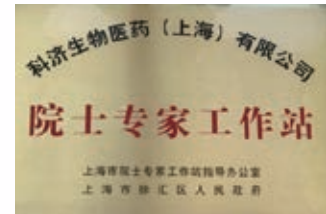
Environmental, Social and Governance Report

2.1.2. Industry-university-research cooperation

We also actively carry out industry-university-research cooperation with government departments, well-known scientific research institutions and universities. We established academican expert workstations, undergraduate industry-university-research practice bases and internship bases, and settled in Xuhui District postdoctoral innovation practice base, thus fully exploit the joint advantages of scientific research workstations, the enterprise, innovative practice base and universities to assist in talents introduction and cultivation as well as promote industry, university and research integration.

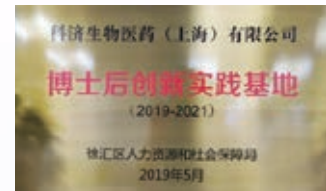
Academician expert workstations

- The workstations were established under approval by Shanghai Association for Science and Technology and Shanghai Academician Expert Workstation Guidance Office in July 2017.



Post-doctoral innovative practice base

- The base was established under approval by Xuhui District Human Resources and Social Security Bureau in 2019.



During the reporting period, CAFA THERAPEUTICS LIMITED under the Group and HK inno.N Corporation of the Republic of Korea reached an licensing agreement on development and commercialization of humanized CD19 (CT032) and fully-human BCMA (CT053) CAR T-cell products in the Republic of Korea. Meanwhile, we also signed a new strategy agreement with Shanghai Cancer Institute for collaboration in oncology scientific and technological research with the aim to enhance our understanding of oncology and technologies in CAR T-cell therapy and enrich our product pipeline.

Environmental, Social and Governance Report

2.1.3. Protection of intellectual property rights

In order to effectively protect our intellectual property rights, we have formulated a series of management documents, including the *Intellectual Property Rights Management Manual*, the *Intellectual Property Rights Management Policy*, the *Intellectual Property Rights Obtaining Control Procedure*, the *Intellectual Property Rights Emergency Plan*, the *Intellectual Property Rights Archives Management Policy*, for specifying intellectual property rights related management specifications and operation process at all stages.

We have developed the *Intellectual Property Rights Incentive Measures*, in order to specify application of related intellectual property rights and incentive rules, and established incentive awards such as the "Technology Invention Award", "Achievement Transformation Award", "Golden Idea Award", "Mastermind Award" and "Major Innovation Award", thus motivating employees' enthusiasm and creativity and encouraging the output of intellectual property rights.

As of the end of the reporting period, we have applied for more than 300 patents worldwide, including 65 authorized patents.



Environmental, Social and Governance Report

2.1.4. Industry empowerment

We have actively participated in industry communication to promote the interaction and communication among industries. We put forward relevant opinions and suggestions to help the healthy development of the industry by attending on-site investigations and thematic meeting held by government administration, as well as submitting written reports to government administration, and participating in industry forums. We have offered feedbacks on the exposure draft issued by administrative departments including NMPA for several times to promote the preparation and improvement of industry specifications.

As of 31 December 2021, main industry associations we participated in were as follows.

Name of association	Position held	Entity
China Society for Drug Regulation	Member unit	CARsgen Therapeutics (Shanghai)
Shanghai Biopharmaceutics Industry Association	Director unit	CARsgen Therapeutics (Shanghai)
Shanghai Medicine Industry Association	Member unit	CARsgen Therapeutics (Shanghai)
Shanghai Biopharmaceuticals Industry Innovation Alliance	Initiating unit	CARsgen Therapeutics (Shanghai)
Cell Immunotherapy Quality Management and Research Committee of Shanghai Medicine Quality Association	Member unit	CARsgen Therapeutics (Shanghai)
Shanghai Zhangjiang High-tech Park Development Affairs Consultation and Promotion Association – Biomedical branch	Executive director unit	CARsgen Therapeutics (Shanghai)
Shanghai Pudong International Chamber of Commerce – Biochemical Committee	Director unit	CARsgen Therapeutics (Shanghai)
Shanghai Jinshan Technology Enterprise Federation	Member unit	CARsgen Therapeutics

Environmental, Social and Governance Report

2.2. Quality management and control

We attach great importance to product quality safety, build up well-established quality management system to implement strict product quality control, and continuously work hard to provide high-quality products for patients.

2.2.1. Quality assurance

We have formulated various SMPs (Standard Management Procedure) and SOPs (Standard Operation Procedure) such as the *Quality Manual*, the *Quality Risk Management Procedure*, the *Management Procedure for Quality Management Review*, strictly in accordance with related laws and regulations including the *Pharmaceutical Administration Law of the People's Republic of China*, the *Regulations on the Implementation of the Pharmaceutical Administration Law of the People's Republic of China* and GMP (Good Manufacturing Practice), as well as industry specifications, covering product full life cycle process to make sure the effective operation of product quality management measures. Meanwhile, we require that all material suppliers and outsourcing service providers shall sign the *Quality Agreement* with to make sure they meet GMP and related quality requirements.

We strictly follow the principles of GMP, clarify the responsibilities of relevant personnel, and standardize the operation specifications of raw material procurement, acceptance, warehousing, equipment and facility management, production management, inspection management and product transportation management, thus avoiding confusion and potential error risk.

In addition, we conduct annual orientation trainings for new employees before starting their work, and conduct re-education trainings to provide interpretation of related laws and regulations and quality culture publicity concerning product manufacturing and quality management for employees of related departments, thus helping enhance their quality management capability. We also carry out skill competition activities on a regular basis such as knowledge contests, in order to help employees learn and consolidate their quality management knowledge while improving their quality inspection skills.



**Professional Skills Competition
(Use of Pipettes)**



**GMP Knowledge Contest
(Quick Answer Session)**

Environmental, Social and Governance Report

2.2.2. Quality control

In order to effectively implement product quality control, we have set up professional quality control teams including physics and chemistry laboratory, microbiology laboratory, biochemistry laboratory, bioactivity laboratory and operating teams, which engaged in establishing and maintaining quality standards and test methods, and conducting detection on raw materials and adjuvants, packaging materials, process water, intermediate products and finished products.

We have established corresponding quality standards, verification regulations and developed sampling plans for various products and key raw materials involved, including quality standards for final products and control requirements on intermediate products and solutions during the manufacturing process. We have formulated the *Materials Management Procedures* to conduct hierarchical control on materials. Based on product quality, product safety and the impacts on manufacturing process, we have divided quality control materials for manufacturing into critical materials and non-critical materials, and classified the raw materials and adjuvants for manufacturing from 1 to 4 level with reference to Chinese Pharmacopoeia.

In order to ensure the accuracy and reliability of inspection results, we have formulated documents including the *QC Laboratory Management Procedures*, the *QC Samples Management Procedures* and the *Management Procedure for QC Records and Inspection Reports*, which specify inspection operations and report specifications corresponding to inspection methods. We have established the management requirements for the use and maintenance of inspection instruments, which require that all the inspection instruments should be necessarily confirmed, verified, measured or checked before being put into use. We have also confirmed the cycle of the instruments and whether the instruments need to be confirmed or verified, measured or checked again based on risk assessment. After the process, the quality control team issues CoA to ensure that all data are accurate, compliant, complete and safe for record, review and filing. We also require that employees sign the *Data Reliability Commitment*, to make sure that the related personnel record the situation and implementation in an unbiased manner during manufacturing, inspection and GMP activities and retain the original data of the activities to ensure the traceability of the data.

As the products of cell therapies are currently at the initial development stage, the product inspection process and methods still need to be improved and optimized. We will continuously summarize the problems arising during product inspection process, and accumulate related experience to better provide services for the Group on product quality control of commercialized manufacturing.

Environmental, Social and Governance Report

2.3. Patient protection

We strictly abide by the laws and regulations and industry requirements in places where we operate, continuously improve our management and service level, and build up a sound mechanism for protecting patients' rights to consistently safeguard patients' health.

2.3.1. R&D ethics

In order to protect the lives and health safety of the subjects as well as respect and protect their lawful rights, we strictly abide by the laws and regulations including the *Consolidation Guidance of Good clinical practice (drug and medical device)*, and the *Review Methods for Biomedical Research Ethics Involving Human* based on related moral principles of the Declaration of Helsinki, and have conducted ethical inspection on all the clinical projects to ensure related biomedical researches comply with ethical principles such as "informed consent", "control risks" and "privacy protection".

Informed consent Respect and guarantee the rights of the subjects to decide whether to participate in the research, strictly implement informed consent procedures, avoid lying, inducing and threatening the subjects to get their consent to participation, and allow the subjects to quit unconditionally at any stages	Control risks Put the personal safety and healthy rights first, followed by science and social interests. Research risks and benefits should be balanced, and avoid hurting the subjects as possible as we can	Free and compensation Select the subjects in a fair and reasonable manner, charge no fees to the subjects for research participation, and give certain compensation on the subjects' fees spent during the process
Privacy protection Practically protect the subjects' privacy, truthfully tell the subjects about the storage, utilization and confidential measures about their personal information, and do not expose the information to any third parties without authorization	Compensation in accordance with the laws Where the subjects suffer any damage while participating in the study, they shall receive timely and free treatment and be compensated according to the laws, regulations and the agreement of both parties	Special protection Give special protection to children, pregnant women, the mentally disabled and patients with mental disorders

We also require that all the design of animal experiments shall comply with ²3R principle, be good to animals, avoid or reduce animals' stress, pain and injury and respect their lives. We strictly abide by relevant requirements of standards and regulations like *Animal Experiment Management Regulations*, *formulate the Standard Operating Procedures for Animal Experiment Barrier Environments* to specify the administrative rules concerning the selection and disposal of related experimental animals, laboratory conditions, professional competence of staff and operation methods.

² 3R principle for experimental animals refers to Reduction, Replacement and Refinement.

Environmental, Social and Governance Report

2.3.2. Drug safety

We have formulated the *Marketing Authorization Procedure for Pharmaceuticals* and strictly abided by the *Pharmaceutical Administration Law of the People's Republic of China* and the *Measures for the Administration of Drug Registration*, in order to standardize the documentation preparation, submitting, review and approval for drug marketing authorization application and ensure the safety, efficacy and quality of the registered medicines.

We also build up relevant internal policies in accordance with ICH related guidelines, *Good Pharmacovigilance Practices*, *Administrative Measures for the Reporting and Monitoring of Adverse Drug Reaction*, *Standards and Procedures for Expedited Reporting of Safety Data During Drug Clinical Trials* and other regulations, which clearly define the collection, handling, reporting, follow-up and other procedures regarding adverse reactions, to ensure the relevant adverse reactions can be processed properly in a timely manner, helping us understand the safety characteristics of product and to protect patient health. In addition, we also continue to provide pharmacovigilance trainings to better fulfill our corporate-related responsibilities.

2.3.3. Products and services

As of the end of the reporting period, most of our products stayed in the pre-market R&D stage and were not produced in large quantities, so we mainly obtained product feedback from CRO (contract research organization) and investigators involved in clinical trials. Once receiving adverse events involving quality complaints or quality investigations, the staff of Pharmacovigilance Department report it to Quality Assurance Department by using the relevant form.

In order to further guarantee the efficiency of communication and feedback channel, we established the *Complaint and Recall Management Procedure*, which defined the process and standards to deal with product complaints and recalls, so as to understand product deficiencies without delay and make timely improvements. During the reporting period, we received 1 complaint on damaged outer packing bag. Then, we promptly investigated the cause of the damage, and resolved the issue by changing the outermost packing. According to follow-up confirmation, the damage to the outer packaging did not affect the quality of the final product and the use of the patient, the patient received drug treatment and achieved good results. As of the end of the reporting period, we had no product recall incident.

Environmental, Social and Governance Report

2.4. Supply chain management

2.4.1. Supplier admission

In order to ensure the stable quality of products and services and business continuity, we constantly optimize supplier screening, appraisal and management mechanism, select the superior and eliminate the inferior, and develop and maintain qualified suppliers. We strictly abide by the *Good Manufacturing Practices for Pharmaceutical Products* and relevant laws and regulations, and formulate the *Supplier Management Policy*, the *Indirect Procurement Management Policy*, the *Procurement and Bidding Procedures* and other internal policies to define our procurement strategy and procedures, and normalize the relevant standards and processes of supplier selection, management and assessment. While ensuring the product quality, service capability, business status, production capacity, quality management system, price, reputation and geographical location of supplier candidates consistent with the relevant admission requirements, we also provide suppliers with an open, fair and impartial platform for competition. In addition to clarifying the responsibilities of the Procurement Department, the Demanding Department and the Quality Assurance Department in general supplier management, we also set up separate admission and appraisal policies and process for clinical development service providers to further strengthen the screening.



Supplier admission process



Environmental, Social and Governance Report

We are committed to building up a sustainable supply chain which is social and environmental responsible, and actively identifying and managing environmental and social risks at each process of the supply chain. We specify the relevant requirements on suppliers' corporate social responsibility in the *Supplier Management Policy*, and take corporate environmental responsibility into account for new supplier admission and the assessment and review of existing suppliers to prioritize cooperation with companies with sound accountability. We also require suppliers to complete relevant questionnaires when assessing their qualification, and purchasers will conduct a corporate background survey via Tianyancha (天眼查). The occupational health and safety, labor rights protection and other relevant provisions are clearly listed in the procurement contract, and suppliers are required to shoulder the responsibility for their decisions and activities on social and environmental impacts. We draw up the *Supplier Compliance Notice* to clarify and standardize supplier procurement work flow, and require qualified suppliers to sign the *Confidentiality Agreement* and the *Integrity Co-construction Agreement* to further guarantee the fairness, impartiality and openness of procurement projects and prevent the violations of disciplines and laws. As of the end of the reporting period, the Group had a total of 276 suppliers, of which approximately 75% held ISO 45001, ISO 9001, GXP and other system certifications.

Number of suppliers by geographical regions

Total in 2021	276
Mainland China	270
Hong Kong, Macao and Taiwan	2
Overseas	4

Environmental, Social and Governance Report

2.4.2. Assessment of suppliers

We carry out periodical assessment and grading on suppliers. Based on the supplier performance management approaches specified in the *Supplier Management Policy*, corresponding performance assessment standards are set up for different categories of suppliers, such as the *Performance Assessment Standards for Service Suppliers* and the *Performance Assessment Standards for Material Suppliers*. Suppliers are classified by assessment scores into four levels, i.e., strategic suppliers, key suppliers, mature suppliers and suppliers to be eliminated. Supplier graded to be eliminated shall take corrective and preventive measures, otherwise the provision of services and materials will be terminated. Upon receipt of measure completion notification and written supporting evidences, we will conduct a follow-up review. Besides, we lay emphasis on key supplier management, and assign reviewers (PSO) of relevant key suppliers to conduct annual appraisal and classification of such suppliers. During the reporting period, no supplier was graded as suppliers to be eliminated.

Meanwhile, we carry out audits on the identified significant and critical suppliers based on the supplier evaluation results and GCP/GMP requirements, and prepare the audit plan for the next year at the end of each year to set up reasonable audit schedule. In addition, we will determine whether an on-site audit is required based on the criticality and materiality of the products or services before acknowledging the suppliers. We also establish the *Supplier Audit Practice Procedures* to elucidate supplier audit details regarding GCP, GMP and GLP. During the reporting period, we organized the audit on 17 related suppliers.



Environmental, Social and Governance Report

2.4.3. Communication with suppliers

We proactively communicate with suppliers to promote win-win cooperation with quality suppliers. During the reporting period, we held a number of Quarterly Business Review (QBR) meetings with different cooperative suppliers, and organized in-depth exchanges between key employees and suppliers to review and summarize the problems arising from past cooperation, and shared future strategic planning both parties. Meanwhile, we also hold annual supplier conference to strengthen training and promotion among employees and cooperative suppliers.

Case: Supplier Conference

During the reporting period, we invited all procurement personnel, internal audit staff and suppliers to participate in the annual supplier conference. At the meeting, we introduced compliance guidelines to all participants to improve our communication with suppliers, raise the awareness of both parties and thus help promote the continuous and healthy development of supply chain.



Photo of 6.18 Supplier Conference

Environmental, Social and Governance Report

3. OPERATING WITH RESPONSIBILITY TO MAINTAIN STABLE AND HEALTHY DEVELOPMENT

Integrity is critical to our success. In our daily business, we are committed to operate responsibly, gradually improve our information security protection, and strive to fulfil our social responsibility in communicating, in this way we are able to protect the rights and interests of our stakeholders.

3.1. Compliance operation

Following the idea of honest operation, we strictly abide by the *Anti-Unfair Competition Law of the People's Republic of China*, the *Code of Conduct for Personnel of Medical Institutions*, the *Interim Provisions on Banning Commercial Bribery*, the *Foreign Corrupt Practices Act* and relevant laws and regulations. We have issued policies and procedures comprising the *Code of Conduct*, the *Anti-Corruption and Anti-Commercial Bribery Management Policy*, the *Anti-Fraud Management Policy* and the *Anti-Money Laundering Management Policy*, which covers a wide range of areas including insider trading and conflicts of interest management, in this way, we establish an effective risk prevention and control mechanism and guide our people to conduct themselves in the right way, in line with the Company's code of ethics.

We attach great importance to the construction of integrity culture. All employees are required to sign *Confidentiality Agreement*, *Intellectual Property Notice and Competition Restriction Agreement* etc., and relevant disciplinary policy and procedures are specified in the employee handbook. For example, the employment contract will be immediately terminated against serious misconducts, and "Zero Tolerance" principle is adopted for falsification, unjust enrichment, fraud and disclosure of business information. We also conduct background checks on candidates for R&D, technical, and other positions, as well as for certain job grades and key sensitive positions, to obtain their information on intellectual property, and competition restrictions and assess whether the employment will expose the Company to intellectual property risks.

In our business relationship, we conduct due diligence on our partners, and specify provisions regarding confidentiality, personal privacy, retention of audit rights, anti-corruption, etc. in contracts. In order to clarify and standardize the procurement process to partners, we develop the *Supplier Compliance Notice* and require all qualified suppliers to sign the *Confidentiality Agreement* and the *Integrity Co-construction Agreement*.

Environmental, Social and Governance Report

We build up a complete reporting channel and handling process to facilitate employees at all levels and all parties in the community to report unprofessional conduct or related incidents via the report mailbox and physical mailbox. If any breaches of policy and procedures have been confirmed upon investigation, we take actions according to the relevant policies, the final disciplinary results are released and archived for future reference. In the *Anti-Fraud Management Policy*, we stipulate measures to protect whistle-blowers, prohibit any unlawful discrimination or retaliation, require each department to effectively protect whistle-blowers' legitimate rights and interests, and forbid disclosure of any whistle-blower's information and reporting contents. During the reporting period, the Group had no corruption events.

We actively cultivate a sound corporate environment featuring compliance, integrity and self-discipline, and regularly conduct Ethics & Integrity training and honest awareness publicity to encourage employees to behave in an ethical way and to do the right thing, in line with compliance policies. During the reporting period, we engaged our employees in business ethics trainings, covering the interpretation of *Anti-Corruption and Anti-Commercial Bribery Policy*, the *Anti-Money Laundering Management Policy*, the *Anti-Fraud Management Policy*, and the *Compliance Management Policy*, and the *Annual Compliance Training Confirmation* was signed by each individual employee. We also arrange Code of Conduct and Compliance Management training for the management personnel, including the Company's code of ethics and compliance management requirements, and require them to sign the *Code of Ethics and Compliance Training Commitment* after the training. Meanwhile, we attach importance to the integrity training to our directors at Board of Directors level, and periodically conduct anti-corruption training for them. Furthermore, we also organize some of our employees to join in the Association of China Compliance Professionals ("ACCP") and regularly participate in its activities to understand the compliance standards and operational practices of the pharmaceutical industry.

3.2. Information security

We focus on information security and personal privacy protection. Stringently following the *Cybersecurity Law of the People's Republic of China*, the *Data Security Law of the People's Republic of China*, the *Personal Information Protection Law of the People's Republic of China* and relevant laws and regulations, we develop relevant management measures, establish and improve the information security system suitable for business development, and clarify the confidentiality obligations of all relevant personnel to guarantee the business continuity at the maximum extent.

Environmental, Social and Governance Report

We formulate the *Computer System Management Procedures*, the *Computer System Change Management Procedures* and other policies, to standardize the work flow of computerized system management, reinforce system permission management and ensure data security and integrity. We set up the *Management Procedures for Computer Viruses Prevention and Control*, the *Computer Room Management Procedures* and other policies, which intensify and standardize network, equipment and computer room management to further reduce network security risk and guarantee the stable operation of system and database. Based on the *Disaster Recovery Management Procedures* and the *Data Backup and System Operation Recovery Procedures*, we also normalize the management and utilization of the Company's data backup and system recovery to ensure the reliability, safety, and stability of the backup system and promptness and effectiveness of data backup and data recovery.

We are committed to protecting personal data and ensuring the privacy right of all employees and third parties engaged in the business. We standardize data retention and utilization process to minimize the collection of unnecessary data, ensure that data is properly used for a specific, explicit legal purpose and is retained only for the period required for processing, and ensure that people whose data is being collected are informed of our obligations to protect their data.

We further strengthen the confidentiality awareness of employees and partners by entering into confidentiality agreements with them and by listing confidentiality clauses in contracts. Besides, we put emphasis on privacy respect and personal data protection in the code of ethics training for all employees, and clarify disciplinary policy and procedures in employee handbook to ensure that every employee understands the importance of company information and customer privacy protection.

3.3. Compliance marketing

In accordance with the *Advertising Law of the People's Republic of China* and relevant laws and regulations, we conduct stringent review of all external publicity materials to avoid exaggeration and deceitful and misleading information. We establish the *Public Sentiment and Publicity Management Policy*, which standardize review of external publicity contents and relevant work processes, clarify the responsibilities of relevant departments and the principle of information disclosure, normalize the management of internal promotional materials, and elucidate the principle of external publicity for all employees.

Environmental, Social and Governance Report

In order to further create a favorable public opinion environment and brand image for the Company's innovation and development, we release the *Issuance Standard and Management Policy of WeChat Official Account*, which clearly defines the specific responsibilities of relevant departments, and reinforces and standardizes the content delivery and management of WeChat official account, in a bid to give full play to the positive role of the official account in the company image building, information spreading and public opinion guidance, and ensure the timeliness, preciseness and authority of promotion contents published by the official account.

In addition, we maintain active communication with the media to share the Company's events and development status, and set up corresponding work process for media enquiries and media visits. In response to crisis incidents, we also develop crisis response management methods and deal with public opinion events according to public opinion classification mechanism to reduce the negative impact on the Company.

We practice unified management of news output, media interviews, advertising and image identity. In order to further improve brand consistency, we illustrate the brand logo and implication in the *Guidance Manual for Brand Identity*, and comprehensively define the application of each element in the Company's visual identification system to ensure that the visual information is completely and inerrably delivered to audiences. Moreover, we conduct internal and external compliance marketing training on a regular basis. During the reporting period, we engaged all employees in the code of ethics training and training on the release process of WeChat official account, and conducted publicity on compliance awareness to all the suppliers at the supplier conference, so as to ensure that employees and partners understand the Company's compliance requirements and reduce and avoid potential compliance risks.

Environmental, Social and Governance Report

4. PURSUING THE VALUE OF PEOPLE-ORIENTATION AND ASSUMING SOCIAL RESPONSIBILITY

We uphold the value of “innovation and creativity, pursuit of progress and truth, and people-orientation”, and strive to cultivate a healthy and harmonious work atmosphere with innovation and diversity for our employees to stimulate the joint growth of our employees and our company. We also actively cooperate with our partners and carry out public welfare undertakings with our own resources and technological advantages to build a harmonious and better society with all sectors of society.

4.1. Employment management

4.1.1. Employment

We strictly adhere to the *Labor Law of the People’s Republic of China*, the *Labor Contract Law of the People’s Republic of China* and the *Provisions on the Prohibition of Child Labor*, and establish a series of rules and regulations regarding employment to effectively safeguard the basic legal rights and interests of each employee or applicant, and provide them with equal opportunities in employment, training, remuneration, welfare and career development. Meanwhile, we prohibit all forms of discriminations as all employees and applicants are not subject to gender, age, race and ethnicity, color, religious belief, nationality, sexual orientation, physical condition and other factors, and any behavior that may be detrimental to personal dignity is forbidden. We also believe that the uniqueness of our employees and partners is a key element of our success, and we pursue fairness and impartiality while promoting diversity. Besides, we explicitly prohibit the recruitment of child labor, and practice stringent recruitment process in accordance with the regulations issued by the labor protection authorities. We require all candidates to go through qualification review, interview and other basic recruitment procedures, and provide the relevant supporting materials truthfully. During the reporting period, the Group had no violations involving child labor or forced labor.



Environmental, Social and Governance Report

As of the end of the reporting period, the Group had a total of 573 employees, with 64.6% of them female.

Employee structure	Number of employees in 2021
Total	573
By gender	
Male	202
Female	371
By employment type	
Full-time	571
Part-time	2
By age	
Under 30 years old	264
30-50 years old	286
Above 50 years old	23

Note: Since the company is still in the initial stage of rapid expansion from listing, there are flexible arrangements for the work place of some employees, as well as offsite deployment for work supporting. Since employees do not belong to a single region, the related figures could not be divided by regions properly at the moment. Therefore, the number of employees and the turnover rate divided by region are not disclosed in this report.

❖ Recruitment

We proactively recruit talents to empower our company, attract applicants via a variety of sourcing channels such as on-line & campus recruitment, internal referral, and identify suitable candidates by proper interview approach, so as to provide fair and reasonable employment and competitive opportunities for all candidates. We develop the *Planning of Human Resources Demands and Recruitment Process*, which standardizes daily recruitment demand application and recruitment process, defines the responsibilities of personnel in the HR Department, department heads and supervisors of hiring departments, and requires hiring departments to submit annual or regular plans for human resource demands to assist the strategic development of the Company. We also maintain active cooperation with universities and continuously improve the cultivation mechanism for fresh graduates to reserve talents for the Company's rapid development.

Environmental, Social and Governance Report

Case: "Future Star" Talent Recruitment Program

During the reporting period, we launched the "Future Star" talent recruitment program for the fresh graduates in biology, pharmaceutical engineering, pharmacy and other related fields at home and abroad, arranged three activity cycles comprising spring recruitment, "Future Star" special training and autumn recruitment, and carried out on-line and off-line job fairs, career talks, on-line recruitment, promotion in the WeChat official account, internal recommendation and university-enterprise cooperation to attract outstanding college students.



"Future Star" special training activities

Case: University-enterprise cooperation project of East China University of Science and Technology ("ECUST")

In response to the call of the national education departments to strengthen university-enterprise cooperation, during the reporting period, we entered into a long-term cooperation agreement with ECUST and jointly established industry-university-research practice base for undergraduates to strengthen mutual cooperation and communication, give full play to mutual advantages, widen employment channels for universities and enterprises, and realize win-win development among enterprises, universities and students.



Awarding ceremony for university-enterprise cooperation project with ECUST

Environmental, Social and Governance Report

❖ Working hours

We formulate the *Overtime and Leave Management Policy*, which standardizes the management of working hours and ensures employees reasonably adequate rest time to achieve a better balance between work and life. We prohibit forced labor and encourage employees to complete their work within normal working hours. Overtime work in special cases is required to obtain prior approval from the department manager and to be reviewed by Human Resource Department. Our employees are entitled to all kinds of leaves, including national statutory holidays, annual leave, sick leave, maternity leave, personal leave, marriage leave, paternity leave, bereavement leave, etc.

❖ Remuneration and benefits

We develop a fair, reasonable and market-competitive compensation and benefits system and establish the *Remuneration Control Process* and the *Performance Management Policy* to illustrate emolument structure and consideration criteria, and standardize the payroll management work flow.



Emolument structure

We pay for social insurance and housing funds for employees in accordance with the relevant regulations of the state and local governments, and provide employees with various welfare benefits. In addition, we implement the employee equity incentive plan, which annually grants equity to eligible employees to attract, retain and motivate outstanding talents.

Environmental, Social and Governance Report

Mandated benefits	Medical insurance, maternity insurance, pension insurance, unemployment insurance, employment injury insurance and housing funds
Other allowances	Overtime meal subsidy, mission allowance, employee dormitory benefits, marriage and maternity allowance, employee recommendation bonus, blood donation subsidy, transportation subsidy, overtime pay, etc.

Composition of welfare benefits

In order to further encourage all employees to continuously improve their professional competitiveness, drive the Company to maintain a leading position in the industry and reduce the outflow of outstanding talents, we formulated the *Employee Honor and Reward Policy*. We set up various awards such as CEO Award, Outstanding Contribution Award, Innovation Award, Dedication Award, Long-term Service Award, etc., to reward outstanding employees who have made great contributions to the company's development and being able to reflect the company's values.

During the reporting period, our turnover rate of employees³ was 12.4%.

Employees turnover rate structure indicator	Turnover rate (%) in 2021
Total	12.4
By gender	
Male	13.3
Female	11.9
By age	
Under 30 years old	12
30-50 years old	13.6
Over 50 years old	0

Note: Since the company is still in the initial stage of rapid expansion from listing, there are flexible arrangements for the work place of some employees, as well as offsite deployment for work supporting. Since employees do not belong to a single region, the related figures could not be divided by regions properly at the moment. Therefore, the number of employees and the turnover rate divided by region are not disclosed in this report.

³ The formula used by the Group to calculate the employees turnover rate is: Employees turnover rate = Turnover number during the reporting period / (Turnover number during the reporting period + Number of employees at the end of the reporting period) * 100%.

Environmental, Social and Governance Report

4.1.2. Employee development

We established a complete assessment and promotion mechanism. According to the *Performance Management Policy*, we set performance goals and personal development goals at the beginning of each year, conduct mid-term review in the middle of the year, advocate to carry out performance conversation and feedback at irregular intervals throughout the year, and carry out employee performance assessment at the end of the year, so as to select outstanding departments, outstanding department heads and high-performance employees. Meanwhile, we make adjustment for employees' salaries according to the assessment results. We have formulated the *Employee Hierarchy Development System and Plan*, publicized the related work process of employee promotion, and clarified the evaluation standards and key behavior indicators, building a fair, open and just promotion system for employees, and providing them with open job shift & transfer opportunities and both technical and management development platforms.

Based on the Company's characteristics, we have formulated the *Employee Training Management Regulations*. According to different work requirements and training needs, we develop a series of courses and development projects and work out a training system suitable for the common development of the Company and employees. We use LMS (Learning Management System) as a system tool to integrate offline customized development projects with online supporting course resources to comprehensively improve employees' professional skills, management capabilities and organizational development capabilities, thereby promoting the realization of the Company's strategies and goals.

Case: C-TOPS workshop for Clinical Operations Development Center team

During the reporting period, we organized a C-TOPS workshop for the clinical operation team. The course was divided into five parts: Creativity, Teamwork, Ownership, Proactivity and Sharing. Through practical exercises, we helped employees master the ability to improve workplace emotional intelligence, broaden their inherent thinking patterns, and understand the different communication styles of team members and their influences to further improve the ability of team cooperation.



Employee training site

Environmental, Social and Governance Report

During the reporting period, the Group's trainings involved more than 80.8% of employees, and the average annual training time of employees was 13.7 hours.

Indicator	Proportion of employees receiving training (%) ⁴	Training hours per employee (hours) ⁵
Total	80.8	13.7
By gender		
Male	79.2	13.6
Female	81.7	13.7
By employment type		
Senior management	45.2	3.0
Middle management	66.2	8.2
Junior employees	93.1	17.8

4.1.3. Health and safety

In strict compliance with the *Labor Law of the People's Republic of China*, the *Work Safety Law of the People's Republic of China*, the *Law of the People's Republic of China on the Prevention and Control of Occupational Diseases* and other laws and regulations, we have established a complete scientific EHS (environment, health, safety) management system covering leadership and commitment, policy, management organization structure and responsibilities, identification of hazard factors, risk assessment and risk control, operation control, inspection and correction and preventive measures, incident investigation, emergency response, audit and other elements. The Company prepares the procedures documents for collection of EHS laws and regulations, and standardize the collection, update, management and implementation processes of EHS laws and regulations within the Company. We make it clear that the EHS department will prepare the list of laws and regulations, update the list in time according to the changes of laws and regulations, carry out a difference analysis based on the latest laws and regulations and the actual situation of the Company, and implement the laws and regulations requirements according to the difference analysis results in a timely manner.

⁴ Proportion of employees = Employees receiving training/Total employees*100

Proportion of employees by category = Employees receiving training under this category/Total employees under this category*100

⁵ Average training hours completed per employee = Total training hours/Total employees

Average training hours completed per employee by category = Total training hours of employees under a particular category/Total employees under a particular category

Environmental, Social and Governance Report

Safety first, focusing on prevention, comprehensive control;
Scientific approach, sufficient risk control, prevent incident;
People oriented, caring for health and safety;
Protect the environment,
Conserve natural resources, sustainable development.

EHS policy of CARsgen Therapeutics

We are committed to protecting the health and safety of our employees and taking responsibility for environmental protection, and continuously improving the Company's environmental health and safety. We provide a safe working environment for all our employees and partners and work to save energy, water and raw materials, and reduce waste. In our daily operations, we comply with relevant laws and regulations. Moreover, we optimize products to minimize unreasonable risks arising from production, use and disposal. We have established the EHS committee with the director as the chairman of the committee, representatives of various functional centers as committee members, and the EHS specialists as the coordinators to clarify the responsibilities of relevant personnel at all levels and the requirements of daily meetings, as well as the inspection cycle and content within the Company, and verify the compliance with EHS related regulations. At the same time, we require all departments to assign safety officers to assist and participate in the Company's safety management work, further implement management practices, and ensure the health and safety of employees. In the past three years, there were no work-related fatalities in the Group. During the reporting period, the number of lost days due to work injury was 5.

Environmental, Social and Governance Report

❖ Safety management

We continue to promote the standardization of production safety to identify, classify and evaluate the potential safety risks in our daily operations. A series of corresponding safety management measures is adopted to further improve the level of safety management. At present, we have obtained the Work Safety Standardization Level 3 Certificate.

We have gradually improved the rules and regulations on biosecurity, laboratory safety, workshop production safety, chemical management and construction safety, such as the *Biosecurity Laboratory Work Conduct Guidelines*, *Laboratory Personnel Management Policy*, *Production Safety Responsibility Policy* and *Company Related Party Management Policy*. We also implement the work access policy and work ticket policy for high-risk operations, and require outsiders to sign relevant safety management agreements; carry out EHS inspections and supervision, make hazard source and risk analysis regarding every process of the Company's production and operation activities, and timely rectify the potential safety hazards, etc. In response to sudden incidents and emergencies, we have formulated relevant documents such as the *Emergency Management Policy* and the *Comprehensive Emergency Plan for Production Safety Incidents*, established emergency organization and defined relevant responsibilities, standardized emergency response work process, and set up different special emergency plans and on-site treatment plans to prevent and deal with situations efficiently and timely. In regard to fire safety management, we strictly follow the *Fire Protection Law of the People's Republic of China*. We have developed specific contingency plans for fire accidents, and entrusted the professional third parties to carry out routine maintenance of fire safety systems in the production plants, and regular inspection and testing on fire safety facilities to reduce risks.



**Work Safety
Standardization
Level 3 Certificate**

Environmental, Social and Governance Report

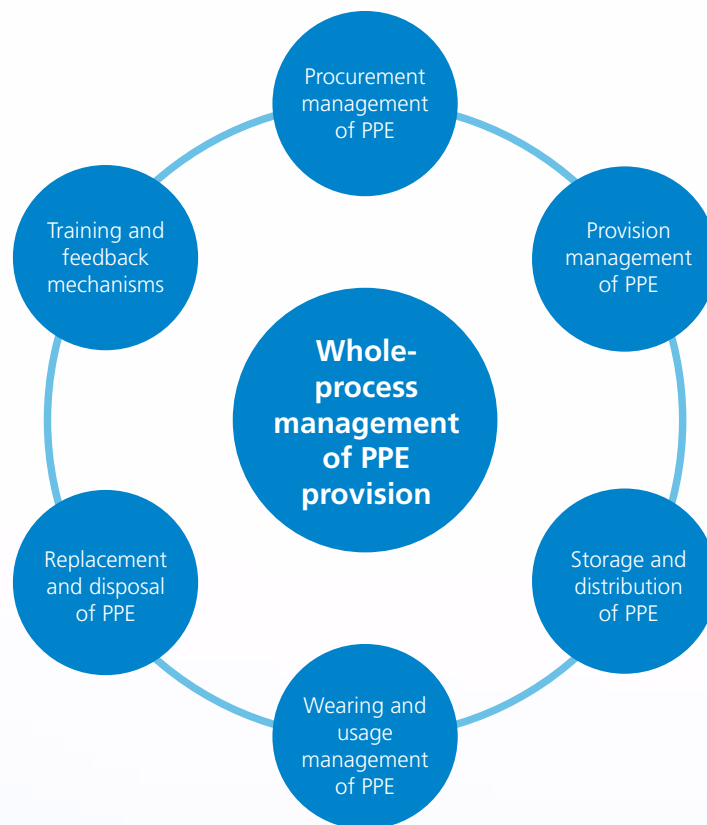
❖ Health management

We attach great importance to occupational health management. The *Occupational Health Management Procedures* formulated by us in accordance with relevant laws and regulations clarifies the specific responsibilities of relevant departments, and standardizes the occupational health management process to control and eliminate occupational disease risks arising from the workplace and production, eradicate and reduce the occurrence of occupational diseases, and protect the health of employees.

We strictly implement the health care policy, and have formulated the *Occupational Health Examination and Management Regulations*, providing pre-job, on-the-job and off-the-job health examinations for all personnel exposed to occupational health hazards, requiring employees to sign the *Health Examination Agreement* and actively organizing occupational disease health examinations. During the reporting period, there were no abnormalities found in the results of the physical examinations.

We regularly check and test the occupational health hazard factors in the workplace, and timely rectify unqualified items. During the reporting period, the testing results were all qualified. We continue to strengthen the establishment and management of occupational disease hazard warning signs, safety risk instructions and necessary protective measures in various workplaces, and provide and distribute various safety, hygiene and other personal protective equipment (PPE) for employees or their respective positions, including head protective supplies, eye and face protective supplies, hearing protective supplies, respiratory protective supplies, torso protective supplies, hand protective supplies, foot protective supplies, anti-fall supplies, cleaning and skin care supplies to comprehensively protect employees' work safety and occupational health. We also, on the basis of the policy for *Personal Protective Supplies Provision*, clarify the responsibilities of relevant departments to effectively ensure the provision and management of personal protective supplies within the Company in terms of PPE provision, procurement, wearing requirements, storage and distribution and usage methods, so as to reduce the Company's production safety and occupational health risks.

Environmental, Social and Governance Report



In order to effectively implement safety education training and awareness publicity, we have formulated the *EHS Training* policy and an annual EHS internal training plan, defining the Company's internal and external EHS training content, and standardizing work processes about training records and assessments to make sure all employees understand laws and regulations, working environment risks and emergency measures related to EHS. In addition to the three-level safety training for new employees and the annual safety training for all employees, we also conduct specific trainings for departments possibly exposed to EHS risks, such as job safety analysis (JSA), hazardous chemical safety management, laws and regulations on environmental protection, and biosecurity leakage emergency drills. For outsiders such as construction parties and service providers, we also conduct safety notification training.

Environmental, Social and Governance Report

At the same time, we have placed safety notification signs and publicity pictures at the production sites, office areas, and key control areas, and regularly carry out safety publicity for all employees such as fire training and drills and safety month activities. During the reporting period, our safety training pass rate was 100%.



Photo of production safety month activities – safety knowledge contest

Fire safety training and drills

During the reporting period, we conducted fire safety training and drills for all employees. The drills included emergency evacuation simulation drills and instruction on the use of fire-fighting equipment. After the drills, fire safety lectures were conducted, in which knowledge of relevant laws and regulations was expounded through video display, image explanation, case analysis and other methods, improving the fire safety awareness and emergency response ability of all employees.

Environmental, Social and Governance Report

4.1.4. Employee communication and caring

We provide employees with a diversified communication channels, and encourage open and frank communication between two parties to create a relaxed, friendly, free and harmonious working atmosphere. We regularly conduct employee surveys to collect employees' opinions, understand organizational health and employee engagement, and solve difficult problems raised by employees in a timely manner.

Employee feedback mailbox	Staff meeting	Face-to-face communication with the management of the Company
Regular communication seminars of the departments	Employee survey /interview	Follow-up interviews with fresh graduates, etc.

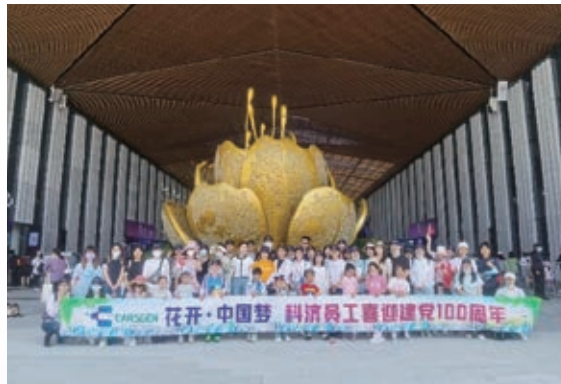
Employee communication channels

In order to enrich employees' leisure time and cultural life and promote the humanized management and care for employees, we have established an employee union organization to regularly organize various types of team activities including team-building tour, birthday parties, care activities for women and fun outward-bound sports games, deepening the relationship between employees and improving the team cohesion. We gave commendation to excellent employees at the 2021 employee meeting, offered various awards such as long-term service award souvenirs to further stimulate the vitality of the organization and employees. In addition, we have given supports to employees in difficulties who suffer from serious illness and disasters, providing financial assistance to them accordingly.



Case: Blossoming Chinese Dream – Photography competition for celebrating the 100th anniversary of the founding of the CPC and the Flower Expo

In order to balance the life and work of employees and cultivate their cultural sentiments, during the reporting period, we organized three groups of employee excursions during the Flower Expo, which were held in the form of Family Day, allowing employees to visit with their children. We held a photography competition at the same time during the excursions, in which photography works were recommended and voted at the department level, and 31 winners were finally selected.



Group photo for Blossoming Chinese Dream – Photography competition for celebrating the 100th anniversary of the founding of the CPC and the Flower Expo

4.2. Social participation

Adhering to the vision of “Making Cancer Curable”, we continue to accelerate our global presence and expand our manufacturing capabilities to support the clinical trials and future commercialization of our candidate products, making cell therapies more accessible and affordable.

At the same time, we continue to make contributions to the industry and society. During the reporting period, we actively responded to the call of the state and conducted actions about poverty alleviation through consumption adopting the model of “purchase instead of donation”. A total of RMB163,000 was invested in purchasing poverty alleviation products as employee benefits. While helping the selected disadvantaged group get rid of poverty, we also enhanced the social participation feel of all employees.

Environmental, Social and Governance Report

During the reporting period, we actively responded to the call of the Shanghai Municipal Government to encourage employees to participate in blood donation. We also encourage employees to contribute to apheresis activities for scientific research and medical activities, and provide gifts to employees who participate.



Group photo of voluntary blood donation

Since the outbreak of COVID-19, facing the severe challenges brought by COVID-19 to all sectors of society, we have actively donated materials including N95 masks and protective clothing to hospitals in areas where medical supplies are in short supply. We set an example to support the front line of the fight against the epidemic.

Environmental, Social and Governance Report

5. GREEN OPERATION AND ENVIRONMENTAL PROTECTION

We strictly abide by the *Environmental Protection Law of the People's Republic of China* and other relevant laws and regulations on environmental protection. We have set up a special EHS team, and formulated the *EHS Policy*, *EHS Inspection and Committee*, *EHS Construction Site Management Policy* and other policies to clarify personnel responsibilities and management process. We also identify environmental risks associated with operations, prepare environmental impact assessment and contingency plans, and formulate and implement controls of and accompanying management procedures for environmental risks. During the reporting period, there were no environmental protection violations.

In the future, we will adhere to the principle of "Green Operation" and continue to reduce the impact of our operations on the environment by improving our management and technology to reduce the impact of our operations on the environment, so as to reduce waste water, waste gas and waste discharge, continue to optimize the structure of resource use, reduce resource consumption, and build a sustainable enterprise.

5.1. Environmental compliance

Following the relevant laws and regulations such as the *Law of the People's Republic of China on the Prevention and Control of Water Pollution*, the *Law of the People's Republic of China on the Prevention and Control of Atmospheric Pollution*, the *Law of the People's Republic of China on the Prevention and Control of Environmental Pollution by Solid Waste*, the *Law of the People's Republic of China on Soil Pollution Prevention and Control*, and the *Regulations on the Management of Medical Waste*, we regularly test waste water and waste gas emission to ensure the discharge of waste water and waste gas up to the standard. At the same time, we have formulated the *Medical Waste Management Procedures*, *Hazardous Waste Management Regulations*, *Standardized Management of Hazardous Waste in Jinshan District*, *Management Policy for Hazardous Chemicals in Construction Site* and other documents to standardize the collection, temporary storage and transfer processes of various wastes, and we also sign contracts with third parties qualified for disposal. These can ensure legal transfer and disposal of wastes.

Environmental, Social and Governance Report

In order to reduce the negative impact on the surrounding atmosphere and water environment, we actively take emission reduction measures, including activated carbon adsorption of waste gas containing volatile organic solvents generated in the process of production, research and development; the use of high-efficiency filter for waste gas that may contain microorganism; and the discharge of production waste water in compliance with the emission standard after waste water is treated by the secondary biochemical sewage treatment facilities. We also take harmless treatment measures such as high temperature and high pressure steam sterilization for all wastes with biohazardous risks to reduce potential environmental pollution risks as much as possible and avoid the environmental pollution incidents.

5.2. Resource management

5.2.1. Energy conservation and carbon reduction

We follow the *Energy Conservation Law of the People's Republic of China* and other relevant laws and regulations to standardize the management rules for energy use. The energies we consume mainly include gasoline, diesel, purchased electricity and purchased steam. In addition to emitting greenhouse gases when consuming energy, the bottled carbon dioxide used for refrigeration during the experiments also produced a small amount of fugitive emissions. We are committed to the rational and efficient use of energy. We actively reduce energy consumption, GHG emissions and corporate carbon footprint through "Green Office" energy saving measures.

- Promote and encourage No-paper Office and reduce printing; set the computers in default printing mode of double-sided printing in black and white; set an upper limit of papers in color printing that can be printed per person per year
- Post signs beside each lighting switch and air conditioner panel to remind employees to save electricity, turn off the power in time, and set proper temperature range of the air conditioners
- Arrange for security personnel to inspect the factory area after work to check whether the lighting facilities and equipment are closed as required
- According to the job characteristics, arrange for the employees engaged in data analysis and others to work from home, and provide a shuttle bus for the employees who come to work at the office

Environmental, Social and Governance Report

5.2.2. Water resource management

We strictly abide by the *Water Law of the People's Republic of China* to standardize the water use management process. We actively develop water-saving technologies, and raise water-saving awareness by posting water-saving slogans to help improve the efficiency of water use during production and operation and avoid water waste. During the year, the Group did not have any illegal water use incidents.

5.2.3. Packaging materials management

Since we have not yet started commercial production, the amount of packaging materials used is extremely small. The packaging materials used in daily production and operation activities are mainly plastic packaging of cell cryopreservation bags.

5.3. Response to climate change

With the increasing frequency and intensity of global extreme weather accidents, climate change has become a major issue that all human beings must face together. In order to mitigate the possible impacts of climate change on the Group's production and operation activities, we actively identify relevant climate change risk events, and define the major physical risks of climate change we face due to the extreme weather accidents caused by typhoon landing or storm.

In order to avoid the possible risk accidents caused by the above extreme weather accidents, such as building flooding, infrastructure damage, and injury and casualties due to the falling of objects from heights, we have formulated the *Emergency Management Policy* and *Typhoon Special Emergency Plan* to clarify the Company's emergency organization system and structure, as well as the responsibilities of related departments and personnel, and provide standardized procedures for accident reporting, response and disposal, so as to ensure the health and safety of employees and security of the Company's properties.

Environmental, Social and Governance Report

5.4. Environmental KPIs

During the reporting period, the Group's products were still in stage of clinical research and have not been put into production on a large scale. Therefore, the environmental KPIs are expected to fluctuate in the coming years. The Group's environmental KPIs⁶ in 2021 is as follows:

Pollutant emissions	Unit	2021
Waste water emissions		
Total waste water emissions	Tons	54,233.3
Including: COD	Tons	1.02
Ammonia nitrogen	Tons	0.06
Waste gas emissions		
Including: VOCs	Tons	0.00018

Waste emissions	Unit	2021
Total hazardous waste	Tons	24.2
Hazardous waste intensity	Ton/product batch	0.08
Total non-hazardous waste	Tons	10.14
Non-hazardous waste intensity	Tons/product batch	0.04

Energy consumption	Unit	2021
Direct energy consumption		
Including: Diesel	Tons	392.67
Gasoline	Tons	68.75
Indirect energy consumption		
Including: Purchased electricity	MWh	8,325.18
Purchased steam	Tons	8,615.28
Total energy consumption	MWh	17,009.21
Energy consumption intensity	MWh/product batch	59.68

⁶ Environmental KPIs cover out office, laboratories and factories in Shanghai.

Environmental, Social and Governance Report

Greenhouse gas emissions	Unit	2021
Total greenhouse gas emissions	tCO ₂ e	9,385.52
Including: Direct greenhouse gas emissions (Scope 1)	tCO ₂ e	117.10
Indirect greenhouse gas emissions (Scope 2)	tCO ₂ e	9,268.41
Greenhouse gas emission intensity	tCO ₂ e/product batch	32.92

Resource consumption	Unit	2021
Water consumption		
Total water consumption	Tons	63,327
Water consumption intensity	Tons/product batch	222.20
Packaging material consumption		
Total packaging material consumption	kg	15.84
Packaging material consumption intensity	kg/product batch	0.056

Independent Auditor's Report



羅兵咸永道

To the Shareholders of CARsgen Therapeutics Holdings Limited

(incorporated in the Cayman Islands with limited liability)

OPINION

What we have audited

The consolidated financial statements of CARsgen Therapeutics Holdings Limited (the "Company") and its subsidiaries (the "Group"), which are set out on pages 141 to 216, comprise:

- the consolidated statement of financial position as at December 31, 2021;
- the consolidated statement of comprehensive loss for the year then ended;
- the consolidated statement of changes in equity for the year then ended;
- the consolidated statement of cash flows for the year then ended; and
- the notes to the consolidated financial statements, which include significant accounting policies and other explanatory information.

Our opinion

In our opinion, the consolidated financial statements give a true and fair view of the consolidated financial position of the Group as at December 31, 2021, and of its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with International Financial Reporting Standards ("IFRSs") and have been properly prepared in compliance with the disclosure requirements of the Hong Kong Companies Ordinance.

BASIS FOR OPINION

We conducted our audit in accordance with International Standards on Auditing ("ISAs"). Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Consolidated Financial Statements section of our report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

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T: +852 2289 8888, F: +852 2810 9888, www.pwchk.com

Independent Auditor's Report

Independence

We are independent of the Group in accordance with the International Code of Ethics for Professional Accountants (including International Independence Standards) issued by the International Ethics Standards Board for Accountants ("IESBA Code"), and we have fulfilled our other ethical responsibilities in accordance with the IESBA Code.

KEY AUDIT MATTERS

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the consolidated financial statements of the current period. These matters were addressed in the context of our audit of the consolidated financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

Key audit matter identified in our audit is related to research and development expenses.

Key Audit Matter	How our audit addressed the Key Audit Matter
<p>Research and development expenses</p> <p>Refer to Note 2.9 and Note 9 to the consolidated financial statements.</p> <p>The Group incurred research and development ("R&D") expenses of RMB502 million for R&D activities, such as testing and clinical expenses, for the year ended December 31, 2021.</p> <p>We considered R&D expenses a key audit matter because the amount of the R&D expenses incurred is significant to the consolidated financial statements, and significant audit effort was involved in auditing the R&D expenses.</p>	<p>We performed the following audit procedures on R&D expenses:</p> <ol style="list-style-type: none">1. Understanding, evaluating and testing the key controls related to R&D expenses;2. Testing R&D expenses, on a sample basis, to supporting evidence such as contracts, invoices and payment slips;3. For the service fees paid to outsourced service providers, primarily related to testing and clinical expenses, assessing whether the service fees were recorded based on the respective contract terms and service progress, on a sample basis, by reading the key terms set out in the agreements with such service providers, and evaluating the completion status with reference to the progress reports provided by outsourced service providers; and4. Performing cut-off test on R&D expenses, on a sample basis, to assess whether the R&D expenses are recorded in the proper financial reporting period, by examining relevant supporting evidence such as contracts, invoices, delivery notice and progress reports. <p>Based on the procedures performed, we found that R&D expenses tested were supported by the audit evidence we obtained.</p>

Independent Auditor's Report

OTHER INFORMATION

The directors of the Company are responsible for the other information. The other information comprises all of the information included in the annual report other than the consolidated financial statements and our auditor's report thereon.

Our opinion on the consolidated financial statements does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the consolidated financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the consolidated financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

RESPONSIBILITIES OF DIRECTORS AND THE AUDIT COMMITTEE FOR THE CONSOLIDATED FINANCIAL STATEMENTS

The directors of the Company are responsible for the preparation of the consolidated financial statements that give a true and fair view in accordance with IFRSs and the disclosure requirements of the Hong Kong Companies Ordinance, and for such internal control as the directors determine is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, the directors are responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the Group or to cease operations, or have no realistic alternative but to do so.

The Audit Committee is responsible for overseeing the Group's financial reporting process.

AUDITOR'S RESPONSIBILITIES FOR THE AUDIT OF THE CONSOLIDATED FINANCIAL STATEMENTS

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. We report our opinion solely to you, as a body, and for no other purpose. We do not assume responsibility towards or accept liability to any other person for the contents of this report. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

Independent Auditor's Report

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the directors.
- Conclude on the appropriateness of the directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the Group audit. We remain solely responsible for our audit opinion.

We communicate with the Audit Committee regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the Audit Committee with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, actions taken to eliminate threats or safeguards applied.

Independent Auditor's Report

From the matters communicated with the Audit Committee, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

The engagement partner on the audit resulting in this independent auditor's report is Wong Kam Chin.

PricewaterhouseCoopers

Certified Public Accountants

Hong Kong,
March 22, 2022



Consolidated Statement of Comprehensive Loss

For the year ended December 31, 2021

	Note	Year ended December 31,	
		2021 RMB'000	2020 RMB'000
Revenue	6	25,813	–
Cost of sales		–	–
Gross profit		25,813	–
Administrative expenses	9	(125,831)	(76,893)
Research and development expenses	9	(501,721)	(281,752)
Other income	7	21,793	9,977
Other gains – net	8	6,041	21,623
Operating loss		(573,905)	(327,045)
Finance income		3,568	763
Finance costs		(10,869)	(13,480)
Finance costs – net	11	(7,301)	(12,717)
Fair value changes in financial instruments issued to investors	30	(4,155,572)	(724,287)
Loss before income tax		(4,736,778)	(1,064,049)
Income tax expense	13	(7,645)	–
Loss for the year and attribute to the equity holders of the Company		(4,744,423)	(1,064,049)
Other comprehensive (loss)/income for the year:			
<i>Items that may be reclassified to profit or loss</i>	–		
Exchange differences on translation of subsidiaries		20,312	55,683
<i>Items that will not be reclassified to profit or loss</i>			
Exchange differences on translation of the Company		(11,328)	29,024
Fair value changes relating to financial instruments issued to investors due to the Company's own credit risk		(25,093)	34,104
Other comprehensive (loss)/income for the year, net of tax		(16,109)	118,811
Total comprehensive loss for the year and attribute to the equity holders of the Company		(4,760,532)	(945,238)
Loss per share for the loss attributable to owners of the Company			
Basic and diluted loss per share (in RMB)	14	(12.26)	(5.37)

The above consolidated statement of comprehensive loss should be read in conjunction with the accompanying notes.

Consolidated Statement of Financial Position

As at December 31, 2021

	Note	As at December 31, 2021 RMB'000	As at December 31, 2020 RMB'000
ASSETS			
Non-current assets			
Property, plant and equipment	15	300,898	129,630
Right-of-use assets	16	85,291	27,139
Intangible assets	17	20,133	23,521
Other non-current assets and prepayments	18	28,460	17,766
		434,782	198,056
Current assets			
Deposits and other receivables	19	41,885	2,418
Other current assets and prepayments	20	22,030	10,408
Term deposits with original maturity between three and twelve months	21	2,315,654	–
Cash and cash equivalents	21	691,284	1,042,969
		3,070,853	1,055,795
Total assets		3,505,635	1,253,851
EQUITY AND LIABILITIES			
Equity attributable to the equity holders of the Company			
Share capital	23	1	–
Reserves	26	2,996,659	(1,676,128)
Total equity/(deficit)		2,996,660	(1,676,128)

Consolidated Statement of Financial Position

As at December 31, 2021

	Note	As at December 31, 2021 RMB'000	As at December 31, 2020 RMB'000
LIABILITIES			
Non-current liabilities			
Financial instruments issued to investors	30	–	2,745,584
Borrowings	27	7,375	11,981
Lease liabilities	28	97,312	14,016
Deferred income	29	15,116	13,167
		119,803	2,784,748
Current liabilities			
Lease liabilities	28	14,027	5,890
Accruals and other payables	31	138,025	67,379
Current income tax payable		7,645	–
Deferred income	29	10,144	3,591
Borrowings	27	219,331	68,371
		389,172	145,231
Total liabilities		508,975	2,929,979
Total equity and liabilities		3,505,635	1,253,851

The above consolidated statement of financial position should be read in conjunction with the accompanying notes.

The financial statement on page 141 to 216 were approved by the Board of Directors on March 22, 2022 and were signed on its behalf.

LI Zonghai
Director

WANG Huamao
Director

Consolidated Statement of Changes in Equity

For the year ended December 31, 2021

	Note	Attributable to equity holders of the Company			
		Share capital RMB'000	Other Reserves RMB'000 (Note 26)	Accumulated losses RMB'000	Total RMB'000
Balance at January 1, 2020		–	26,150	(758,754)	(732,604)
Loss for the year		–	–	(1,064,049)	(1,064,049)
Other comprehensive income	26	–	118,811	–	118,811
Total comprehensive loss		–	118,811	(1,064,049)	(945,238)
Transactions with owners					
Share-based compensation	24	–	1,714	–	1,714
Total transactions with owners		–	1,714	–	1,714
Balance at December 31, 2020		–	146,675	(1,822,803)	(1,676,128)
Balance at January 1, 2021		–	146,675	(1,822,803)	(1,676,128)
Loss for the year		–	–	(4,744,423)	(4,744,423)
Other comprehensive loss	26	–	(16,109)	–	(16,109)
Total comprehensive loss		–	(16,109)	(4,744,423)	(4,760,532)
Transactions with owners					
Share-based compensation	24	–	13,504	–	13,504
Conversion of Preferred Shares to Common Shares upon Global Offering	23	1	6,913,526	17,438	6,930,965
Gross proceeds from Global Offering	23	–	2,576,082	–	2,576,082
Listing fees through equity	23	–	(88,349)	–	(88,349)
Exercise of option related to employee shared-base payment	23	–	1,118	–	1,118
Total transactions with owners		1	9,415,881	17,438	9,433,320
Balance at December 31, 2021		1	9,546,447	(6,549,788)	2,996,660

The above consolidated statement of changes in equity should be read in conjunction with the accompanying notes.

Consolidated Statement of Cash Flows

For the year ended December 31, 2021

	Note	Year ended December 31,	
		2021 RMB'000	2020 RMB'000
Cash flows from operating activities			
Cash used in operations	32	(515,890)	(295,913)
Interest received		3,568	763
Net cash used in operating activities		(512,322)	(295,150)
Cash flows from investing activities			
Payments for acquisition of property, plant and equipment		(175,841)	(17,727)
Proceeds from disposals of property, plant and equipment		11	–
Proceeds from receiving term deposits with original maturity between three and twelve months		2,443,168	–
Payments for term deposits with original maturity between three and twelve months		(4,758,822)	–
Interest received from term deposits with original maturity between three and twelve months		5,235	–
Payment for acquisition of intangible assets		(2,612)	(1,008)
Refund of input VAT related to acquisition of non-current assets		–	11,838
Government grant received in relation to acquisition of non-current assets		17,540	–
Net cash used in investing activities		(2,471,321)	(6,897)

Consolidated Statement of Cash Flows

For the year ended December 31, 2021

	Note	Year ended December 31,	
		2021 RMB'000	2020 RMB'000
Cash flows from financing activities			
Proceeds from issuance of ordinary shares	23	2,576,082	–
Proceeds from issuance of financial instruments to investors	30	64,900	1,283,565
Principal element of lease payments		(16,079)	(7,494)
Interest paid for lease liabilities		(2,846)	(376)
Proceeds from bank borrowings		293,219	70,000
Repayments of bank borrowings		(146,865)	(30,152)
Interest paid for bank borrowings		(7,839)	(2,975)
Proceeds from loans with conversion option		–	100,000
Repayments of loans with conversion option		–	(100,000)
Repayment of convertible loans		–	(27,625)
Injection of cash to the Company by investors with proceeds from repayment of convertible loans		–	27,625
Interest paid for loans with conversion option		–	(10,095)
Payment for listing expenses through equity		(86,540)	–
Net cash generated from financing activities		2,674,032	1,302,473
Net (decrease)/increase in cash and cash equivalents			
Cash and cash equivalents at beginning of the year		1,042,969	96,476
Exchange loss on cash and cash equivalents		(42,074)	(53,933)
Cash and cash equivalents at end of the year		691,284	1,042,969

The above consolidated statement of cash flows should be read in conjunction with the accompanying notes.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

1. GENERAL INFORMATION

CARsgen Therapeutics Holdings Limited (hereinafter the “Company”) was incorporated under the law of Cayman Islands as a limited liability company on 9 February 2018. The address of the Company’s registered office is P.O. Box 31119 Grand Pavilion, Hibiscus Way, 802 West Bay Road, Grand Cayman, KY1 – 1205 Cayman Islands.

The Company is an investment holding company. The Company and its subsidiaries (hereinafter collectively referred to as the “Group”) are a global clinical-stage biopharmaceutical company discovering, researching and developing cell therapies in the People’s Republic of China (the “PRC”) and United States of America (the “US”).

The Company’s shares began to list on the Main Board of The Stock Exchange of Hong Kong Limited (the “Stock Exchange”) on June 18, 2021 (the “Listing”).

The consolidated financial statements are presented in thousands of Renminbi (“RMB”), unless otherwise stated, and were approved and authorized for issue by the Board of Directors of the Company on March 22, 2022.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

This note provides a list of the significant accounting policies adopted in the preparation of these consolidated financial statements. These policies have been consistently applied to all the years presented, unless otherwise stated. The financial statements are for the group consisting of the Company and its subsidiaries.

2.1. Basis of preparation

The consolidated financial statements of the Group have been prepared in accordance with International Financial Reporting Standards (“IFRSs”) issued by International Accounting Standards Board (“IASB”) and disclosure requirements of the Hong Kong Companies Ordinance (“HKCO”). The consolidated financial statements have been prepared under the historical cost convention, as modified by the revaluation of financial assets and liabilities at fair value through profit or loss, which are carried at fair value.

The preparation of the consolidated financial statements in conformity with IFRSs requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the Group’s accounting policies. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in Note 4 below.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

2.1. Basis of preparation (continued)

(i) *New and amended standards adopted by the Group*

The Group has applied the following amendments for the first time for their annual reporting period commencing January 1, 2021:

- Amendments to IFRS 16, COVID-19-Related Rent Concessions
- Amendments to IFRS9, IAS39, IFRS7, IFRS4 and IFRS16 Interest Rate Benchmark Reform-phase 2

The amendments listed above did not have any impact on the amounts recognized in prior periods and are not expected to significantly affect the current or future periods.

The following new standards and amendments to existing standards have been issued but are not yet effective for the annual period after January 1, 2021 and which the Group has not early adopted.

(ii) *New standards and interpretation not yet adopted*

Standards	Key requirements	Effective for annual periods beginning on or after
IFRS 17	Insurance Contracts	January 1, 2023
Amendments to IFRS 17		January 1, 2023
Amendments to IAS 1	Classification of Liabilities as Current or Non-current	January 1, 2023
Amendments to IAS 16	Property, plant and equipment: Proceeds before intended use	January 1, 2022
Amendments to IAS 37	Onerous contract – cost of fulfilling a contract	January 1, 2022
Annual improvements	Annual improvements to IFRS 2018-2020	January 1, 2022
Amendments to IFRS 10 and IAS 28	Sale or contribution of assets between an investor and its associate or joint venture	To be determined
Amendments to IFRS 3	Reference to the Conceptual Framework	January 1, 2022
Amendments to IAS 1 and IFRS Practice Statement 2	Disclosure of Accounting Policies	January 1, 2023
Amendments to IAS 8	Definition of Accounting Estimates	January 1, 2023

The Group has already commenced an assessment of the impact of these new or revised standards and amendments, certain of which are relevant to the Group's operations. According to the preliminary assessment made by the directors, these standards and amendments are not expected to have a significant impact on the Group's financial performance and position.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

2.2. Contractual arrangement

Due to the restrictions imposed by the relevant laws and regulatory regime of the PRC on foreign ownership of companies engaged in the gene therapy business carried out by subsidiaries of the Group, namely CARsgen Therapeutics Co., Ltd. (科濟生物醫藥(上海)有限公司) (“CARsgen Therapeutics (Shanghai)”) and its wholly owned subsidiaries, CARsgen Pharmaceuticals Co., Ltd. (上海科濟製藥有限公司) and CARsgen Therapeutics International Group Limited (科濟藥業國際集團有限公司), hereinafter collectively “CARsgen Therapeutics Group”, CARsgen Life Sciences Co., Ltd. (愷興生命科技(上海)有限公司) (“CARsgen Life Sciences”) entered into the contractual arrangements (the “Contractual Arrangements”) with CARsgen Therapeutics (Shanghai) and its registered shareholders who collectively hold 100% equity interests of CARsgen Therapeutics (Shanghai) on April 18, 2018, which enable CARsgen Life Science and the Group to:

- expose, or have rights, to variable returns from their involvement with the investee and have ability to affect those returns through its power over CARsgen Therapeutics Group;
- exercise equity holders’ controlling voting rights of CARsgen Therapeutics Group;
- receive substantially all of the economic interest returns generated by CARsgen Therapeutics Group in consideration for the business support, technical and consulting services provided by CARsgen Therapeutics Group;
- obtain an irrevocable and exclusive right to purchase all or part of equity interests in CARsgen Therapeutics Group from its equity holders at the same amount of its registered capital. CARsgen Life Science may exercise such options at any time until it has acquired all equity interests and/or all assets of CARsgen Therapeutics Group. In addition, CARsgen Therapeutics Group is not allowed to sell, transfer, or dispose of any assets, or make any distributions to its equity holders without prior consent of CARsgen Life Science; and
- obtain a pledge over the entire equity interest of CARsgen Therapeutics Group from its equity holders as collateral security to guarantee performance of their contractual obligations under the Contractual Arrangements.

The Group does not have any legal equity interest in CARsgen Therapeutics Group. However, as a result of the Contractual Arrangements, the Group has power over CARsgen Therapeutics Group, has rights to variable returns from its involvement with CARsgen Therapeutics Group and has the ability to affect those returns through its power over CARsgen Therapeutics Group and is considered to have control over CARsgen Therapeutics Group. Consequently, the Company regards CARsgen Therapeutics Group as controlled structure entities and consolidated the financial position and result of operations of CARsgen Therapeutics Group.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

2.3. Principles of consolidation

(i) *Subsidiaries*

Subsidiaries are all entities (including structured entities) over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. Subsidiaries are consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date that control ceases.

Intercompany transactions, balances and unrealized gains on transactions between entities within the Group are eliminated. Unrealized losses are also eliminated unless the transaction provides evidence of an impairment of the transferred asset.

2.4. Business combination

The acquisition method of accounting is used to account for all business combinations, regardless of whether equity instruments or other assets are acquired. The consideration transferred for the acquisition of a subsidiary comprises the:

- fair values of the assets transferred
- liabilities incurred to the former owners of the acquired business
- equity interests issued by the group
- fair value of any asset or liability resulting from a contingent consideration arrangement, and
- fair value of any pre-existing equity interest in the subsidiary.

Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are, with limited exceptions, measured initially at their fair values at the acquisition date. The group recognizes any non-controlling interest in the acquired entity on an acquisition-by-acquisition basis either at fair value or at the non-controlling interest's proportionate share of the acquired entity's net identifiable assets.

Acquisition-related costs are expensed as incurred.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

2.4. Business combination (continued)

The excess of the:

- consideration transferred,
- amount of any non-controlling interest in the acquired entity, and
- acquisition-date fair value of any previous equity interest in the acquired entity

over the fair value of the net identifiable assets acquired is recorded as goodwill. If those amounts are less than the fair value of the net identifiable assets of the business acquired, the difference is recognized directly in profit or loss as a bargain purchase.

Where settlement of any part of cash consideration is deferred, the amounts payable in the future are discounted to their present value as at the date of exchange. The discount rate used is the entity's incremental borrowing rate, being the rate at which a similar borrowing could be obtained from an independent financier under comparable terms and conditions. Contingent consideration is classified either as equity or a financial liability. Amounts classified as a financial liability are subsequently remeasured to fair value with changes in fair value recognized in profit or loss.

If the business combination is achieved in stages, the acquisition date carrying value of the acquirer's previously held equity interest in the acquiree is remeasured to fair value at the acquisition date. Any gains or losses arising from such remeasurement are recognized in profit or loss.

2.5. Separate financial statements

Investments in subsidiaries are accounted for at cost less impairment. Cost includes direct attributable costs of investment. The results of subsidiaries are accounted for by the company on the basis of dividend received and receivable.

Impairment testing of the investments in subsidiaries is required upon receiving a dividend from these investments if the dividend exceeds the total comprehensive income of the subsidiary in the period the dividend is declared or if the carrying amount of the investment in the separate financial statements exceeds the carrying amount in the consolidated financial statements of the investee's net assets including goodwill.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

2.6. Segment reporting

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker. The chief operating decision-maker, who is responsible for allocating resources and assessing performance of the operating segments, has been identified as the executive directors that makes strategic decisions.

2.7. Foreign currency translation

(i) *Functional and presentation currency*

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the "functional currency"). The Company's functional currency is United States Dollars ("USD"); however the consolidated financial statements are presented in RMB. As the major operations of the Group are within the PRC, the Group determined to present its consolidated financial statements in RMB (unless otherwise stated).

(ii) *Transactions and balances*

Foreign currency transactions are translated into the functional currency using the exchange rates at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year end exchange rates are generally recognized in profit or loss. They are deferred in equity if they relate to qualifying cash flow hedges and qualifying net investment hedges or are attributable to part of the net investment in a foreign operation.

Foreign exchange gains and losses that relate to borrowings are presented in the statement of comprehensive income, within finance costs. All other foreign exchange gains and losses are presented in the statement of comprehensive income on a net basis within other gains/(losses).

Non-monetary items that are measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined. Translation differences on assets and liabilities carried at fair value are reported as part of the fair value gain or loss. For example, translation differences on non-monetary assets and liabilities such as equities held at fair value through profit or loss are recognized in profit or loss as part of the fair value gain or loss and translation differences on non-monetary assets such as equities classified as fair value through other comprehensive income are recognized in other comprehensive income.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

2.7. Foreign currency translation (continued)

(iii) Group companies

The results and financial position of foreign operations (none of which has the currency of a hyperinflationary economy) that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- assets and liabilities for each balance sheet presented are translated at the closing rate at the date of that balance sheet,
- income and expenses for each statement of comprehensive income are translated at average exchange rates (unless this is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the dates of the transactions), and
- all resulting exchange differences are recognized in other comprehensive income.

On consolidation, exchange differences arising from the translation of any net investment in foreign entities, and of borrowings and other financial instruments designated as hedges of such investments, are recognized in other comprehensive income. When a foreign operation is sold or any borrowings forming part of the net investment are repaid, the associated exchange differences are reclassified to profit or loss, as part of the gain or loss on sale.

2.8. Property, plant and equipment

Property, plant and equipment are stated at historical cost less accumulated depreciation and accumulated impairment losses. Historical cost includes expenditure that is directly attributable to the acquisition of the items. Cost may also include transfers from equity of any gains or losses on qualifying cash flow hedges of foreign currency purchases of property, plant and equipment.

Subsequent costs are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably. The carrying amount of the replaced part is derecognized. All other repairs and maintenance are charged to the statement of profit or loss during the financial period in which they are incurred.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

2.8. Property, plant and equipment (continued)

Depreciation of property, plant and equipment is calculated using the straight-line method to allocate their costs less their residual values over their estimated useful lives, as follows:

- Building 20 years
- Equipment 5-10 years
- Electronic equipment 3 years
- Fixture 5 years
- Furniture 5-7 years
- Vehicles 4 years
- Leasehold improvements Over the shorter of the lease term or the estimated useful life

The assets' residual value and useful life are reviewed, and adjusted if appropriate, at the end of each reporting period.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount (Note 2.10).

Gains and losses on disposals are determined by comparing proceeds with carrying amount. These are included in profit or loss. When revalued assets are sold, it is group policy to transfer any amounts included in other reserves in respect of those assets to retained earnings.

Construction in progress represents unfinished construction and equipment under construction or pending installation, and is stated at cost less impairment losses. Cost comprises direct costs of construction including borrowing costs attributable to the construction during the period of construction. No provision for depreciation is made on construction in progress until such time as the relevant assets are completed and ready for intended use.

2.9. Intangible assets

(i) Software

Computer software is recognized at historical cost and subsequently carried at cost less accumulated amortization and accumulated impairment losses. The Group amortized on a straight-line basis over their estimated useful lives of 3-5 years.

(ii) Patent

Patents are shown at fair value when acquired. Patents have a finite life and are carried at cost less accumulated amortization and impairment, if any. Amortization is calculated using the straight-line method to allocate the cost of patents over their estimated useful lives of ten years.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

2.9. Intangible assets (continued)

(iii) Research and development

The Group incurs significant costs and efforts on research and development activities, which include expenditures on drug products. Research expenditures are charged to the profit or loss as an expense in the period the expenditures are incurred. Development costs are recognized as assets if they can be directly attributable to a newly developed drug products and all the followings can be demonstrated:

- the technical feasibility of completing the intangible assets so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible assets;
- the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

The cost of an internally generated intangible asset is the sum of the expenditures incurred from the date the asset meets the recognition criteria above to the date when it is available for use. The costs capitalized in connection with the intangible asset include costs of consumables and services used or consumed, employee costs incurred in the creation of the asset and an appropriate portion of relevant overheads. The Group generally considers capitalization criteria for internally generated intangible assets is met when obtaining regulatory approval of new drug license.

Capitalized development expenditures are amortized using the straight-line method over the life of the related drug products. Amortization shall begin when the asset is available for use. Subsequent to initial recognition, internally generated intangible assets are reported as cost less accumulated amortization and accumulated impairment losses (if any).

Development expenditures not satisfying the above criteria are recognized in the profit or loss as incurred and development expenditures previously recognized as an expense are not recognized as an asset in a subsequent period.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

2.10. Impairment of non-financial assets

Intangible assets, right-of-use assets and property, and plant and equipment that are subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units). Non-financial assets other than goodwill that suffered an impairment are reviewed for possible reversal of the impairment at the end of each reporting period.

2.11. Financial assets

(i) Classification

The Group classifies its financial assets in the following measurement categories:

- Those to be measured subsequently at fair value (either through other comprehensive income or through profit or loss), and
- Those to be measured at amortized cost.

The classification depends on the Group's business model for managing the financial assets and the contractual terms of the cash flows.

For assets measured at fair value, gains and losses will either be recorded in profit or loss or other comprehensive income. For investments in equity instruments that are not held for trading, this will depend on whether the Group has made an irrevocable election at the time of initial recognition to account for the equity investment at fair value through other comprehensive income ("FVOCI").

The Group reclassifies debt investments when and only when its business model for managing those assets changes.

(ii) Measurement

At initial recognition, the Group measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss ("FVPL"), transaction costs that are directly attributable to the acquisition of the financial asset. Transaction costs of financial assets carried at FVPL are expensed in profit or loss.

Financial assets with embedded derivatives are considered in their entirety when determining whether their cash flows are solely payment of principal and interest.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

2.11. Financial assets (continued)

(ii) **Measurement** (continued)

Debt instruments

Subsequent measurement of debt instruments depends on the group's business model for managing the asset and the cash flow characteristics of the asset. There are three measurement categories into which the Group classifies its debt instruments:

- **Amortized cost:** Assets that are held for collection of contractual cash flows where those cash flows represent solely payments of principal and interest are measured at amortized cost. A gain or loss on a debt investment that is subsequently measured at amortized cost and is not part of a hedging relationship is recognized in profit or loss when the asset is derecognized or impaired. Interest income from these financial assets is included in income using the effective interest method.
- **FVOCI:** Assets that are held for collection of contractual cash flows and for selling the financial assets, where the assets cash flows represent solely payments of principal and interest, are measured at FVOCI. Movements in the carrying amount are taken through OCI, except for the recognition of impairment gains or losses, interest income and foreign exchange gains and losses which are recognized in profit or loss. When the financial asset is derecognized, the cumulative gain or loss previously recognized in OCI is reclassified from equity to profit or loss and recognized in "other gains/losses". Interest income from these financial assets is included in finance income using the effective interest method. Foreign exchange gains and losses and impairment expenses are presented in "Other gains – net".
- **FVPL:** Assets that do not meet the criteria for amortized cost or FVOCI are measured at fair value through profit or loss. A gain or loss on a debt investment that is subsequently measured at fair value through profit or loss and is not part of a hedging relationship is recognized in profit or loss and presented net in the consolidated statements of comprehensive loss within "Other gains – net" in the period in which it arises.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

2.11. Financial assets (continued)

(ii) Measurement (continued)

Equity instruments

The Group subsequently measures all equity investments at fair value. Where the Group's management has elected to present fair value gains and losses on equity investments in OCI, there is no subsequent reclassification of fair value gains and losses to profit or loss following the derecognition of the investment. Dividends from such investments continue to be recognized in profit or loss as other income when the Group's right to receive payments is established.

Changes in the fair value of financial assets at FVPL are recognized in other gains – net in the consolidated statements of comprehensive loss as applicable. Impairment losses (and reversal of impairment losses) on equity investments measured at FVOCI are not reported separately from other changes in fair value.

2.12. Offsetting financial assets and liabilities

Financial assets and liabilities are offset and the net amount reported in the consolidated balance sheets when there is a legally enforceable right to offset the recognized amounts and there is an intention to settle on a net basis or realize the asset and settle the liability simultaneously. The legally enforceable right must not be contingent on future events and must be enforceable in the normal course of business and in the event of default, insolvency or bankruptcy of the company or the counterparty.

2.13. Impairment of financial assets

The Group assesses on a forward-looking basis the expected credit loss associated with its debt instruments carried at amortized cost. The impairment methodology applied depends on whether there has been a significant increase in credit risk. Note 3.1(b) details how the Group determines whether there has been a significant increase in credit risk.

Impairment on other receivables is measured as either 12-month expected credit loss or lifetime expected credit loss, depending on whether there has been a significant increase in credit risk since initial recognition. If a significant increase in credit risk of a receivable has occurred since initial recognition, then impairment is measured as lifetime expected credit loss.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

2.14. Derivatives

Derivatives are initially recognized at fair value on the date a derivative contract is entered into and are subsequently remeasured to their fair value at the end of each reporting period.

2.15. Cash and cash equivalents

Cash and cash equivalents include cash in hand, deposits held at call with banks and other short-term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

2.16. Share capital and share held for employee share scheme

Ordinary shares are classified as equity. Preferred shares are classified as liabilities based on the respective contract terms.

Incremental costs directly attributable to the issue of equity instruments are shown in equity as a deduction, net of tax, from the proceeds.

Shares held for the share award scheme are disclosed as "Issue of shares held in trust" and deducted from equity until the shares are vested or cancelled.

2.17. Accruals and other payables

Accruals and other payables mainly represent the obligations to pay for consumables and services that have been acquired in the ordinary course of business. Accruals and other payables are presented as current liabilities unless payment is not due within one year or less after the reporting period.

Accruals and other payables are recognized initially at their fair value and subsequently measured at amortized cost using the effective interest method.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

2.18. Financial instruments issued to investors

Financial instruments issued to investors consist of preferred shares and convertible loans. Accounting policies and other explanatory information of these financial instruments are elaborated as follows:

(i) Preferred shares

Before and during the year ended December 31, 2020, the Group entered into a series of share purchase agreements with financial investors and issued Series A, Series B, Series Pre-C, Series C-1 and Series C-2 preferred shares, respectively (collectively, "Preferred Shares"). Preferred Shares are redeemable upon occurrence of certain events. This instrument can be converted into ordinary shares of the Company at any time at the option of the holders or automatically converted into ordinary shares upon occurrence of an initial public offering ("IPO") of the Company. The Group designated the Preferred Shares as financial liabilities at fair value through profit or loss. They are initially recognized at fair value. Subsequent to initial recognition, the Preferred Shares are carried at fair value with changes in fair value recognized in the profit or loss. If the Company's own credit risk results in fair value changes in financial liabilities designated as at fair value through profit or loss, they are recognized in other comprehensive income.

(ii) Convertible loans

Before and during the year ended December 31, 2020, the Group issued certain convertible loans to investors. Convertible loans bear no interest and are convertible into preference shares of the Company at the option of the holders under certain conditions. The Group designated the convertible loans as financial liabilities at fair value through profit or loss, which is initially recognized at fair value. Subsequent to initial recognition, the convertible loans are carried at fair value with changes in fair value recognized in the profit or loss. If the Company's own credit risk results in fair value changes in financial liabilities designated as at fair value through profit or loss, they are recognized in other comprehensive income.

2.19. Borrowings

Borrowings are recognized initially at fair value, net of transaction costs incurred. Borrowings are subsequently carried at amortized cost; any difference between the proceeds (net of transaction costs) and the redemption value is recognized in consolidated statements of comprehensive loss over the period of the borrowings using the effective interest method.

Borrowings are classified as current liabilities unless the Group has an unconditional right to defer settlement of the liability for at least 12 months after the end of the reporting period.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

2.20. Borrowing costs

General and specific borrowing costs directly attributable to the acquisition, construction or production of a qualifying asset are capitalized during the period of time that is required to complete and prepare the asset for its intended use. Qualifying assets are assets that necessarily take a substantial period of time to get ready for their intended use or sale. Other borrowing costs are expensed as incurred.

2.21. Current and deferred income tax

The income tax expense or credit for the period is the tax payable on the current period's taxable income based on the applicable income tax rate for each jurisdiction adjusted by changes in deferred tax assets and liabilities attributable to temporary differences and to unused tax losses.

(i) Current income tax

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the end of the reporting period in the countries where the company and its subsidiaries and associates operate and generate taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation and considers whether it is probable that a taxation authority will accept an uncertain tax treatment. The Group measures its tax balances either based on the most likely amount or the expected value, depending on which method provides a better prediction of the resolution of the uncertainty.

(ii) Deferred income tax

Deferred income tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. However, deferred tax liabilities are not recognized if they arise from the initial recognition of goodwill. Deferred income tax is also not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss and does not give rise to equal taxable and deductible temporary differences. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantively enacted by the end of the reporting period and are expected to apply when the related deferred income tax asset is realised or the deferred income tax liability is settled.

Deferred tax assets are recognized only if it is probable that future taxable amounts will be available to utilise those temporary differences and losses.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

2.21. Current and deferred income tax (continued)

(ii) *Deferred income tax* (continued)

Deferred tax liabilities and assets are not recognized for temporary differences between the carrying amount and tax bases of investments in foreign operations where the company is able to control the timing of the reversal of the temporary differences and it is probable that the differences will not reverse in the foreseeable future.

Deferred tax assets and liabilities are offset where there is a legally enforceable right to offset current tax assets and liabilities and where the deferred tax balances relate to the same taxation authority. Current tax assets and tax liabilities are offset where the entity has a legally enforceable right to offset and intends either to settle on a net basis, or to realise the asset and settle the liability simultaneously.

Current and deferred tax is recognized in profit or loss, except to the extent that it relates to items recognized in other comprehensive income or directly in equity. In this case, the tax is also recognized in other comprehensive income or directly in equity, respectively.

2.22. Employee benefits

(i) *Short-term obligations*

Liabilities for wages and salaries, including non-monetary benefits and accumulating sick leave that are expected to be settled wholly within 12 months after the end of the period in which the employees render the related service are recognized in respect of employees' services up to the end of the reporting period and are measured at the amounts expected to be paid when the liabilities are settled. The liabilities are presented as current employee benefit obligations in the balance sheet.

(ii) *Pension obligations*

Full-time employees in the PRC are covered by various government-sponsored defined contribution pension plans under which the employees are entitled to a monthly pension based on certain formulas. The relevant government agencies are responsible for the pension liability to these retired employees. The Group contributes on a monthly basis to these pension plans. Under these plans, the Group has no further payment obligation for post-retirement benefits beyond the contributions made. Contributions to these plans are expensed as incurred and contributions paid to the defined-contribution pension plans for an employee are not available to reduce the Group's future obligations to such defined-contribution pension plans even if the employee leaves.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

2.22. Employee benefits (continued)

(iii) Housing funds, medical insurance and other social insurance

Employees in the PRC are entitled to participate in various government-supervised housing funds, medical insurance and other employee social insurance plans. The Group contributes on a monthly basis to these funds based on certain percentages of the salaries of the employees, subject to certain ceiling. The Group's liability in respect of these funds is limited to the contribution payable.

(iv) Bonus plan

The expected cost of bonus is recognized as a liability when the Group has a present legal or constructive obligation for payment of bonus as a result of services rendered by employees and a reliable estimate of the obligation can be made. Liabilities for bonus plans are expected to be settled within 12 months and are measured at the amounts expected to be paid when they are settled.

2.23. Share-based payment

(i) Equity-settled share-based payment transactions

The Group operates stock options granted to employees, under which the Group receives services from employees as consideration for equity instruments of the Group. The fair value of the employee services received in exchange for the grant of equity instruments (options) is recognized as an expense in the consolidated financial statements. The total amount to be expensed is determined by reference to the fair value of the equity instruments granted:

- including any market performance conditions;
- excluding the impact of any service and non-market performance vesting conditions (for example, the requirement for employees to serve);
- including the impact of any non-vesting conditions.

At the end of each reporting period, the Group revises its estimates of the number of options that are expected to vest based on the non-market vesting performance and service conditions. It recognizes the impact of the revision to original estimates, if any, in the consolidated statements of comprehensive loss, with a corresponding adjustment to equity.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

2.23. Share-based payment (continued)

(i) *Equity-settled share-based payment transactions* (continued)

In addition, in some circumstances employees may provide services in advance of the grant date and therefore the grant date fair value is estimated for the purposes of recognizing the expense during the period between service commencement date and grant date.

Where there is any modification of terms and conditions which increases the fair value of the equity instruments granted, the Group includes the incremental fair value granted in the measurement of the amount recognized for the services received over the remainder of the vesting period. The incremental fair value is the difference between the fair value of the modified equity instrument and that of the original equity instrument, both estimated as at the date of the modification. An expense based on the incremental fair value is recognized over the period from the modification date to the date when the modified equity instruments vest in addition to any amount in respect of the original instrument, which should continue to be recognized over the remainder of the original vesting period.

(ii) *Share-based payment transaction among group entities*

The grant by the Company of options over its equity instruments to the employees of subsidiaries in the Group is treated as a capital contribution. The fair value of employee services received, measured by reference to the grant date fair value, is recognized over the vesting period as an increase to investment in subsidiaries undertakings, with a corresponding credit to equity in separate financial statements of the Company.

2.24. Provisions

Provisions are recognized when the Group has a present legal or constructive obligation as a result of past events, it is probable that an outflow of resources will be required to settle the obligation and the amount can be reliably estimated. Provisions are not recognized for future operating losses.

Where there are a number of similar obligations, the likelihood that an outflow will be required in settlement is determined by considering the class of obligations as a whole. A provision is recognized even if the likelihood of an outflow with respect to any one item included in the same class of obligations may be small.

Provisions are measured at the present value of management's best estimate of the expenditure required to settle the present obligation at the end of the reporting period. The discount rate used to determine the present value is a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the liability. The increase in the provision due to the passage of time is recognized as interest expense.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

2.25. Revenue recognition

Licence fee income

The Group provides licence of its patented intellectual property (“IP”) or commercialisation licence to customers and revenue is recognized when the customers obtain rights to access or use the underlying IP or licence. Licence fee income is recognized at a point of time upon the customer obtains control of IP.

The consideration for licence comprises a fixed element (the upfront payment) and variable elements (including but not limited to development milestones and royalties).

For licence that the Group provided for customers’ right to access, upfront fee is recognized as revenue when customers have ability to use the underlying IP of the licence and variable consideration is recognized only to the extent that it is highly probable that such an inclusion will not result in a significant revenue reversal in the future.

For licence associate with customers’ right to use, upfront fee and variable consideration received are recorded under contract liabilities and recognized as revenue only when customers have ability to use the licence and variable consideration is recognized only to the extent that it is highly probable that such an inclusion will not result in a significant revenue reversal in the future.

During the year ended December 31, 2021, the Group received an upfront payment up to an aggregate amount of USD4,000,000 (equivalent to RMB25,813,000) (2020: nil).

2.26. Loss per share

Basic loss per share is calculated by dividing the loss of the Group attribute to equity holders of the Company by weighted average number of ordinary shares outstanding during the year.

Diluted loss per share is calculated by adjusting the weighted average number of ordinary shares outstanding to assume conversion of all dilutive potential ordinary shares.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

2.27. Leases and right of use assets

The Group leases various properties. Property leases are typically made for fixed periods of one to five years. Lease terms are negotiated on an individual basis and contain various different terms and conditions.

Leases are recognized as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the Group.

Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions. The lease agreements do not impose any covenants other than the security interests in the leased assets that are held by the lessor. Leased assets may not be used as security for borrowing purposes.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments:

- fixed payments (including in-substance fixed payments), less any lease incentives receivable;
- variable lease payment that are based on an index or a rate, initially measured using the index or rate as at the commencement date;
- amounts expected to be payable by the lessee under residual value guarantees;
- the exercise price of a purchase option if the lessee is reasonably certain to exercise that option; and
- payments of penalties for terminating the lease, if the lease term reflects the lessee exercising that option.

Lease payments to be made under reasonably certain extension options are also included in the measurement of the liability.

The lease payments are discounted using the interest rate implicit in the lease. If that rate cannot be readily determined, which is generally the case for leases in the group, the lessee's incremental borrowing rate is used, being the rate that the individual lessee would have to pay to borrow the funds necessary to obtain an asset of similar value to the right-of-use asset in a similar economic environment with similar terms, security and conditions.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

2.27. Leases and right of use assets (continued)

To determine the incremental borrowing rate, the Group:

- where possible, uses recent third-party financing received by the individual lessee as a starting point, adjusted to reflect changes in financing conditions since third party financing was received
- uses a build-up approach that starts with a risk-free interest rate adjusted for credit risk for leases held by the Group, which does not have recent third-party financing, and
- makes adjustments specific to the lease, eg term, country, currency and security.

If a readily observable amortizing loan rate is available to the individual lessee (through recent financing or market data) which has a similar payment profile to the lease, then the Group use that rate as a starting point to determine the incremental borrowing rate.

Lease payments are allocated between principal and finance cost. The finance cost is charged to profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period.

Right-of-use assets are measured at cost comprising the following:

- the amount of the initial measurement of lease liabilities;
- any lease payments made at or before the commencement date, less any lease incentive received;
- any initial direct costs; and
- restoration costs.

Right-of-use assets are generally depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis. If the group is reasonably certain to exercise a purchase option, the right-of-use asset is depreciated over the underlying asset's useful life.

Payments associated with short-term leases and leases of low-value assets are recognized on a straight-line basis as an expense in profit or loss. Short-term leases are leases with a lease term of less than 12 months. Low-value assets comprise equipment and small items of office furniture.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

2.28. Dividend distribution

Provision is made for the amount of any dividend declared, being appropriately authorized and no longer at the discretion of the entity, on or before the end of the reporting period but not distributed at the end of reporting period.

2.29. Government grants

Government grants are recognized at their fair value where there is a reasonable assurance that the grant will be received, and the Group will comply with all the attached conditions.

Government grants relating to costs are deferred and recognized in consolidated statements of comprehensive loss over the period necessary to match them with the costs that they are intended to compensate.

Government grants relating to property, plant and equipment are included in non-current liabilities as deferred income and are credited to consolidated statements of comprehensive loss over the estimated useful lives of the related assets using the straight-line method.

2.30. Interest income

Interest income is calculated by applying the effective interest rate to the gross carrying amount of a financial asset except for financial assets that subsequently become credit-impaired. For credit-impaired financial assets, the effective interest rate is applied to the net carrying amount of the financial asset (after deduction of the loss allowance).

Interest income is presented as finance income where it is earned from financial assets that are held for cash management purposes. Any other interest income is included in other income.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

3. FINANCIAL RISK MANAGEMENT

3.1. Financial risk factors

The Group's risk management is predominantly controlled by the treasury department under policies approved by the board of directors. The Group treasury identifies, evaluates and hedges financial risks in close co-operation with the Group's operating units. The board provides written principles for overall risk management, as well as policies covering specific areas, such as foreign exchange risk, interest rate risk, credit risk, use of derivative financial instruments and non-derivative financial instruments, and investment of excess liquidity.

(a) Market risk

(i) Foreign exchange risk

Foreign exchange risk arises when future commercial transactions or recognized assets and liabilities are denominated in a currency that is not the functional currency of the relevant group entity.

The Group has entities operating in the United States of America and in the People's Republic of China and there are certain cash and cash equivalent, other receivables, accruals and other payables denominated in a currency that is not the functional currency of the relevant group entity. The Group constantly reviews the economic situation and its foreign exchange risk profile, and will consider appropriate hedging measures, as may be necessary.

At December 31, 2021 and 2020, if the USD strengthened/weakened by 5% against the RMB with all other variables held constant, net loss for the years would have been RMB44,237,000 lower/higher and RMB35,477,000 lower/higher, respectively.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

3. FINANCIAL RISK MANAGEMENT (continued)

3.1. Financial risk factors (continued)

(a) Market risk (continued)

(ii) Cash flow and fair value interest rate risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The Group's exposure to the risk of changes in market interest rates relates primarily to the Group's interest-bearing borrowings. Borrowings obtained at variable rates expose the Group to cash flow interest-rate risk. The Group has not hedged its cash flow or fair value interest-rate risk.

If interest rates on borrowings had been 50 basis point higher with all other variables held constant, the Group's loss would approximately increase RMB402,000 and RMB274,864 for each of the years ended December 31, 2021 and 2020, respectively.

(b) Credit risk

The Group has no significant concentrations of credit risk. The carrying amounts of cash and cash equivalents, other receivables included in the consolidated statements of financial position represent the Group's maximum exposure to credit risk in relation to its financial assets.

As at December 31, 2021 and 2020, cash and cash equivalents were all deposited with high quality financial institutions without significant credit risk.

Management has assessed that during the year ended December 31, 2021 and 2020, other receivables have not had a significant increase in credit risk since initial recognition. Thus, a 12-month expected credit loss approach that results from possible default event within 12 months of each reporting date is adopted by management. The Group does not expect any losses from non-performance by the counterparties of other receivables and no loss allowance provision for other receivables was recognized.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

3. FINANCIAL RISK MANAGEMENT (continued)

3.1. Financial risk factors (continued)

(c) Liquidity risk

The Group aims to maintain sufficient cash and cash equivalents. Due to the dynamic nature of the underlying business, the policy of the Group is to regularly monitor the Group's liquidity risk and to maintain adequate cash and cash equivalents or adjust financing arrangements to meet the Group's liquidity requirements.

The Group recognizes financial instruments issued to investors at fair value through profit or loss. Accordingly, the financial instruments issued to investors are managed on a fair value rather than by matching dates.

The table below analyzes the Group's non-derivative financial liabilities that will be settled into relevant maturity grouping based on the remaining period at each balance sheet date to the contractual maturity date. The amounts disclosed in the table are the contractual undiscounted cash flows.

	Less than 1 year RMB'000	Between 1 and 2 years RMB'000	Between 2 and 5 years RMB'000	Over 5 years RMB'000	Total RMB'000
As at December 31, 2021					
Accruals and other payables	89,568	–	–	–	89,568
Borrowings	225,921	5,470	2,789	–	234,180
Lease liabilities	18,446	19,853	49,842	43,698	131,839
Total	333,935	25,323	52,631	43,698	455,587
As at December 31, 2020					
Accruals and other payables	44,749	–	–	–	44,749
Borrowings	70,448	5,143	8,999	–	84,590
Lease liabilities	6,610	4,894	10,449	–	21,953
Financial instruments issued to investors	–	–	1,832,617	–	1,832,617
Total	121,807	10,037	1,852,065	–	1,983,909

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

3. FINANCIAL RISK MANAGEMENT (continued)

3.2. Capital management

The Group's objectives of managing capital are to safeguard the Group's ability to continue as a going concern in order to provide returns for equity holders and benefits for other stakeholders and to maintain an optimal capital structure to reduce the cost of capital.

In order to maintain or adjust the capital structure, the Group may return capital to equity holders, issue new shares, make borrowings or sell assets to reduce debt.

The Group monitors capital (including share capital and reserves, and preferred Shares on an as-if-converted basis) by regularly reviewing the capital structure. As a part of this review, the Company considers the cost of capital and the risks associated with the issued share capital. In the opinion of the directors of the Company, the Group's capital risk is low.

3.3. Fair value estimation

(i) Fair value hierarchy

This section explains the judgements and estimates made in determining the fair values of the financial instruments that are recognized and measured at fair value in the financial statements. To provide an indication about the reliability of the inputs used in determining fair value, the Group has classified its financial instruments into the three levels prescribed under the accounting standards.

Level 1: The fair value of financial instruments traded in active markets (such as trading and available-for-sale securities) is based on quoted market prices at the end of the reporting period. The quoted market price used for financial assets held by the Group is the current bid price.

Level 2: The fair value of financial instruments that are not traded in an active market is determined using valuation techniques which maximize the use of observable market data and rely as little as possible on entity-specific estimates. If all significant inputs required to fair value an instrument are observable, the instrument is included in level 2.

Level 3: If one or more of the significant inputs is not based on observable market data, the instrument is included in level 3.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

3. FINANCIAL RISK MANAGEMENT (continued)

3.3. Fair value estimation (continued)

(i) Fair value hierarchy (continued)

The following table presents the Group's liabilities that are measured at fair value at December 31, 2021:

	Level 1 RMB'000	Level 2 RMB'000	Level 3 RMB'000	Total RMB'000
Liabilities				
Financial instruments issued to investors	-	-	-	-

The following table presents the Group's liabilities that are measured at fair value at December 31, 2020:

	Level 1 RMB'000	Level 2 RMB'000	Level 3 RMB'000	Total RMB'000
Liabilities				
Financial instruments issued to investors	-	-	2,745,584	2,745,584

There were no transfers between levels 1, 2 and 3 for recurring fair value measurements for the year ended December 31, 2021.

Specific valuation techniques used to value financial instruments include Binomial option-pricing model or discounted cash flow analysis.

(ii) Valuation techniques used to determine fair values

Specific valuation techniques used to value financial instruments include Binomial option-pricing model or discounted cash flow analysis.

There were no changes in valuation techniques for the year ended December 31, 2021.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

3. FINANCIAL RISK MANAGEMENT (continued)

3.3. Fair value estimation (continued)

(iii) Valuation processes

The finance department of the Group has a team that performs the valuation of financial instruments required for financial reporting purposes, including level 3 fair values. On an annual basis, the team adopts various valuation techniques to determine the fair value of the Group's level 3 instruments. This team reports directly to the chief finance officer and the board of directors.

The changes in level 3 financial instruments issued to investors for the year ended December 31, 2021 and 2020 and the quantitative information about the significant unobservable inputs used in level 3 fair value measurements used are presented in Notes 30.

4. CRITICAL ESTIMATES, JUDGEMENTS

The preparation of financial statements requires the use of accounting estimates which, by definition, will seldom equal the actual results. Management also needs to exercise judgement in applying the group's accounting policies.

Estimates and assumptions are continually evaluated. They are based on historical experience and other factors, including expectations of future events that may have a financial impact on the entity and that are believed to be reasonable under the circumstances.

4.1. Critical accounting estimates

(i) Impairment of non-current asset

The Group assesses impairment based on its subjective judgement and determines the separate cash flows of a specific group of assets, useful lives of assets and the future possible income and expenses arising from the assets depending on how assets are utilized and industrial characteristics. Any changes of economic circumstances or estimates due to the change of Group strategy might cause material impairment on assets in the future.

(ii) Recognition of deferred tax asset

The Group recognizes deferred tax assets based on estimates that is probable to generate sufficient taxable profits in the foreseeable future against which the deductible losses will be utilized. The recognition of deferred tax assets mainly involved management's judgements and estimations about the timing and the amount of taxable profits of the companies who had tax losses. During the year ended December 31, 2021 and 2020, deferred tax assets have not been recognized in respect of these accumulated tax losses and other deductible temporary differences based on the fact that there were several drug candidates of the Group and most of them were in earlier research and development stage and the future taxable profits would be uncertain.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

4. CRITICAL ESTIMATES, JUDGEMENTS (continued)

4.1. Critical accounting estimates (continued)

(iii) Accruals of research and development expenses

Research and development expenses include costs related to clinical trials paid to hospitals and third-party contract research organizations (CROs). The estimate of accrual of research and development expenses related to clinical trials is complex because billing terms under relevant contracts often do not coincide with the timing of when the work is performed, which in turn requires estimates of outstanding obligations as of period end. These estimates are based on a number of factors, including management's knowledge of the research and development ("R&D") programs and activities associated with timelines, invoicing to date, and the provisions in the contracts.

(iv) Estimation of fair value of intellectual property rights

During the year ended December 31, 2021, CARsgen Therapeutics (Shanghai) and CARsgen Life Sciences transferred certain of their intellectual property rights to a newly set up subsidiary of the Company, CAFA THERAPEUTICS LIMITED, a corporation organized under the law of the Republic of Ireland. The Group engaged an independent valuer to assess the fair value of these intellectual property rights and determined the transfer price based on the valuation result. Valuation of the intellectual property rights involves significant estimates and are based on a number of factors, such as selection of valuation method, the costs involved to develop the intellectual property rights, reasonable profit margins, etc. If the fair value of these intellectual property rights differs significantly from the valuation result, the Group may need accrue and pay income tax in the People's Republic of China.

4.2. Critical accounting judgements

(i) Capitalization of research and development expenses

Development costs incurred on the Group's drug product pipelines are capitalized only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, the Group's intention to complete and the Group's ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the pipeline and the ability to measure reliably the expenditure during the development. Development costs which do not meet these criteria are expensed when incurred. Determining the amounts to be capitalized requires management to make judgement regarding the expected future cash generation of the assets, discount rates to be applied and the expected period of benefits. During the year ended December 31, 2021 and 2020, all expenses incurred for research and development activities were regarded as research expenses and therefore were expensed when incurred.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

4. CRITICAL ESTIMATES, JUDGEMENTS (continued)

4.2. Critical accounting judgements (continued)

(ii) Contractual arrangement

The Group conducts its business through CARsgen Therapeutics Group in the PRC. Due to the regulatory restrictions on the foreign ownership of the Listing Business in the PRC, the Group does not have any legal equity interest in CARsgen Therapeutics Group. The Directors assessed whether or not the Group has control over CARsgen Therapeutics Group by assessing whether it has the rights to variable returns from its involvement with CARsgen Therapeutics Group and has the ability to affect those returns through its power over CARsgen Therapeutics Group. After assessment, the Directors concluded that the Group has control over CARsgen Therapeutics Group as a result of the Contractual Arrangements and accordingly the financial position and the operating results of CARsgen Therapeutics Group are included in the Group's consolidated financial statements throughout the year ended December 31, 2021 and 2020. Nevertheless, the Contractual Arrangements may not be as effective as direct legal ownership in providing the Group with direct control over CARsgen Therapeutics Group and uncertainties presented by the PRC legal system could impede the Groups beneficiary rights of the results, assets and liabilities of CARsgen Therapeutics Group. The Directors, based on the advice of its legal counsel, consider that the Contractual Arrangements with CARsgen Therapeutics Group and its equity holders are in compliance with the relevant PRC laws and regulations and are legally enforceable.

5. SEGMENT INFORMATION

The Group's business activities are regularly reviewed and evaluated by the chief operating decision-makers. The chief operating decision-makers, who is responsible for allocating resources and assessing performance of the operating segment, has been identified as the executive directors of the Group.

As a result of this evaluation, the executive directors of the Group consider that the Group's operations are operated and managed as a single operating segment. Since this is the only reportable operating segment of the Group, no further operating segment analysis thereof is presented.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

6. REVENUE

	Year ended December 31,	
	2021 RMB'000	2020 RMB'000
Revenue from customers recognized at a point in time		
License fee	25,813	–

CAFA THERAPEUTICS LIMITED, a subsidiary of CARsgen Therapeutics (Shanghai), has entered into a license agreement with HK inno.N Corporation, a pharmaceutical company, during the year ended December 31, 2021 to develop and commercialize two Chimeric Antigen Receptor T cell (CAR-T cell) product candidates, CT032 and CT053, targeting CD19 and BCMA respectively, for the potential treatment of various cancers in the Republic of Korea. Under the terms of the agreement, CARsgen will receive an upfront of USD4 million and additional milestone payments totalling up to USD50 million as well as royalties on net sales in the Republic of Korea. As of December 31, 2021, the transfer of the related documentation, technology and other efforts have been completed and hence revenue was recognized amounted to RMB25,813,000 (equivalent to USD4,000,000) for the year ended December 31, 2021.

There was no material assets and liabilities related to contracts with customers which shall be recognized as at December 31, 2021 and 2020.

Contract liabilities are recognized when payments are received before the transfer of goods. As at December 31, 2021 and 2020, there are no material unsatisfied performance obligations resulting from contracts.

During the year ended December 31, 2021 and 2020, there were no significant incremental costs to obtain or fulfil a contract, and accordingly no asset was recognized.

Majority of the cost related to the licence fee was incurred and recorded in research and development expenses in prior years, hence no cost of sales was recognized during the year ended December 31, 2021.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

7. OTHER INCOME

	Year ended December 31,	
	2021 RMB'000	2020 RMB'000
Government grants (i)	14,513	9,977
Interest income on term deposits with original maturity between three and twelve months	6,043	–
Others	1,237	–
Total	21,793	9,977

- (i) The government grants mainly represent subsidies received from the government in relation to the support on certain research and development projects. There are no unfulfilled conditions or other contingencies attached to these grants.

8. OTHER GAINS – NET

	Year ended December 31,	
	2021 RMB'000	2020 RMB'000
Net foreign exchange gains – net	7,451	21,623
Others	(1,410)	–
Total	6,041	21,623

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

9. EXPENSE BY NATURE

	Year ended December 31,	
	2021 RMB'000	2020 RMB'000
Employee benefit expenses (Note 10)	235,435	97,144
Testing and clinical expenses	204,309	124,269
Research and development consumables	53,456	30,240
Depreciation of property, plant and equipment (Note 15)	29,647	26,792
Listing expenses through statement of profit and loss	26,580	4,323
Professional service expenses	23,500	34,021
Depreciation of right-of-use assets (Note 16)	16,799	7,459
Utilities	11,183	9,511
Office expenses	10,789	7,455
Amortization of intangible assets (Note 17)	6,000	5,858
Auditors' remuneration	3,793	1,100
– Audit service	3,585	600
– Non-audit service	208	500
Travelling and transportation expenses	3,781	2,073
Short term lease and low value lease expenses	791	719
Other expenses	1,489	7,681
Total	627,552	358,645
Administrative expenses	125,831	76,893
Research and development expenses	501,721	281,752
Total	627,552	358,645

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For the year ended December 31, 2021

10. EMPLOYEE BENEFIT EXPENSES

	Year ended December 31,	
	2021 RMB'000	2020 RMB'000
Wages and salaries	178,613	83,703
Pension costs (a)	13,020	7,124
Share-based compensation (Note 24)	13,504	1,714
Other employee benefits	30,298	4,603
Total	235,435	97,144

(a) Pension costs

Employees of the Group's PRC subsidiaries are required to participate in a defined contribution scheme administrated and operated by government. The Group's PRC subsidiaries contribute funds which are calculated on certain percentages of the employee salary as agreed by the local government to the scheme to fund the retirement benefits of the employees. There were no forfeited contributions under this pension plan for the years ended December 31, 2021 and 2020.

Employees of CARsgen Therapeutics Corporation participate in a defined contribution scheme called 401(k) plan in which the Company matches 6% of the employees' contribution. There were no forfeited contributions under this pension plan for the years ended December 31, 2021 and 2020.

As one of the relief policies on COVID-19 in the PRC, the Group enjoyed certain exemption and deduction of contribution to the state-managed retirement benefit schemes, and contributions to medical insurance and other social securities for the period from February 1, 2020 to December 31, 2020 according to the relief policies issued by Shanghai Municipal Finance Bureau and Shanghai Municipal Human Resources And Social Security Bureau.

The Group has no other material obligation for the payment of retirement benefits associated with these schemes beyond the annual contributions described above.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

10. EMPLOYEE BENEFIT EXPENSES (continued)

(b) Five highest paid individuals

The five individuals whose emoluments were the highest in the Group include nil directors for the years ended December 31, 2021 (2020:2), whose emoluments are reflected in the analysis shown in Note 35. The emoluments payable to the remaining 5 individuals (2020: 3) during the year are as follows:

	Year ended December 31,	
	2021 RMB'000	2020 RMB'000
Basic salaries, housing allowances, share options, other allowances and benefits in kind	14,554	6,442
Contribution to pension scheme	269	322
Discretionary bonuses	2,326	1,616
Total	17,149	8,380

The emoluments fell within the following bands:

	Year ended December 31,	
	2021	2020
Emolument bands		
HKD2,000,001 to HKD2,500,000	–	1
HKD2,500,001 to HKD3,000,000	–	1
HKD3,000,001 to HKD3,500,000	1	1
HKD3,500,001 to HKD4,000,000	2	–
HKD4,000,001 to HKD4,500,000	–	–
HKD4,500,001 to HKD5,000,000	–	–
HKD5,000,001 to HKD5,500,000	2	–
Total	5	3

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

11. FINANCE COSTS – NET

	Year ended December 31,	
	2021 RMB'000	2020 RMB'000
Finance Income		
Interest income	3,568	763
Finance costs		
Interest expense on lease liabilities (Note 28)	(2,846)	(376)
Interest expense on loans with conversion option (Note)	–	(10,095)
Interest expense on bank borrowings (Note 27)	(8,023)	(3,009)
Total finance cost	(10,869)	(13,480)
Total finance costs-net	(7,301)	(12,717)

Note: For the year ended December 31, 2020, the Group borrowed RMB95 million from investors, RMB68 millions of which are from the then existing preference share investors of CARsgen Therapeutics (Shanghai) (Note 34) and RMB27 millions of which are from third parties. The loans bear interest at 24% per annum. The lenders were entitled with the right to convert their lending into preferred share of the Company within a certain period of time if the Company had completed Series C Financing but failed to repay the borrowing before a specified date. Fair value of such conversion right is not significant. The total fair value of the loans and the attached conversion rights approximates the nominal amount of the loans at transaction date. The Group repaid such borrowings in 2020.

12. SUBSIDIARIES

The Group's principal subsidiaries at December 31, 2021 are set out below. Unless otherwise stated, they have share capital consisting solely of ordinary shares that are held directly by the Group, and the proportion of ownership interests held equals the voting rights held by the Group. The country of incorporation or registration is also their principal place of business.

Name of entity	Place of incorporation and kind of legal entity	Principal activities and place of operation	Registered/ issued and paid-up capital	Ownership interest held by the Group		Ownership interest held by non-controlling interests	
				2021	2020	2021	2020
Directly hold							
CARsgen Pharma Holdings Limited	Hong Kong, February 21, 2018, Limited liability company	Holding company, Hong Kong	HKD10	100	100	–	–

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12. SUBSIDIARIES (continued)

Name of entity	Place of incorporation and kind of legal entity	Principal activities and place of operation	Registered/ issued and paid-up capital	Ownership interest held by the Group		Ownership interest held by non-controlling interests	
				2021	2020	2021	2020
Indirectly hold							
Cleanings Biotech Limited	British Virgin Islands, September 11, 2018, Limited liability company	Holding company, British Virgin Islands	USD1	100	100	-	-
Excelsory Biotech Limited	British Virgin Islands, September 11, 2018, Limited liability company	Holding company, British Virgin Islands	USD1	100	100	-	-
Panzenith Biotech Limited	British Virgin Islands, September 11, 2018, Limited liability company	Holding company, British Virgin Islands	USD1	100	100	-	-
CARsgen Therapeutics International Group Limited 科濟藥業國際集團有限公司	Hong Kong, April 1, 2016, Limited liability company	Holding company, Hong Kong	HKD1,000	100	100	-	-
CARsgen Therapeutics Corporation ("CARsgen USA")	United States of America, May 4, 2016, Limited liability company	Drug research and development and manufacturing and import and export handling, United States of America	USD1,000	100	100	-	-
CARsgen Life Sciences Co., Ltd. 愷興生命科技(上海)有限公司#	the PRC, March 22, 2018, Limited liability company (Registered as wholly foreign owned enterprises under PRC law)	Drug research and development and manufacturing and import and export handling, the PRC	USD40,000,000/ USD17,000,000	100	100	-	-

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

12. SUBSIDIARIES (continued)

Name of entity	Place of incorporation and kind of legal entity	Principal activities and place of operation	Registered/ issued and paid-up capital	Ownership interest held by the Group		Ownership interest held by non-controlling interests	
				2021 %	2020 %	2021 %	2020 %
Directly hold							
Shanghai Kaixing Diagnostic Limited 上海愷興診斷技術有限公司#	the PRC, November 23, 2020, Limited liability company	Drug research and development and manufacturing and import and export handling, the PRC	RMB10,000,000	100	100	-	-
CAFA THERAPEUTICS LIMITED 佻瑛藥業有限公司	Ireland, January 8, 2021, Limited liability company	Drug research and development and manufacturing and import and export handling, Ireland	Euro1,000	100	100	-	-
CRAGE Medical Co., Limited 克萊格醫學有限公司	Hong Kong, December 9, 2021, Limited liability company	Drug research and development and manufacturing and import and export handling, Hong Kong	HKD1,000	100	100	-	-
Controlled by the Company pursuant to the Contractual Agreements (Note 2.2)							
CARsgen Therapeutics Co., Ltd 科濟生物醫藥(上海)有限公司	the PRC, October 30, 2014, Limited liability company	Drug research and development and manufacturing and import and export handling, the PRC	RMB40,000,000	100	100	-	-
CARsgen Pharmaceuticals Co., Ltd 上海科濟製藥有限公司 ("CARsgen Pharmaceuticals")	the PRC, November 15, 2017, Limited liability company	Drug research and development and manufacturing and import and export handling, the PRC	RMB50,000,000/ RMB35,082,900	100	100	-	-

Registered as wholly foreign owned enterprises under PRC law

All the subsidiaries are limited liabilities companies.

Save for disclosed in this report, none of the subsidiaries had issued any debt securities at the end of the year.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

13. INCOME TAX EXPENSE

	Year ended December 31,	
	2021 RMB'000	2020 RMB'000
Current income tax		
– PRC Corporate Tax	–	–
– Ireland Capital Gains Tax	7,645	–
Deferred income tax	–	–
	7,645	–

Current income tax

The Group is subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of the Group are domiciled and operated.

(a) Cayman Islands income tax

The Company was incorporated in the Cayman Islands as an exempted company with limited liability under the Companies Law of the Cayman Islands and accordingly, is exempted from Cayman Islands income tax.

(b) Hong Kong income tax

No provision for Hong Kong profits tax has been provided for at the rate of 16.5% as the Company has no estimated assessable profit.

(c) PRC corporate income tax

Subsidiaries in Mainland China are subject to income tax at a rate of 25% pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the "CIT Law"), with the exception of CARsgen Therapeutics obtained its High and New Technology Enterprises status in year 2020 and hence is entitled to a preferential tax rate of 15% for a three-year period commencing 2020.

No provision for Mainland China corporate income tax was provided for, as there's no assessable profit.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

13. INCOME TAX EXPENSE (continued)

Current income tax (continued)

(d) The US corporate income tax

CARsgen USA, which was incorporated in Delaware, the United States on May 4, 2016, was subject to statutory U.S. Federal corporate income tax at a rate of 21% for the year ended December 31, 2021 and 2020. CARsgen USA was also subject to the state income tax for the years ended December 31, 2021 and 2020.

No provision for US corporate income tax was provided for as there's no assessable profit.

(e) British Virgin Islands income tax

Under the current laws of BVI, the subsidiary incorporated in BVI is not subject to tax on income or capital gains. In addition, upon payments of dividends by our BVI subsidiaries to us, no BVI withholding tax is imposed.

(f) Ireland Corporation income tax and Ireland Capital Gains Tax

Subsidiary in Ireland is subject to income tax at a rate of 12.5% on the estimated assessable profit and 33% on the capital gains. Provision for Ireland capital gain tax has been provided as the subsidiary has realized capital gain for the year ended December 31, 2021.

(g) The taxation of the Group's loss before taxation differs from the theoretical amount that would arise using the rates prevailing in the jurisdictions in which the Group operates as follows:

	Year ended December 31,	
	2021	2020
	RMB'000	RMB'000
Loss before income tax	(4,736,778)	(1,064,049)
Tax calculated at Mainland China tax rate of 25%	(1,184,195)	(266,012)
Effect of different tax rate	13,870	17,908
Expenses not deductible for taxation purposes	1,049,921	183,890
Tax loss not recognized as deferred tax assets	204,987	87,716
Super deduction for research and development expenses	(76,938)	(23,502)
	7,645	—

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

13. INCOME TAX EXPENSE (continued)

Current income tax (continued)

(h) Deferred tax assets not recognized:

The Group has not recognized any deferred tax assets in respect of the following items:

	Year ended December 31,	
	2021 RMB'000	2020 RMB'000
Deductible losses	1,862,740	1,002,977

(i) Deductible losses that are not recognized as deferred tax assets will be expired are analyzed as follows:

	Year ended December 31,	
	2021 RMB'000	2020 RMB'000
2022	–	–
2023	–	–
2024	75,757	75,757
2025	134,188	134,188
2026	793,032	793,032
Later than 2027	859,763	–
Unrecognized tax losses carried forward	1,862,740	1,002,977

The tax losses of the Company's Mainland China subsidiaries with the exception of those of CARsgen Therapeutics (Shanghai) will expire within five years. CARsgen Therapeutics (Shanghai), as a High and New Technology Enterprise can carry forward losses for 10 years. The tax losses of the Company's other subsidiaries can be carried forward indefinitely. No deferred tax asset has been recognized in respect of the tax losses due to the unpredictability of future profit streams.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

14. LOSS PER SHARE

(a) Basic loss per share

Basic loss per share is calculated by dividing the loss of the Group attributable to the equity holders of the Company by weighted average number of ordinary shares outstanding during the years.

	Year ended December 31,	
	2021	2020
Loss attributable to the ordinary equity holders of the company (RMB'000)	(4,744,423)	(1,064,049)
Weighted average number of ordinary shares in issue (in thousand)	386,835	198,140
Basic loss per share (RMB)	(12.26)	(5.37)

(b) Diluted loss per share

Diluted loss per share is calculated by adjusting the weighted average number of ordinary shares outstanding to assume conversion of all dilutive potential ordinary shares. For the years ended December 31, 2021 and 2020, the Company had three categories of potential ordinary shares including: loans with conversion option (Note 11), financial instruments issued to investors (Note 30) and share-based payments (Note 24). As the Group incurred losses for the years ended December 31, 2021 and 2020, the potential ordinary shares were not included in the calculation of diluted loss per share as their inclusion would be anti-dilutive. Accordingly, diluted loss per share for the years ended December 31, 2021 and 2020 are the same as basic loss per share of the respective periods.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

15. PROPERTY, PLANT AND EQUIPMENT

	Building RMB'000	Equipment RMB'000	Electronic equipment RMB'000	Furniture RMB'000	Vehicle RMB'000	Fixture RMB'000	Leasehold Improvements RMB'000	Construction in progress RMB'000	Total RMB'000
As at January 1, 2020									
Cost	36,823	89,405	3,772	1,894	741	37,217	3,017	1,841	174,710
Accumulated depreciation	-	(16,938)	(1,402)	(916)	(527)	-	(1,283)	-	(21,066)
Net book amount	36,823	72,467	2,370	978	214	37,217	1,734	1,841	153,644
For the year ended December 31, 2020									
Opening net book amount	36,823	72,467	2,370	978	214	37,217	1,734	1,841	153,644
Additions	-	2,048	575	101	-	87	-	-	2,811
Completion of construction in progress	-	1,841	-	-	-	-	-	(1,841)	-
Disposals	-	(33)	-	-	-	-	-	-	(33)
Depreciation charges	(1,841)	(15,075)	(856)	(317)	(91)	(7,472)	(1,140)	-	(26,792)
Closing net book amount	34,982	61,248	2,089	762	123	29,832	594	-	129,630
As at December 31, 2020									
Cost	36,823	93,106	4,347	1,995	741	37,304	3,017	-	177,333
Accumulated depreciation	(1,841)	(31,858)	(2,258)	(1,233)	(618)	(7,472)	(2,423)	-	(47,703)
Net book amount	34,982	61,248	2,089	762	123	29,832	594	-	129,630

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

15. PROPERTY, PLANT AND EQUIPMENT (continued)

	Building RMB'000	Equipment RMB'000	Electronic equipment RMB'000	Furniture RMB'000	Vehicle RMB'000	Fixture RMB'000	Leasehold Improvements RMB'000	Construction in progress (Note) RMB'000	Total RMB'000
As at 1 January 2021									
Cost	36,823	93,106	4,347	1,995	741	37,304	3,017	-	177,333
Accumulated depreciation	(1,841)	(31,858)	(2,258)	(1,233)	(618)	(7,472)	(2,423)	-	(47,703)
Net book amount	34,982	61,248	2,089	762	123	29,832	594	-	129,630
For the year ended December 31, 2021									
Opening net book amount	34,982	61,248	2,089	762	123	29,832	594	-	129,630
Additions	-	31,039	2,984	760	-	-	2,701	163,525	201,009
Completion of construction in progress	-	-	-	-	967	4,354	6,069	(11,390)	-
Disposals	-	(42)	-	(52)	-	-	-	-	(94)
Depreciation charges	(1,876)	(16,398)	(1,592)	(404)	(90)	(7,834)	(1,453)	-	(29,647)
Closing net book amount	33,106	75,847	3,481	1,066	1,000	26,352	7,911	152,135	300,898
As at December 31, 2021									
Cost	36,823	123,745	7,331	2,251	1,708	41,658	11,787	152,135	377,438
Accumulated depreciation	(3,717)	(47,898)	(3,850)	(1,185)	(708)	(15,306)	(3,876)	-	(76,540)
Net book amount	33,106	75,847	3,481	1,066	1,000	26,352	7,911	152,135	300,898

Note As at December 31, 2021, the construction in progress amounted at RMB152 million mainly represented the leasehold improvements of the factory in US amounted at approximately RMB137 million, which is expected to be completed in 2022.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

15. PROPERTY, PLANT AND EQUIPMENT (continued)

As at December 31, 2021 and 2020, the Group's building with carrying values of RMB33,106,000 and RMB34,982,000 respectively were pledged for certain of the Group's borrowings (Note 27).

In 2019, the Group acquired building and land use right (Note 16) with total cost of RMB43,921,000 from a third-party seller. According to the agreement entered into by the Group and the local authorities, the third party seller or its designated entity has the right to repurchase the building and the land use right from the Group if the Company's subsidiary holding the building and the land use right failed to meet the minimum RMB8 million annual tax payment requirement from the third year of commencement of production. Total carrying amount of such building and land use right was RMB39,892,000 and RMB41,924,000 respectively as at December 31, 2021 and 2020.

Depreciation of the Group charged to consolidated statements of comprehensive loss is analyzed as follows:

	Year ended December 31,	
	2021 RMB'000	2020 RMB'000
Administrative expenses	1,492	2,021
Research and development expenses	28,155	24,771
Total	29,647	26,792

Notes to the Consolidated Financial Statements

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16. RIGHT-OF-USE ASSETS

The Group leases land, offices and dormitory for its own use. Information about leases for which the Group is a lessee is presented below:

	Land use right <i>RMB'000</i>	Offices and dormitory <i>RMB'000</i>	Total <i>RMB'000</i>
As at January 1, 2020			
Cost	7,098	17,697	24,795
Accumulated depreciation	–	(6,772)	(6,772)
Net book amount	7,098	10,925	18,023
For the year ended December 31, 2020			
Opening net book amount	7,098	10,925	18,023
Additions	–	16,575	16,575
Depreciation charge	(156)	(7,303)	(7,459)
Closing net book amount	6,942	20,197	27,139
As at December 31, 2020			
Cost	7,098	34,272	41,370
Accumulated depreciation	(156)	(14,075)	(14,231)
Net book amount	6,942	20,197	27,139
For the year ended December 31, 2021			
Opening net book amount	6,942	20,197	27,139
Additions	–	107,512	107,512
Leasing incentive	–	(32,660)	(32,660)
Depreciation charge	(156)	(16,643)	(16,799)
Foreign exchange difference	–	99	99
Closing net book amount	6,786	78,505	85,291
As at December 31, 2021			
Cost	7,098	109,223	116,321
Accumulated depreciation	(312)	(30,718)	(31,030)
Net book amount	6,786	78,505	85,291

As at December 31, 2021 and December 31, 2020, the Group's land use right with carrying values of RMB6,786,000 and RMB6,942,000 respectively was pledged as collateral for the Group's borrowings (Note 27).

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

16. RIGHT-OF-USE ASSETS (continued)

(i) Amounts recognized in the consolidated statement of comprehensive loss

The consolidated statements of comprehensive loss contain the following amounts relating to leases:

	Year ended 31 December,	
	2021 RMB'000	2020 RMB'000
Depreciation charge of right-to-use assets		
– Land use right	156	156
– Offices and staff housing	16,643	7,303
	16,799	7,459
Interest expenses (Note 11)	2,846	376
Expenses relating to short-term leases (included in administrative expenses and research and development expenses)	791	719
Expenses relating to variable lease payments not included in lease liabilities	–	–

The total cash outflow for leases in year 2021 and 2020 were RMB19,716,000 and RMB8,589,000 respectively.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

17. INTANGIBLE ASSETS

	Software RMB'000	Patents RMB'000	Total RMB'000
As at January 1, 2020			
Cost	1,137	54,800	55,937
Accumulated amortization	(166)	(27,400)	(27,566)
Net book amount	971	27,400	28,371
For the year ended December 31, 2020			
Opening net book amount	971	27,400	28,371
Additions	1,008	–	1,008
Amortization charges	(378)	(5,480)	(5,858)
Closing net book amount	1,601	21,920	23,521
As at December 31, 2020			
Cost	2,145	54,800	56,945
Accumulated amortization	(544)	(32,880)	(33,424)
Net book amount	1,601	21,920	23,521
For the year ended December 31, 2021			
Opening net book amount	1,601	21,920	23,521
Additions	2,612	–	2,612
Amortization charges	(737)	(5,263)	(6,000)
Closing net book amount	3,476	16,657	20,133
As at December 31, 2021			
Cost	4,757	54,800	59,557
Accumulated amortization	(1,281)	(38,143)	(39,424)
Net book amount	3,476	16,657	20,133

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

17. INTANGIBLE ASSETS (continued)

Amortization of intangible assets has been charged to the consolidated statements of comprehensive loss as follows:

	Year ended December 31,	
	2021 RMB'000	2020 RMB'000
Administrative expenses	679	364
Research and development expenses	5,321	5,494
Total	6,000	5,858

18. OTHER NON-CURRENT ASSETS AND PREPAYMENT

	As at December 31, 2021 RMB'000	As at December 31, 2020 RMB'000
Value-added tax recoverable (<i>Note</i>)	20,402	9,338
Prepayments for purchase of property, plant and equipment	5,363	8,428
Rental deposits – non-current	2,695	–
Total	28,460	17,766

Note: Value added tax recoverable are mainly input VAT on acquisition of property, plant and equipment and the research and development expenses. According to Announcement of the General Administration of Taxation and Customs of the Ministry of Finance on Policies for Deepening the Reform of Value-Added Tax (Announcement of the General Administration of Taxation and Customs of the Ministry of Finance, (2019) No.39), entities with value added tax recoverable balance can, starting from 1 April 2019, apply for 60% refund on a semi-annual basis. Value added tax recoverable which are expected to be recovered within 12 months were recorded as other current assets and prepayments, and those which are expected to be recovered after 12 months were recorded as other non-current assets.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

19. DEPOSITS AND OTHER RECEIVABLES

	As at December 31, 2021 RMB'000	As at December 31, 2020 RMB'000
Lease incentive receivables	32,660	–
Deposits – current	5,298	1,813
Others	3,927	605
Total	41,885	2,418

None of the above assets is past due. The financial assets included in the above balances related to deposits and others for which there was no history of default and the expected credit losses are considered minimal.

The maximum exposure to credit risk at the reporting date is the carrying value of receivables mentioned above.

The carrying amounts of the Group's other receivables approximate their fair values.

20. OTHER CURRENT ASSETS AND PREPAYMENT

	As at December 31, 2021 RMB'000	As at December 31, 2020 RMB'000
Value-added tax recoverable (Note 18)	12,460	5,305
Prepayments to suppliers	9,570	4,124
Prepayments for listing expenses	–	979
Total	22,030	10,408

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

21. CASH AND CASH EQUIVALENTS AND TERM DEPOSITS WITH ORIGINAL MATURITY BETWEEN THREE AND TWELVE MONTHS

	As at December 31, 2021 RMB'000	As at December 31, 2020 RMB'000
Cash at banks		
– RMB	33,773	121,393
– USD	657,511	921,576
Total	691,284	1,042,969
Term deposits with original maturity between three and twelve months – USD	2,315,654	–

The carrying amount of cash and cash equivalents approximates their fair value.

22. FINANCIAL INSTRUMENTS BY CATEGORY

	As at December 31, 2021 RMB'000	As at December 31, 2020 RMB'000
Financial assets at amortized costs:		
– Other receivables	41,885	2,418
– Other non-current assets – rental deposit	2,695	–
– Cash and cash equivalents	691,284	1,042,969
– Term deposits with original maturity between three and twelve months	2,315,654	–
Total	3,051,518	1,045,387

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

22. FINANCIAL INSTRUMENTS BY CATEGORY (continued)

	As at December 31, 2021 RMB'000	As at December 31, 2020 RMB'000
Liabilities		
Financial liabilities at fair value:		
– Financial instruments issued to investors	–	2,745,584
Financial liabilities at amortized costs:		
– Borrowings-current	219,331	68,371
– Borrowings-non-current	7,375	11,981
– Accruals and other payables (excluding staff salaries and welfare payables, and payroll and other tax)	89,568	44,749
– Lease liabilities-current	14,027	5,890
– Lease liabilities-non-current	97,312	14,016
Total	427,613	2,890,591

23. SHARE CAPITAL

Authorized:

	Number of shares <i>In thousands</i>	Nominal value of shares <i>USD</i>	RMB equivalent value <i>RMB'000</i>
As at January 1, 2020	50,000,000	50,000	349
Share subdivision (<i>Note (a)</i>)	150,000,000	–	–
As at December 31, 2020	200,000,000	50,000	349
As at January 1, 2021 and December 31, 2021	200,000,000	50,000	349

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23. SHARE CAPITAL (continued)

Issued and fully paid:

	Number of ordinary shares at USD0.0000025 par value <i>In thousands</i>	RMB equivalent value <i>RMB'000</i>
As at January 1, 2021	198,140	—*
Issue of shares held in trust (<i>Note(b)</i>)	19,623	—*
Conversion of Preferred Shares to Ordinary Shares upon Global Offering (<i>Note(c)</i>)	254,837	1
Issue of shares by Global Offering (<i>Note(d)</i>)	94,747	—*
Share option scheme (<i>Note(e)</i>)	190	—*
As at December 31, 2021	567,537	1

* The amounts are less than RMB1,000.

Note(a): On September 11, 2020, the Company issued 2,476,745 ordinary shares to YIJIE Biotech BVI at par value of USD0.000001.

On September 11, 2020, the Company underwent a subdivision of shares whereby the Company's authorized share capital of USD50,000 was amended by re-designation from 50,000,000,000 ordinary shares at USD0.000001 par value each into 200,000,000,000 ordinary shares at USD0.0000025 par value each. Accordingly, the issued 49,534,883 shares were divided into 198,139,532 shares.

Note(b): On May 11, 2021, the Company allotted and issued 12,497,947 Shares to Carfa Unity Limited and 7,125,575 Shares to Carfe Unity Limited, both of which were wholly-owned by the 2019 Equity Incentive Plan Trustee. Such Shares are to be held in trust by the 2019 Equity Incentive Plan Trustee to facilitate the transfer of Shares to the grantees upon vesting of the relevant Share Options and Share Awards. The Shares of the Company held in Carfa Unity Limited and Carfe Unity Limited were accounted as "Reserve-Treasury shares held in trust".

Note(c): All 254,836,638 preferred shares were automatically converted into ordinary shares at HK\$32.8 per share upon the completion of Global Offering. The difference between HK\$32.8 and the par value of each share were capitalized as "Reserve-Share premium". In addition, the cumulative fair value changes due to credit risk related to the preferred shares were transferred from other reserve to accumulated losses on the same date.

Note(d): In connection with the Company's listing, 94,747,000 ordinary shares of the Company at US\$0.0000025 par value each were issued at HK\$32.8 per share for a total cash consideration of HK\$3,107,701,000 (equivalent to RMB2,576,082,000) on June 18, 2021. Netting off underwriting commissions and other issuance costs through equity with the amount of RMB88,349,000, the Group received RMB2,487,733,000. Excluding the par value, the amount was recorded as "Reserve-Share premium".

Note(e): During the year ended December 31, 2021, the Company issued 190,390 shares at the cost of HKD1,278,699 (equivalent to RMB1,118,000 approximately) as certain employees of the Group exercised their options under 2019 Stock Option Scheme ("2019 Plan").

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

24. SHARE-BASED PAYMENTS

(a) Employee Stock option

The Group adopted a number of employee stock option plans to provide long-term incentives for its employees and directors of the Group to deliver long-term shareholder returns. Under the plans, participants are granted options which only vest if certain conditions are met. Participation in the plan is at the Board's discretion and no individual has a contractual right to participate in the plan or to receive any guaranteed benefits.

During the Year ended December 31, 2021 and 2020, the Group adopted the following stock option plans to certain employees and directors of the Group, as rewards for their services, full time devotion and professional expertise to certain of the Group's subsidiaries.

Stock Option Scheme executed by the Company	Number of options granted	Exercise Price per option (HKD)
2019 Stock Option Scheme ("2019 Plan")	245,018	0 – 27.92
2019 Additional Stock Option Scheme ("2019 Additional Plan").	1,441,701	0 – 27.92
2020 Stock Option Scheme ("2020 Plan").	215,021	0 – 43.28
2021 Stock Option Scheme ("2021 Plan").	730,578	31.00

Under the stock option scheme, those grant options can be vested in several tranches with the following vesting schedule: 25% of the stock option can be vested on the first anniversary of the vesting commencement date and the remaining 75% are to be vested monthly thereafter in 36 equal monthly instalments.

The following table summarizes the Group's stock option activities during the year ended December 31, 2021 and 2020.

	Year ended 31 December			
	2021		2020	
	Average exercise price per share option HKD	Number of stock options	Average exercise price per share option HKD	Number of stock options
Outstanding as at beginning of the year	2.71	20,412,187	12.02	5,159,597
Execution of employee stock option	5.61	(254,187)	–	–
Granted during the year	31.00	730,578	37.85	215,021
Forfeited during the year	8.25	(237,240)	26.76	(271,571)
Subdivision during the year (Note 23)	–	–	–	15,309,140
Outstanding as at year end	3.62	20,651,338	2.71	20,412,187

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

24. SHARE-BASED PAYMENTS (continued)

(b) Employee restricted share

The Group adopted a number of employee restricted share plans to provide long-term incentives for its employees and directors of the Group to deliver long-term shareholder returns. Under the plans, participants are granted restricted share which only vest if certain conditions are met. Participation in the plan is at the Board's discretion and no individual has a contractual right to participate in the plan or to receive any guaranteed benefits.

During the year ended December 31, 2021, the Group adopted the following restricted share plans to certain employees and directors of the Group, as rewards for their services, full time devotion and professional expertise to certain of the Group's subsidiaries.

Stock Option Scheme	Number of options granted	Exercise Price per option (HKD)
2021 Employee RSU Scheme ("2021 RSU Plan")	1,616,867	–

(c) Fair value of stock option and restricted share granted

The assessed fair value at grant date of options granted during the years ended December 31, 2021 and 2020 was as follows:

Stock Option Scheme executed	Fair value as at grant date (RMB'000)
2019 Plan	720
2019 Additional Plan	3,450
2020 Plan	538
2021 Plan	8,895
2021 RSU Plan	41,689

The fair value at grant date is independently determined using an adjusted Binomial option-pricing model that takes into account the exercise price, fair value of ordinary shares at the grant date, the term of the option, the expected price volatility, the expected dividend yield, the risk free interest rate.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

24. SHARE-BASED PAYMENTS (continued)

(c) Fair value of stock option and restricted share granted (continued)

The model inputs for options granted during the year ended December 31, 2021 and 2020 are:

	2021 Plan	2020 Plan
Exercise price	HKD31.00	HKD0 – 10.78
Risk-free interest rate	0.87%	0.70%
Volatility	48.09%	46.28%
Expected dividend yield	Nil	Nil

The directors estimated the risk-free interest rate based on the yield of curve of US Treasury strips with a maturity life close to the life of stock option. Volatility was estimated at grant date based on average of historical volatilities of the comparable companies with length commensurable to the time to maturity of the stock option. Dividend yield is based on the directors' estimation at the grant date.

(d) Expenses arising from share-based compensation transactions

Expenses for the share-based compensation have been charged to the consolidated statements of comprehensive loss as follows:

	Year ended December 31,	
	2021 RMB'000	2020 RMB'000
Administrative expenses	1,890	411
Research and development expenses	11,614	1,303
Total	13,504	1,714

25. DIVIDEND

No dividend was declared or paid by the Company or the companies now comprising the Group during the year ended December 31, 2021 and 2020.

Notes to the Consolidated Financial Statements

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26. RESERVE

	Capital reserve <i>RMB'000</i> <i>Note(a)</i>	Share premium <i>RMB'000</i>	Currency translation reserve <i>RMB'000</i>	Other reserve <i>RMB'000</i>	Share-based compensation <i>RMB'000</i> <i>Note(b)</i>	Accumulated loss <i>RMB'000</i>	Total <i>RMB'000</i>
Balance at January 1, 2020	54,800	-	(49,215)	8,427	12,138	(758,754)	(732,604)
Loss for the year	-	-	-	-	-	(1,064,049)	(1,064,049)
Exchange differences on translation	-	-	84,707	-	-	-	84,707
Fair value changes relating to financial instruments issued to investors due to the Company's own credit risk	-	-	-	34,104	-	-	34,104
Share-based compensation	-	-	-	-	1,714	-	1,714
Balance at December 31, 2020	54,800	-	35,492	42,531	13,852	(1,822,803)	(1,676,128)
Balance at January 1, 2021	54,800	-	35,492	42,531	13,852	(1,822,803)	(1,676,128)
Loss for the year	-	-	-	-	-	(4,744,423)	(4,744,423)
Exchange differences on translation	-	-	8,984	-	-	-	8,984
Fair value changes relating to financial instruments issued to investors due to the Company's own credit risk	-	-	-	(25,093)	-	-	(25,093)
Share-based compensation	-	-	-	-	13,504	-	13,504
Automatic conversion of Preferred Shares upon Global Offering <i>(Note 23)</i>	-	6,930,964	-	(17,438)	-	17,438	6,930,964
Shares issued upon global offering <i>(Note 23)</i>	-	2,576,082	-	-	-	-	2,576,082
Issue ordinary shares for exercise of share-based payment	-	1,118	-	-	-	-	1,118
Capitalised listing fee	-	(88,349)	-	-	-	-	(88,349)
Balance at December 31, 2021	54,800	9,419,815	44,476	-	27,356	(6,549,788)	2,996,659

Note(a): Capital reserve arose from the capital contribution of patents, which were recognized as intangible assets, from CARsgen Therapeutics (Shanghai)'s equity shareholder, YIJIE Biotech (Shanghai) Holding Limited (上海益傑生物技術有限公司) on the date of CARsgen Therapeutics (Shanghai)'s incorporation.

Note(b): Share-based compensation arose from share-based compensation granted to employees of the Group (Note 24).

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27. BORROWINGS

Group

	As at December 31, 2021 RMB'000	As at December 31, 2020 RMB'000
<i>Non-current</i>		
Secured bank borrowings	7,375	11,981
<i>Current</i>		
Unsecured borrowings	214,727	64,000
Secured bank borrowings	4,604	4,371
	219,331	68,371
Total	226,706	80,352

As at December 31, 2021 and 2020, the Group's bank borrowings of approximately RMB11,979,000 and RMB16,352,000 respectively are pledged by property, plant and equipment and right-of-use assets of the Group (Notes 15 and 16).

At December 31, 2021 and 2020, the Group's borrowings were repayable as follows:

	As at December 31, 2021 RMB'000	As at December 31, 2020 RMB'000
Within 1 year	219,331	68,371
Between 1 and 2 years	4,835	4,603
Between 2 and 3 years	2,540	4,838
Between 3 and 4 years	–	2,540
Total	226,706	80,352

The weighted average effective interest rates at each balance sheet date were as follows:

	As at December 31, 2021 RMB'000	As at December 31, 2020 RMB'000
Bank borrowings	4.88%	5.54%

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

27. BORROWINGS (continued)

Group (continued)

The fair values of the borrowings approximate their carrying amounts as the discounting impact is not significant.

As at December 31, 2021, the Group's unsecured borrowings are mature within six to twelve months with the interest rate ranging between 3.5000% – 5.5000% (2020: 3.5000% – 5.5000%)

As at December 31, 2021, the Group's secured borrowings is mature within three years with the interest rate of 5.2250% (2020: 5.2250%).

28. LEASE LIABILITIES

	As at December 31, 2021 RMB'000	As at December 31, 2020 RMB'000
Minimum lease payments due		
– Within 1 year	18,446	6,610
– Between 1 and 2 years	19,853	4,894
– Between 2 and 5 years	49,842	10,449
– Over 5 years	43,698	–
	131,839	21,953
Less: future finance charges	(20,500)	(2,047)
Present value of lease liabilities	111,339	19,906
Less: Current portion Lease liabilities	(14,027)	(5,890)
Non-current portion of lease liabilities	97,312	14,016
– Within 1 year	14,027	5,890
– Between 1 and 2 years	16,114	4,401
– Between 2 and 5 years	42,138	9,615
– Over 5 years	39,060	–
Present value of lease liabilities	111,339	19,906

The Group leases land use right and properties. Lease on land use right has been fully paid and lease on properties were measured at net present value of the lease payments to be paid during the lease terms.

Lease liabilities were discounted at incremental borrowings rates of the Group.

Notes to the Consolidated Financial Statements

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29. DEFERRED INCOME

	As at December 31, 2021 RMB'000	As at December 31, 2020 RMB'000
Non-current	15,116	13,167
Current	10,144	3,591
Total	25,260	16,758

Deferred income represented government grants received relating to property, plant and equipment to be recognized over the estimated useful lives of the related assets and government grant received relating to costs to be recognized over the period necessary to match the costs they are intended to compensate.

30. FINANCIAL INSTRUMENTS ISSUED TO INVESTORS

	As at December 31, 2021 RMB'000	As at December 31, 2020 RMB'000
Non-current		
Series A	–	348,435
Series B	–	512,095
Series Pre-C	–	648,207
Series C1	–	479,682
Series C2	–	757,165
Series C+ (Note)	–	–
Total	–	2,745,584

In 2020, the Company issued 31,111,111 shares of Series C1 Preferred Shares to Series C1 Investors at cash consideration of USD70 million (equivalent to RMB498 million approximately).

In 2020, the Company issued 46,400,000 shares of Series C2 Preferred Shares to Series C2 Investors at cash consideration of USD116 million (equivalent to RMB786 million approximately).

On January 25, 2021, the Company issued 2,984,444 Series C+ Preferred Shares to NVMB XIII Holdings Limited at a subscription price of US\$3.35 per share at a total consideration of USD10 million (equivalent to RMB65 million approximately).

All the preferred shares were automatically converted to ordinary shares upon the completion of Global Offering in accordance with the agreed terms.

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30. FINANCIAL INSTRUMENTS ISSUED TO INVESTORS (continued)

Movements of financial instruments issued to investors for the year ended December 31, 2021 and 2020 are set out below:

	Series A RMB'000	Series B RMB'000	Series Pre-C RMB'000	Series C1 RMB'000	Series C2 RMB'000	Series C+ RMB'000	Total RMB'000
At January 1, 2020	145,024	326,555	465,833	-	-	-	937,412
Issuance	-	-	-	497,724	785,841	-	1,283,565
Changes in fair value recognized in profit or loss	225,144	227,750	237,830	13,064	20,499	-	724,287
Changes in fair value recognized in other comprehensive loss	(487)	(9,969)	(14,178)	(3,644)	(5,826)	-	(34,104)
Currency translation difference – recognized in equity	(21,246)	(32,241)	(41,278)	(27,462)	(43,349)	-	(165,576)
At December 31, 2020	348,435	512,095	648,207	479,682	757,165	-	2,745,584
At January 1, 2021	348,435	512,095	648,207	479,682	757,165	-	2,745,584
Issuance	-	-	-	-	-	64,900	64,900
Changes in fair value recognized in profit or loss	1,008,863	1,075,154	1,168,611	372,703	513,230	17,011	4,155,572
Changes in fair value recognized in other comprehensive loss	296	6,993	11,731	2,383	3,819	(129)	25,093
Currency translation difference – recognized in equity	(10,795)	(13,492)	(15,955)	(8,891)	(10,414)	(638)	(60,185)
Conversion of Preferred Shares to Common shares upon Global Offering (Note 23)	(1,346,799)	(1,580,750)	(1,812,594)	(845,877)	(1,263,800)	(81,144)	(6,930,964)
At December 31, 2021	-	-	-	-	-	-	-

All the preferred shares were automatically converted to ordinary shares upon the completion of Global Offering. The difference between the fair value of the Preferred Shares as at December 31, 2020 and offer price of HK\$32.8 per share of the Global Offering is accounted for as fair value loss for the year ended December 31, 2021. The fair value loss of financial instruments is a non-cash item, and there will be no further gains or losses on fair value changes from these financial instruments after the automatic conversion from preferred shares to ordinary shares upon the closing of the Global Offering.

Notes to the Consolidated Financial Statements

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31. ACCRUALS AND OTHER PAYABLES

	As at December 31, 2021 RMB'000	As at December 31, 2020 RMB'000
Accrued expenses	45,520	33,903
Payables for acquisition of property, plant and equipment	37,969	2,244
Payables for research and development consumables	340	2,367
Staff salaries and welfare payables	45,837	20,825
Listing expenses payable	–	5,190
Other taxes payable	2,620	1,805
Interest payables	393	209
Others	5,346	836
Total	138,025	67,379

The carrying amounts of accruals and other payables of the Group are denominated in the following currencies:

	As at December 31, 2021 RMB'000	As at December 31, 2020 RMB'000
RMB	85,992	30,319
USD	52,033	37,060
Total	138,025	67,379

Notes to the Consolidated Financial Statements

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32. CASH FLOW INFORMATION

(a) Reconciliation of loss before income tax to net cash used in operation

	As at 31 December	
	2021 RMB'000	2020 RMB'000
Loss before income tax	(4,736,778)	(1,064,049)
Adjustments for		
– Depreciation and amortization (Note 15, 16 and 17)	52,446	40,109
– Share-based compensation expenses (Note 24)	13,504	1,714
– Finance costs – net (Note 11)	7,301	12,717
– Interest income on term deposits with original maturity between three and twelve months (Note 7)	(6,043)	–
– Net foreign exchange gain (Note 8)	(7,451)	(21,623)
– Losses on disposals of property, plant and equipment	83	–
– Fair value losses on financial instruments issued to investors (Note 30)	4,155,572	724,287
– Government grants relating to financing activities	(7,903)	(2,552)
– Others	–	33
	(529,269)	(309,364)
Changes in working capital:		
– (Increase)/decrease in other receivables	(6,543)	364
– Increase in other current assets and prepayment	(5,109)	(6,504)
– Increase in accruals and other payables	39,925	14,681
– (Decrease)/increase in deferred income on government grants (excluding those relating to acquisition of non-current assets)	(1,135)	2,889
– (Increase)/Decrease in other non-current assets and prepayments	(13,759)	2,021
Cash used in operations	(515,890)	(295,913)

Notes to the Consolidated Financial Statements

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32. CASH FLOW INFORMATION (continued)

(b) Reconciliation of liabilities from financing activities

	Financial instruments issued to investors <i>RMB'000</i>	Loans with conversion option <i>RMB'000</i>	Lease Liabilities <i>RMB'000</i>	Borrowings and interest payables <i>RMB'000</i>	Total <i>RMB'000</i>
At January 1, 2020	937,412	–	10,825	40,679	988,916
Cash flows	1,283,565	(10,095)	(7,870)	36,873	1,302,473
New lease agreement entered into	–	–	16,575	–	16,575
Interest expenses	–	10,095	376	3,009	13,480
Fair value losses	724,287	–	–	–	724,287
Fair value changes relating to financial instruments issued to investors due to the Company's own credit risk	(34,104)	–	–	–	(34,104)
Currency translation differences	(165,576)	–	–	–	(165,576)
At December 31, 2020	2,745,584	–	19,906	80,561	2,846,051

	Financial instruments issued to investors <i>RMB'000</i>	Loans with conversion option <i>RMB'000</i>	Lease Liabilities <i>RMB'000</i>	Borrowings and interest payables <i>RMB'000</i>	Total <i>RMB'000</i>
At January 1, 2021	2,745,584	–	19,906	80,561	2,846,051
Cash flows	64,900	–	(18,381)	138,515	185,034
New lease agreement entered into	–	–	106,968	–	106,968
Interest expenses	–	–	2,846	8,023	10,869
Fair value losses	4,155,572	–	–	–	4,155,572
Fair value changes relating to financial instruments issued to investors due to the Company's own credit risk	25,093	–	–	–	25,093
Currency translation differences	(60,185)	–	–	–	(60,185)
Automatic conversion of Preferred Shares upon Global Offering	(6,930,964)	–	–	–	(6,930,964)
At December 31, 2021	–	–	111,339	227,099	338,438

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33. COMMITMENTS

(a) Capital commitments

Capital expenditure contracted for by the Group at the balance sheet date but not yet incurred is as follows:

	As at December 31, 2021 RMB'000	As at December 31, 2020 RMB'000
Property, plant and equipment	80,999	8,471

(b) Lease commitments — where the Group is the lessee

At the balance sheet dates, lease commitments of the Group for leases not yet commenced for short-term lease and low-value lease are as follows:

	As at December 31, 2021 RMB'000	As at December 31, 2020 RMB'000
No later than 1 year	46	154

34. RELATED PARTY TRANSACTIONS

Parties are considered to be related in one party has the ability, directly or indirectly, to control the other part or exercise significant influence over the other party in making financial and operation decisions. Parties are also considered to be related if they are subject to common control. The following is a summary of the significant transactions carried out between the Group and its related parties in the ordinary course of business during the year ended December 31, 2021 and 2020 respectively.

(a) Transactions with related parties

During the year ended December 31, 2020, CARsgen Therapeutics Co., Ltd. entered into financial instrument agreements with two preference shareholders with the total amount of RMB68 million and repaid the amount in full in the same year to settle the financial instrument (Note 30).

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34. RELATED PARTY TRANSACTIONS (continued)

(b) Key management compensation

Compensations for key management other than those for directors as disclosed in Note 35 is set out below.

	Year ended December 31,	
	2021 RMB'000	2020 RMB'000
Basic salaries, share options, other allowances and benefits in kind	15,299	1,064
Discretionary bonus	2,599	676
Social security costs	620	202
Total	18,518	1,942

35. DIRECTORS' BENEFITS AND INTERESTS

(a) Directors' emoluments

Directors and chief executives' emoluments for the years ended December 31, 2021 and 2020 are set out as follows:

	Fees RMB'000	Salary RMB'000	Discretionary bonus RMB'000	Allowances and benefits in kind RMB'000	Pension costs RMB'000	Other benefits RMB'000	Total RMB'000
Year ended December 31, 2020							
<i>Chairman and executive director</i>							
Dr. Li (i)	-	574	460	-	4	61	1,099
<i>Executive director</i>							
Huamao Wang (ii)	-	676	462	-	4	44	1,186
<i>Non-executive director</i>							
Bingsen Guo (iii)	-	-	-	-	-	-	-
Yachao Zhao (iv)	-	-	-	-	-	-	-
Mr. Chihoon Hyun (v)	-	-	-	-	-	-	-
Ronggang Xie (vi)	-	-	-	-	-	-	-
Huaqing Guo (vii)	-	-	-	-	-	-	-
	-	1,250	922	-	8	105	2,285

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

35. DIRECTORS' BENEFITS AND INTERESTS (continued)

(a) Directors' emoluments (continued)

	Fees RMB'000	Salary RMB'000	Discretionary bonus RMB'000	Allowances and benefits in kind RMB'000	Pension costs RMB'000	Other benefits RMB'000	Total RMB'000
Year ended December 31, 2021							
<i>Chairman and executive director</i>							
Dr. Li (i)	-	920	503	-	57	82	1,562
<i>Executive director</i>							
Huamao Wang (ii)	-	1,448	500	-	57	148	2,153
<i>Non-executive director</i>							
Bingsen Guo (iii)	-	-	-	-	-	-	-
Yachao Zhao (iv)	-	-	-	-	-	-	-
Ronggang Xie (vi)	-	-	-	-	-	-	-
Huaqing Guo (vii)	-	-	-	-	-	-	-
<i>Independent non-executive director</i>							
Chunhai Fan (viii)	184	-	-	-	-	-	184
Guangmei Yan (ix)	184	-	-	-	-	-	184
Deyang Su (x)	184	-	-	-	-	-	184
	552	2,368	1,003	-	114	230	4,267

- (i) Mr. Dr. Li was appointed as director on February 9, 2018, appointed as chairman of the Board and redesignated as an executive Director on February 23, 2021.
- (ii) Mr. Huamao Wang was appointed as director on September 13, 2018 and redesignated as an executive Director on February 23, 2021.
- (iii) Mr. Bingsen Guo was appointed as director on September 13, 2018 and re-designated as a non-executive Director on February 23, 2021.
- (iv) Ms. Yachao Zhao was appointed as director on September 13, 2018 and re-designated as a non-executive Director on February 23, 2021.
- (v) Mr. Chihoon Hyun was appointed as director on September 13, 2018 and resigned as a director on February 18, 2021.
- (vi) Mr. Ronggang Xie was appointed as director on September 18, 2020 and re-designated as a non-executive Director on February 23, 2021.
- (vii) Mr. Huaqing Guo was appointed as director on September 18, 2020 and re-designated as a non-executive Director on February 23, 2021.
- (viii) Dr. Chunhai Fan was appointed as an independent non-executive director on June 18, 2021.
- (ix) Dr. Guangmei Yan was appointed as an independent non-executive director on June 18, 2021.
- (x) Mr. Deyang Su was appointed as an independent non-executive director on June 18, 2021.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

35. DIRECTORS' BENEFITS AND INTERESTS (continued)

(b) Directors' retirement benefits

None of the directors received or will receive any retirement benefits during the years ended December 31, 2021 and 2020.

(c) Directors' termination benefits

None of the directors received or will receive any termination benefits during the years ended December 31, 2021 and 2020.

(d) Consideration provided to third parties for making available directors' services

During the years ended December 31, 2021 and 2020, the Company did not pay consideration to any third parties for making available directors' services.

(e) Information about loans, quasi-loans and other dealings in favor of directors, bodies corporate controlled by or entities connected with directors

Save as disclosed in Note 35(b), there were no loans, quasi-loans and other dealings in favor of directors, controlled bodies corporate by and connected entities with such directors during the years ended December 31, 2021 and 2020.

(f) Directors' material interests in transactions, arrangements or contracts

No significant transactions, arrangements and contracts in relation to the Group's business to which the Company was a party and in which a director of the Company had a material interest, whether directly or indirectly, subsisted at the end of the years or at any time during the years ended December 31, 2021 and 2020.

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

36. FINANCIAL POSITION AND RESERVE MOVEMENT OF THE COMPANY

(a) Statement of Financial Position of the Company

	As at December 31,	
	2021 RMB'000	2020 RMB'000
ASSETS		
Non-current assets		
Investment in subsidiaries	604,515	605,009
Other receivables	1,500,005	686,843
	2,104,520	1,291,852
Current assets		
Cash and cash equivalents	430,642	918,987
Time deposits with original maturity over three months	2,154,987	–
	2,585,629	918,987
Total assets	4,690,149	2,210,839
EQUITY AND LIABILITIES		
Equity attributable to owners of the Company		
Share capital	1	–
Reserves	4,688,896	(539,935)
Total equity/(deficit)	4,688,897	(539,935)
Liabilities		
Non-current liabilities		
Financial instruments issued to investors	–	2,745,584
	–	2,745,584
Current liabilities		
Accruals and other payables	1,252	5,190
	1,252	5,190
Total liabilities	1,252	2,750,774
Total equity and liabilities	4,690,149	2,210,839

The above Company statement of financial position should be read in conjunction with the accompanying notes.

The statement of financial position of the Company was approved and authorised for issue by the board of directors on March 22, 2022.

LI Zonghai
Director

WANG Huamao
Director

Notes to the Consolidated Financial Statements

For the year ended December 31, 2021

36. FINANCIAL POSITION AND RESERVE MOVEMENT OF THE COMPANY (continued)

(b) Reserve movement of the Company

	Share premium <i>RMB'000</i>	Currency translation reserve <i>RMB'000</i>	Other reserve <i>RMB'000</i>	Share-based compensation <i>RMB'000</i>	accumulated loss <i>RMB'000</i>	T'otal <i>RMB'000</i>
Balance at January 1, 2020	262,672	(6,321)	8,427	12,138	(151,401)	125,515
Loss for the year	-	-	-	-	(730,292)	(730,292)
Exchange differences on translation	-	29,024	-	-	-	29,024
Fair value changes relating to financial instruments issued to investors due to the Company's own credit risk	-	-	34,104	-	-	34,104
Share-based compensation	-	-	-	1,714	-	1,714
Balance at December 31, 2020	262,672	22,703	42,531	13,852	(881,693)	(539,935)
Balance at January 1, 2021	262,672	22,703	42,531	13,852	(881,693)	(539,935)
Loss for the year	-	-	-	-	(4,165,874)	(4,165,874)
Exchange differences on translation	-	(11,328)	-	-	-	(11,328)
Fair value changes relating to financial instruments issued to investors due to the Company's own credit risk	-	-	(25,093)	-	-	(25,093)
Share-based compensation	-	-	-	13,504	-	13,504
Automatic conversion of Preferred Shares upon Global Offering (Note 23)	6,930,964	-	(17,438)	-	15,245	6,928,771
Shares issued upon global offering (Note 23)	2,576,082	-	-	-	-	2,576,082
Issue ordinary shares for exercise of share-based payment	1,118	-	-	-	-	1,118
Capitalised listing fee	(88,349)	-	-	-	-	(88,349)
Balance at December 31, 2021	9,682,487	11,375	-	27,356	(5,032,322)	4,688,896

37. CONTINGENCIES

The Group did not have any material contingent liabilities as at December 31, 2021 and December 31, 2020.

Financial Summary

	As at December 31		
	2021 RMB'000	2020 RMB'000	2019 RMB'000
Total current assets	3,070,853	1,055,795	115,000
Total non-current assets	434,782	198,056	210,811
Total assets	3,505,635	1,253,851	325,811
Total current liabilities	389,172	145,231	1,021,370
Total non-current liabilities	119,803	2,784,748	37,045
Total liabilities	508,975	2,929,979	1,058,415
Equity attributable to equity holders of the Company	2,996,660	(1,676,128)	(732,604)
Total equity/(deficit)	2,996,660	(1,676,128)	(732,604)
Total equity and liabilities	3,505,635	1,253,851	325,811

	For the year ended 31 December		
	2021 RMB'000	2020 RMB'000	2019 RMB'000
Revenue	25,813	–	–
Gross profit	25,813	–	–
Operating loss	(573,905)	(327,045)	(227,400)
Loss before income tax	(4,736,778)	(1,064,049)	(265,133)
Loss for the year	(4,744,423)	(1,064,049)	(265,133)
Loss attributable to equity holders of the Company	(4,744,423)	(1,064,049)	(265,133)

Definitions

“2019 Equity Incentive Plan”	the equity incentive plan of our Company as adopted by way of written resolutions of the Board on January 22, 2019, the principal terms of which are set out in the section headed “Statutory and General Information — D. 2019 Equity Incentive Plan” in the Prospectus
“affiliate”	any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
“Audit Committee”	the audit committee of the Company
“Board of Directors”, “Board” or “our Board”	our board of Directors
“BVI”	the British Virgin Islands
“CARsgen Life Sciences”	CARsgen Life Sciences Co., Ltd (愷興生命科技(上海)有限公司), a wholly foreign-owned enterprise incorporated in the PRC on March 22, 2018 and an indirectly wholly-owned subsidiary of our Company
“CARsgen Pharmaceuticals”	CARsgen Pharmaceuticals Co., Ltd (上海科濟製藥有限公司), a company incorporated in the PRC with limited liability on November 15, 2017 and wholly-owned by CARsgen Therapeutics (Shanghai)
“CARsgen Therapeutics (Shanghai)”	CARsgen Therapeutics Co., Ltd (科濟生物醫藥(上海)有限公司), a company incorporated in the PRC with limited liability on October 30, 2014, and one of our Consolidated Affiliated Entities
“China” or “PRC”	the People’s Republic of China, which for the purpose of the Prospectus and for geographical reference only, excludes Hong Kong, Macao and Taiwan
“Company”, “our Company”, “the Company”, “CARsgen Therapeutics” or “CARsgen”	CARsgen Therapeutics Holdings Limited (科濟藥業控股有限公司), an exempted company incorporated in the Cayman Islands with limited liability on February 9, 2018
“Companies Ordinance”	the Companies Ordinance (Cap. 622), as amended, supplemented or otherwise modified from time to time
“Consolidated Affiliated Entities”	the entities we control through the Contractual Arrangements, namely CARsgen Therapeutics (Shanghai) and its wholly-owned subsidiary, CARsgen Pharmaceuticals
“Contractual Arrangements”	the series of contractual arrangements entered into among CARsgen Life Sciences, CARsgen Therapeutics, the Corporate Registered Shareholder and the Individual Registered Shareholders details of which are described in the section headed “Contractual Arrangements” in this report

Definitions

“Core Product Candidate”	has the meaning ascribed to it in Chapter 18A of the Listing Rules and in this context, refers to CT053
“Corporate Governance Code” or “CG Code”	the Corporate Governance Code set out in Appendix 14 to the Listing Rules
“Corporate Registered Shareholder”	YIJIE Biotech (Shanghai) Holding Limited (上海益傑生物技術有限公司), being the registered shareholder of CARsgen Therapeutics
“Director(s)”	the director(s) of the Company
“FDA” or “U.S. FDA” or “US FDA”	U.S. Food and Drug Administration
“Group”, “our Group”, “we”, “us” or “our”	our Company, its subsidiaries and consolidated affiliated entities from time to time or, where the context so requires, in respect of the period prior to our Company becoming the holding company of its present subsidiaries and consolidated affiliated entities, such subsidiaries and consolidated affiliated entities as if they were subsidiaries and consolidated affiliated entities of our Company at the relevant time
“HK\$” or “Hong Kong dollars”	Hong Kong dollars, the lawful currency of Hong Kong
“Hong Kong” or “HK”	the Hong Kong Special Administrative Region of the People’s Republic of China
“Individual Registered Shareholders”	Dr. Li, Mr. GUO Bingsen, Dr. WANG Huamao, Mr. GUO Huaqing and Mr. CHEN Haiou, being the registered shareholders of the Corporate Registered Shareholder
“Latest Practicable Date”	April 13, 2022, being the latest practicable date prior to the printing of this report for the purpose of ascertaining certain information contained in this report
“Listing Date”	June 18, 2021
“Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time
“Model Code”	Model Code for Securities Transactions by Directors of Listed Issuers
“MOFCOM”	the Ministry of Commerce of the PRC (中華人民共和國商務部)
“NDRC”	the National Development and Reform Commission of the PRC (中華人民共和國國家發展和改革委員會)
“Nomination and Corporate Governance Committee”	the nomination and corporate governance committee of the Company

Definitions

“NMPA”	National Medical Products Administration (國家藥品監督管理局), the successor of the China Food and Drug Administration (國家食品藥品監督管理總局), or the CFDA, the State Food and Drug Administration (國家食品藥品監督管理局), or the SFDA and the State Drug Administration (國家藥品監督管理局), or the SDA
“Post-IPO RSU Scheme”	the post-IPO RSU scheme adopted by our Company on April 30, 2021, the principal terms of which are set out in the section headed “Appendix V — Statutory and General Information” in the Prospectus
“Post-IPO Share Option Scheme”	the post-IPO share option scheme adopted by our Company on April 30, 2021, the principal terms of which are set out in the section headed “Appendix V — Statutory and General Information” in the Prospectus
“Prospectus”	the prospectus issued by the Company on June 7, 2021 in connection with the IPO
“Relevant Period”	the period from the Listing Date to December 31, 2021
“Reporting Period”	the period from January 1, 2021 to December 31, 2021
“RMB” or “Renminbi”	Renminbi, the lawful currency of China
“RSU(s)”	restricted share unit(s)
“Remuneration Committee”	the remuneration committee of the Company
“Share(s)”	ordinary share(s) in the share capital of our Company with a par value of US\$0.00000025 each
“SFO”	the Securities and Futures Ordinance (Cap. 571), as amended, supplemented or otherwise modified from time to time
“United States” or “U.S.” or “US”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“US\$” or “U.S. dollars” or “USD”	United States dollars, the lawful currency of the United States

In this report, the terms “associate”, “connected person”, “controlling shareholder” and “subsidiary” shall have the meanings given to such terms in the Listing Rules, unless the context otherwise requires.

Glossary

"ADCC"	antibody-dependent cell-mediated cytotoxicity, a mechanism of cell-mediated immune defense whereby an effector cell of the immune system actively lyses a target cell, whose membrane-surface antigens have been bound by specific antibodies
"antigen"	the substance that is capable of stimulating an immune response, specifically activating lymphocytes, which are the body's infection-fighting white blood cells
"BCMA"	B-cell maturation antigen, a protein that is highly expressed in several hematologic malignancies
"BLA"	biologics license application
"B2M"	beta 2 microglobulin
"CAR(s)"	chimeric antigen receptor(s)
"CAR-T" or "CAR T"	chimeric antigen receptor T cell
"CD19"	a cell surface protein expressed on the surface of almost all B cell leukemia and lymphoma
"CDC"	complement-dependent cytotoxicity, an effector function of IgG and IgM antibodies
"CDE"	Center for Drug Evaluation, an institution under the NMPA
"CDMO(s)"	contract development manufacturing organization(s), a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from drug development through drug manufacturing
"CGMP"	current good manufacturing practices
"chemotherapy"	a category of cancer treatment that uses one or more anti-cancer chemotherapeutic agents as part of its standardized regimen
"CLDN18.2"	Claudin18.2, an attractive target in the treatment of certain solid tumors such as gastric cancer, esophageal cancer and pancreatic cancer
"CMC"	chemistry, manufacturing, and controls processes in the development, licensure, manufacturing, and ongoing marketing of pharmaceutical products
"cohort"	a group of patients as part of a clinical study who share a common characteristic or experience within a defined period and who are monitored over time

Glossary

"combination therapy"	treatment in which a patient is given two or more therapeutic agents for a single disease
"CR"	complete response, the disappearance of all signs of cancer in response to treatment
"CRS"	cytokine release syndrome, a form of systemic inflammatory response syndrome that arises as a complication of some diseases or infections, and is also an adverse effect of some monoclonal antibody drugs, as well as adoptive T cell therapies
"CTA"	Clinical Trial Application
"CycloCAR®"	a next-generation CAR-T technology under development by the Company, which features co-expression of cytokines IL-7 and chemokine CCL21 in the CAR T-cells to potentially improve clinical efficacy and reduced requirement for lymphodepletion conditioning
"cytokine"	a broad and loose category of small proteins that are important in cell signaling. Their release has an effect on the behavior of cells around them
"cytotoxic"	toxic to living cells
"DOR"	duration of response
"EGFR"	epidermal growth factor receptor
"EGFRVIII"	variant III of epidermal growth factor receptor
"EMA"	European Medicines Agency
"GPC3"	Glypican-3, an oncofetal antigen expressed in a variety of tumors including certain liver and lung cancers
"Grade"	term used to refer to the severity of adverse events
"GvHD"	graft versus host disease
"HCC"	hepatocellular carcinoma, a type of cancer arising from hepatocytes in predominantly cirrhotic liver
"Health Canada"	the department of Canada's government with responsibility for national public health
"HLA"	human leukocyte antigen
"HvGR"	host versus graft response
"IIT" or "investigator-initiated trial"	clinical trial sponsored and conducted by independent investigators

"IND"	investigational new drug or investigational new drug application, also known as clinical trial application in China
"LADAR®"	Local Action Driven by Artificial Receptor technology, with similar mechanism of synNotch system, in which the intracellular transcription of the gene of interest is controlled by a chimeric regulatory antigen receptor
"mAb" or "monoclonal antibody"	antibodies that are made by identical immune cells which are all clones belonging to a unique parent cell
"mesothelin"	cell-surface protein whose expression is mostly restricted to mesothelial cell layers lining the pleura, pericardium and peritoneum
"MM" or "R/R MM"	multiple myeloma, a type of cancer that forms in the white blood cells; cancer that relapses or does not respond to treatment is called relapsed and/or refractory multiple myeloma
"NDA"	new drug application
"NHL"	non-Hodgkin's lymphoma
"NK cell"	natural killer cell, the human body's first line of defense due to their innate ability to rapidly seek and destroy abnormal cells
"NKG2A"	also named KLRC1, killer cell lectin-like receptor subfamily C, member 1
"neurotoxicity"	possible adverse side effect of T cell therapies that leads to a state of confusion, aphasia, encephalopathy, tremor, muscular weakness, and somnolence
"ORR"	objective response rate
"OS"	overall survival
"Phase I"	a study in which a drug is introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage, tolerance, absorption, metabolism, distribution, excretion, and if possible, to gain an early indication of its effectiveness
"Phase Ib"	a phase of clinical trials that primarily assesses safety, tolerability and pharmacokinetics/pharmacodynamics at multiple ascending dose levels prior to commencement of a Phase II or Phase III clinical trial

Glossary

"Phase II"	a study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the drug for specific targeted disease, and to determine dosage tolerance and optimal dosage
"confirmatory trial" or "pivotal trial"	the controlled trial or study intended to demonstrate the required clinical efficacy and safety evidence before submission for drug marketing approval
"PR"	partial response
"PRIME"	PRiority MEdicine. A scheme launched by the EMA to offer early and proactive support to medicine developers to optimize the generation of robust data on medicine's benefits and risks, and accelerate assessment of medicines applications, for medicines that target an unmet medical need with advantages over existing treatments
"progressive-free survival" or "PFS"	the length of time during and after the treatment of a disease, such as cancer, that a patient lives without tumor progression or death
"regenerative medicine advanced therapy" or "RMAT"	a special status granted by the FDA to regenerative medicine therapies, including cell therapies, intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition
"registrational trial"	large confirmatory studies meant to establish an acceptable benefit/safety profile in order to gain regulatory approval for a precisely defined indication
"solid tumor"	an abnormal mass of tissue that usually does not contain cysts or liquid areas
"TCR"	T cell receptor
"TCR/HLA"	the deficiency of T cell receptor and human leukocyte antigen
"THANK-uCAR®"	the Company's proprietary technology to generate CAR T cells with improved expansion and persistence from T cells that are sourced from third-party donors
"TKI"	tyrosine kinase inhibitor, a pharmaceutical drug that inhibits tyrosine kinases