CARsgen Therapeutics Holdings Limited
科濟藥業控股有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2171)

ANNOUNCEMENT OF INTERIM RESULTS FOR THE SIX MONTHS ENDED JUNE 30, 2021

The board of directors (the "**Board**") of CARsgen Therapeutics Holdings Limited (the "**Company**", "**CARsgen Therapeutics**" or "**CARsgen**") is pleased to announce the unaudited consolidated interim results of the Company, its subsidiaries and consolidated affiliated entities (the "**Group**" or "**We**") for the six months ended June 30, 2021 (the "**Reporting Period**"), together with comparative figures for the same period of 2020.

FINANCIAL HIGHLIGHTS

	Six months ended June 30	
	2021	2020
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Net loss	**(4,393,846)**	(540,842)
Net loss per share	**(19.68)**	(2.73)
Non-IFRS Measures		
Adjusted net loss[(1)]	**(210,248)**	(149,782)
Adjusted net loss per share[(1)]	**(0.94)**	(0.76)

	As at	
	June 30,	As at December 31,
	2021	2020
	RMB'000	*RMB'000*
	(Unaudited)	(Audited)
Cash and cash equivalents	**1,895,475**	1,042,969
Term deposits with original maturity between three and twelve months	**1,558,176**	–
Total	**3,453,651**	1,042,969

Net loss was RMB4,394 million for the six months ended June 30, 2021, representing an increase of RMB3,853 million from RMB541 million for the six months ended June 30, 2020. The increase was primarily due to increased fair value loss in financial instruments issued to investors, which totaled RMB4,156 million for the six months ended June 30, 2021, representing an increase of RMB3,768 million from RMB388 million for the six months ended June 30, 2020. The related financial instruments were converted to ordinary shares upon the completion of the Company's IPO in June 2021, hence no loss would be recognized after the IPO.

Adjusted net loss was RMB210 million for the six months ended June 30, 2021, representing an increase of RMB60 million from RMB150 million for the six months ended June 30, 2020. The increase was primarily due to higher research and development expenses and higher administrative expenses.

The Group's cash and cash equivalents and term deposits with original maturity between three and twelve months as at June 30, 2021 were RMB3,454 million, representing an increase of RMB2,411 million compared to RMB1,043 million as at December 31, 2020. The increase was primarily attributable to the net proceeds from the IPO.

(1) Adjusted net loss and adjusted net loss per share are non-IFRS measures. They exclude the impact of the fair value loss of the financial instrument issued to investors, the expenses incurred in conjunction with the IPO and share-based compensation. For details of non-IFRS measures, please refer to "Non-IFRS Measures" sub-section for details.

BUSINESS HIGHLIGHTS

During the first half of 2021, we have made significant advancements in the areas of clinical development of our pipeline products, technology innovation, manufacturing facility expansion, and external partnership establishment. Specifically, we made progress in the following areas:

CT053

CT053 is an autologous CAR-T product candidate against BCMA being developed for the treatment of relapsed/refractory multiple myeloma. A pivotal Phase II clinical trial is on-going in China. In addition, we have recently started our pivotal Phase II clinical trial in the United States and enrolled our first patient in July 2021. As recommended by the US FDA, we are adding outpatient administration of CT053 into our U.S. clinical investigations. We plan to submit an NDA to China NMPA in the first half of 2022 and a BLA to U.S. FDA in the first half of 2023.

CT041

CT041 is a globally potential first-in-class, autologous CAR-T product candidate against CLDN18.2 being developed for the treatment of CLDN18.2 positive solid tumors. We have completed the China Phase I patient enrollment for the treatment of advanced gastric/gastroesophageal junction cancer and have applied to NMPA for the initiation of a pivotal Phase II clinical trial. In addition, a multi-center Phase Ib clinical trial is ongoing in the U.S. We anticipate filing an NDA in China in 2022 and a BLA in the United States in 2023.

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

CT011

CT011 is a globally potential first-in-class, autologous CAR-T product candidate against GPC3 being developed for the treatment of HCC. We have completed the enrollment for the 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 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.

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 hematological 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 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 to enhance drug target availability and make undruggable targets druggable.

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 August 15, 2021, we owned 52 issued patents and 231 patent applications in more than 19 countries and regions, including China, the United States, Europe and Japan. This is an increase of 2 issued patents and 17 patent applications from the last disclosure with the cut-off date on May 29, 2021. These new patents cover our THANK-uCAR technology and new product candidates and related technologies. Our R&D activities continue to generate substantial intellectual properties in our areas of expertise.

Manufacturing

We have well established end-to-end clinical and commercial manufacturing capabilities and have manufactured CAR-T products fully in-house in support of our China clinical trials and manufactured lentiviral vectors in support of our clinical trials outside of China. We can manufacture all essential components and the final product in-house, including the production of plasmids, lentiviral vectors and CAR-T cell products. We currently have manufacturing facilities in Xuhui, Shanghai and Jinshan, Shanghai, and are expanding production capacity to the United States. We have initiated the construction of and are making preparation for the technical transfer to our new manufacturing facility in the Research Triangle Park (RTP) area of Durham, North Carolina.

External license agreement and research collaboration

CAFA therapeutics, a subsidiary of CARsgen Therapeutics, entered into a license agreement with HK inno.N Corporation (KOSDAQ: 195940) to develop and commercialize CT032 and CT053 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 technological 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

I. OVERVIEW

We are a biopharmaceutical company with operations in China and the U.S. focused on innovative CAR-T cell therapies for the treatment of hematologic malignancies and solid tumors. Since our inception in 2014, we have built an integrated cell therapy platform with in-house capabilities that span from target discovery and lead antibody development to clinical trials and commercial-scale manufacturing. We 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 in treating solid tumors and reducing treatment costs.

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

During the first half of 2021, we have made significant advancements in the areas of clinical development of our pipeline products, technology innovation, manufacturing facility expansion, and external partnership establishment. 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 product candidate against BCMA being developed for the treatment of relapsed/refractory multiple myeloma, we have made good progress on our pivotal Phase II trial in China (LUMMICAR STUDY 1). Our Phase I trial showed no dose limiting toxicities, treatment-related deaths, or grade 3 or higher cytokine release syndrome. No subject developed any grade of immune effector cell-associated neurotoxicity syndrome (ICANS). By the cut-off date as June 30, 2021, we had observed 100% objective response rate (ORR) and deep response as indicated by increased stringent complete response (sCR) rate.

In North America, we have initiated our Phase II trial of the CT053 LUMMICAR STUDY 2 after receiving feedback from the US FDA. As recommended by the FDA, we are adding outpatient administration of CT053 into our clinical investigations. We have enrolled our first patient in July 2021. In Phase Ib of the clinical trial in North America, by the cut-off date of June 17, 2021, a total of 27 heavily pretreated subjects were administered a single infusion of CT053. Of the 26 subjects with at least 4 weeks of efficacy follow-up, 25 responded to the CT053 treatment. We observed no dose limiting toxicities, no treatment-related deaths, and no grade 3 or higher cytokine release syndrome. One subject experienced a transient grade 3 immune effector cell-associated neurotoxicity syndrome (ICANS) and fully recovered.

We plan to submit an NDA to China NMPA in the first half of 2022 and a BLA to U.S. FDA in the first half of 2023.

CT041

CT041 is a globally potential first-in-class, autologous CAR-T product candidate against CLDN18.2, being developed for the treatment of CLDN18.2 positive solid tumors. 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 therapies for solid tumors in which CLDN18.2 is prevalently or highly expressed. To further address the challenges of CAR-T 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 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 December 18, 2020, a total of 31 patients, including 22 patients with gastric/gastroesophageal junction cancer, 5 with pancreatic ductal adenocarcinoma and 4 with other types of solid tumors, received CT041 infusion and completed at least 8 weeks' safety, efficacy and cytokinetic assessment after the first infusion. Within the 22 patients with gastric/gastroesophageal junction cancer, 18 received at least 2 prior lines of therapies and 4 received 1 prior line therapy. For the 22 patients with gastric/gastroesophageal junction cancer, CT041 showed an ORR of 50%, a median PFS of 4.2 months, and a median OS of 9.5 months. CT041 also showed preliminary efficacy in five evaluable patients with pancreatic cancer who failed at least two prior lines of systemic treatment. There were no reported Grade 3 or higher CRS or neurotoxicities, and the most common Grade 3/4 adverse events were hematologic toxicities which were generally related to the lymphodepletion preconditioning. Update on this investigator-initiated trial has been accepted to be orally presented at the European Society for Medical Oncology Congress 2021 ("**ESMO Congress 2021**") on September 19, 2021.

We are moving forward with a Phase Ib/II clinical trial for advanced gastric/gastroesophageal junction cancer or pancreatic cancer in China and a Phase Ib clinical trial for advanced gastric or pancreatic cancer in the United States. We have applied to China NMAP for approval to initiate a pivotal Phase II clinical trial and are awaiting feedbacks.

Other candidates

We are also on track in progressing other pipeline product candidates including (i) CT011, an autologous CAR-T product candidate against GPC3 being developed for the treatment of HCC. We have completed enrollment of the Phase I trial in China; (ii) CT032, an autologous CAR-T 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 CDE regarding the addition of chemotherapy combination cohort with AB011 in Phase Ib, and subsequently we have initiated the combination cohort; and (iv) the IND-enabling or pre-clinical stage product candidates including CT017, KJ-C1807, KJ-C2112, KJ-C2113, KJ-C2114, and KJ-C2111. We continue to drive the development and expect to submit IND applications as planned.

Continuous discovery and technology development

Despite the approval of 5 CAR-T products by US FDA for the treatment of terminal line hematologic malignancies, significant challenges exist with CAR-T cell therapies, such as limited efficacy against solid tumors, significant safety concerns, and high production and treatment costs. We continue to explore innovative technologies to address these challenges. Our main focus include:

1) Increasing efficacy against solid tumors: developing innovative technologies, such as our CycloCAR technology, to enhance efficacies of CAR-T cells 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 to enhance drug target availability and make undruggable targets druggable.

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

As of August 15, 2021, we owned 52 issued patents and 231 patent applications in more than 19 countries and regions, including China, the United States, Europe and Japan. This is an increase of 2 issued patents and 17 patent applications from our last disclosure as of May 29, 2021. These new patents and patent applications mainly cover the areas of our THANK-uCAR technology and the new candidate product or technology. Our R&D activities 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, production of lentiviral vectors and CAR-T cell product manufacturing. With the clinical manufacturing facility in Xuhui, Shanghai and commercial manufacturing facility in Jinshan, Shanghai, we have been manufacturing lentiviral vectors and CAR-T cells in house to support clinical trials in China and manufacturing the lentiviral vectors in house to support clinical trials outside of China.

We've been expanding our manufacturing capacity in China to the US to support both the clinical trials and the subsequent commercialization of our pipeline product candidates. As of the date of this announcement, we have initiated the construction of the clinical manufacturing facility in the United States with a total GFA of approximately 3,300 sq.m. The clinical manufacturing facility is designed with a capacity to support CAR-T treatment for approximately 700 patients annually. As of the date of this announcement, we are formulating the construction plan for the commercial manufacturing facility with a total GFA of approximately 10,000 sq.m. The commercial manufacturing facility is designed with a manufacturing capacity to support CAR-T treatment for approximately 3,000-5,000 patients annually.

External license agreement and research collaboration

In addition to the internal research and development activities, we are also active in seeking extensive collaborations with external partners. CAFA therapeutics, 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 $50 million USD as well as up to double-digit percentage royalties on net sales in the Republic of Korea. The collaboration with HK inno.N showcases our commitment to establishing more external partnership 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.

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 and technologies in CAR-T cell therapy and enrich our product pipeline.

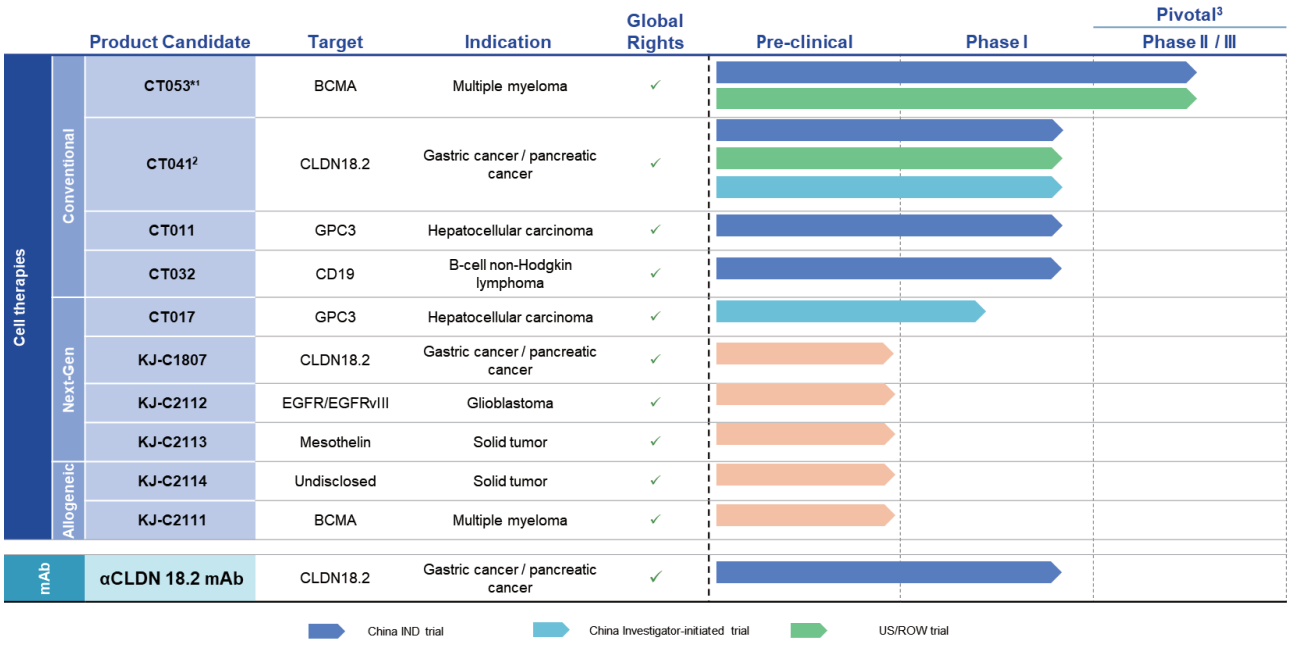
Expansion and retention of talent

In the first half of 2021, we have expanded our team from about 330 employees as at December 31, 2020 to 444 employees as at June 30, 2021. We have also strengthened the leadership team in particular. As of the date of this announcement, we have hired Ms. Caihua Jiang as Senior Vice President of Quality, responsible for the establishment and implementation of global quality system for CARsgen. We have hired Dr. Heyi Li as Vice President of Analytical, responsible for CARsgen analytical method development strategy. We have hired Dr. Guanjun Zhou 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 to support business development and strategic decisions for CARsgen China.

II. BUSINESS REVIEW

Our Products 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 sole 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 to CT053, CT041, CT011 and AB011 in our pipeline are for the treatment of solid tumors which are in Phase Ib and Phase I clinical trials. The following chart summarizes our pipeline and the development status of each product candidate as of the date of this announcement. Our product candidates are discovered and developed in-house, and we own global rights over our product candidates. The clinical-stage product candidates are currently being developed for treating advanced stage cancers.



Notes:

* Denotes our sole Core Product Candidate

1. RMAT designation from the U.S. FDA, PRIME designation from the EMA, Breakthrough Therapy Designation from the NMPA, Orphan Drug designation from the U.S. FDA and Orphan Medicinal Product designation from the EMA. The PRIME designation from the EMA provides us with various benefits, such as engaging in enhanced interactions and early dialogues with the EMA to optimize our development plans and accelerate regulatory evaluation. The RMAT designation brings benefits of both Fast Track and Breakthrough Therapy designations. The ongoing Phase II trial in China is a pivotal trial.

   We received the IND approval from the NMPA in February 2019 for initiating an open-label, single-arm, multi-center Phase I/II clinical trial in patients with R/R MM in China. We were permitted by the NMPA to launch the pivotal Phase II part of the aforementioned clinical trial in the fourth quarter of 2020 after the required communication meeting with the NMPA. In addition, we have started our pivotal Phase II clinical trial in the United States and enrolled our first patient in July 2021. As recommended by the US FDA, we are adding outpatient administration of CT053 into our future clinical investigations. The Phase II trial in North America is a pivotal trial.

2. Orphan Drug designation from the U.S. FDA and Orphan Medicinal Product designation from the EMA.

3. Phase II trials of some indications are pivotal studies.

4. Category 1 refers to therapeutic biological products that have not been marketed anywhere in the world as classified by the Registration Category of Biological Products and the Data Requirements for Declaration (《生物製品註冊分類及申報資料要求》) issued by the NMPA. There is no equivalent classification scheme in the U.S..

5. We are developing a companion diagnostic kit for CT041 and AB011 to measure the expression level of CLDN18.2. We have developed the prototype and completed the analytical validation of the companion diagnostic kit. We are currently conducting clinical validation of the kit in clinical trials of CT041 in China and the U.S. and in the clinical trial of AB011 in China.

6. The clinical trials are conducted under the clinical trial protocol covering Phase I and Phase II for each product candidate.

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

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

We have completed the Phase I trials and are conducting the pivotal Phase II trial portion of a Phase I/II clinical trial of CT053 for R/R MM in China (LUMMICAR STUDY 1) and in North America (LUMMICAR STUDY 2) to evaluate the safety and efficacy of CT053.

A total of 14 heavily pretreated subjects received a single dose infusion of CT053 BCMA CAR-T in our Phase I LUMMICAR STUDY 1. There were no dose limiting toxicities and no treatment-related deaths. In addition, no grade 3 or higher cytokine release syndrome was observed. No subject developed any grade of immune effector cell-associated neurotoxicity syndrome (ICANS). By the cut-off date of June 30, 2021, the objective response rate (ORR) was 100%, and deep response had been observed as indicated by increased stringent complete response (sCR) rate. The Phase II LUMMICAR STUDY 1 is actively recruiting patients. The updated Phase I results are planned to be disclosed at a future medical conference.

Our Investigator initiated trials (IITs) were initiated in September 2017. 24 heavily pretreated subjects received CT053 BCMA CAR-T infusion. No treatment-related deaths nor grade 3 or higher cytokine release syndrome was observed. Only 1 subject developed grade 3 ICANS and resolved quickly. The ORR and sCR/CR were 87.5% and 79.2%, respectively. As of June 30, 2021, with a median follow up of 17.4 (0.9, 39.4) months, the median duration of response (DOR) and median progression-free survival (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 subjects are still in remission and in long-term follow-up.

We have received feedback on the pivotal Phase II design from the US FDA. The Phase II study is active, and the first subject was enrolled in July 2021. As recommended by the FDA, we are adding outpatient administration of CT053 into our future clinical investigations.

As of June 17, 2021, a total of 27 heavily pretreated subjects were administered a single infusion of CT053 BCMA CAR-T in Phase Ib of LUMMICAR STUDY 2. There were no dose limiting toxicities and no treatment-related deaths. In addition, no grade 3 or higher cytokine release syndrome was observed. One subject experienced a transient grade 3 ICANS and fully recovered. One subject had less than 4 weeks of efficacy follow-up at the data cut-off date. Of the 26 subjects with at least 4 weeks of efficacy follow-up, 25 responded to the CT053 treatment. As recommended by FDA, we are adding outpatient administration of CT053 into our future clinical investigations. The detailed Phase II study design and updated Phase Ib results are planned to be disclosed at a future medical conference.

We plan to make regulatory submissions for marketing approval to the NMPA in the first half of 2022 and the U.S. FDA in the first half of 2023, as well as to conduct additional clinical trials to develop CT053 as an earlier line of treatment for MM. We have developed CT053 in-house with our integrated research and development platform. CT053 has received Regenerative Medicine Advanced Therapy (RMAT) and Orphan Drug designations from the U.S. FDA in 2019, as well as PRIority MEdicines (PRIME) and Orphan Medicinal Product designations from the EMA in 2019 and 2020, respectively, and the Breakthrough Therapy designation from the NMPA in 2020.

We believe that CT053, the BCMA CAR-T product candidate with an upgraded, fully-human CAR, has a promising efficacy profile and a favorable safety profile, as evidence by the absence of Grade 3 or above CRS and 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 a globally potential first-in-class, autologous CLDN18.2 CAR-T product candidate for the treatment of CLDN18.2 positive solid tumors. 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 therapies for solid tumors in which CLDN18.2 is prevalently or highly expressed. To further address the challenges of CAR-T 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 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 and the Phase I/II clinical trial in China and Phase Ib clinical trial in the United States for CLDN18.2 positive gastric cancer and pancreatic cancer. An ongoing investigator-initiated trial is led by Dr. Lin Shen at the Beijing Cancer Hospital. As of the latest data cut-off date of December 18, 2020, a total of 31 patients, including 22 patients with gastric/gastroesophageal junction cancer, 5 with pancreatic ductal adenocarcinoma and 4 with other types of solid tumors, received CT041 infusion and completed at least 8 weeks' safety, efficacy and cytokinetic assessment after the first infusion. Within the 22 patients with gastric/gastroesophageal junction cancer, 18 received at least 2 prior lines of therapies and 4 received 1 prior line therapy. For the 22 patients with gastric/gastroesophageal junction cancer, CT041 showed an ORR of 50%, a median PFS of 4.2 months, and a median OS of 9.5 months. CT041 also showed preliminary efficacy in five evaluable patients with pancreatic cancer who failed at least two prior lines of systemic treatment. There were no reported Grade 3 or higher CRS or neurotoxicities, and most common Grade 3/4 adverse events were hematologic toxicities which were generally related to the preconditioning regimen. 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.

Data updates on this investigator-initiated trial has been accepted as an oral presentation at the European Society for Medical Oncology Congress 2021 ("**ESMO Congress 2021**") on September 19, 2021.

Name of the Research Study	**Presentation No.**	**Presentation Type**
CLDN 18.2-targeted CAR-T cell therapy in patients with cancers of the digestive system	1372O	Oral presentation

We are conducting a Phase Ib/II clinical trial of CT041 for advanced gastric/gastroesophageal junction cancer and pancreatic cancer in China and a Phase Ib clinical trial of CT041 for advanced gastric or pancreatic cancer in the United States to evaluate the safety and efficacy of the CT041 therapy. CT041 received the Orphan Drug designation for the treatment of gastric/gastroesophageal junction cancer from the U.S. FDA in 2020 and the Orphan Medicinal Product designation for the treatment of gastric cancer from the EMA in 2021.

In China we had applied for the required regulatory approval from NMPA for initiating the pivotal Phase II clinical trials. Following the pivotal trial, we plan to submit the NDA to the NMPA in the second half of 2022 for the treatment of gastric cancer patients who have failed at least two prior lines of systemic therapies. We also intend to conduct a pivotal Phase II trial in the United States in 2022 and submit the BLA to the U.S. FDA in 2023.

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 to apply CAR-T modality to treating solid tumors.

Humanized GPC3 CAR-T (CT011)

CT011 is a globally potential first-in-class CAR-T product candidate with proof-of-concept clinical data for the treatment of HCC. Our co-founder, CEO and Chief Scientific Officer Dr. Li led the world's first successful effort in identifying, validating and reporting GPC3 as a tumor-associated target for the development of CAR-T therapies to treat HCC. Our previous 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 3 years, 1 year and 6 months being 10.5%, 42.0% and 50.3%, respectively, with a median overall of 278 days. We have completed enrollment for the Phase I trial in China.

Humanized CD19 CAR-T (CT032)

CT032 is an autologous CAR-T 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 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.

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 2Q 2021 we received supplemental application approval by 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 plan to consult with the NMPA in the second half of 2022 and to initiate a Phase II/III clinical trial with an adaptive two-stage design in a single protocol with a leading indication of gastric/gastroesophageal junction cancer.

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 six IND-enabling or pre-clinical stage product candidates as described below. We expect to submit IND applications for these product candidates within the next three years.

CT017 is a next-generation autologous CAR-T product candidate that targets GPC3 and is armored with a transcription factor, which is a master regulator essential for inducing T cells to reside in non-lymphoid tissues. Our preclinical studies have shown that CT017 is able to better reside and persist in non-lymphoid tissues such as solid tumor masses, therefore exhibit enhanced anti-solid tumor efficacy. CT017 is currently being under an investigator-initiated trial to assess its safety and efficacy for treating GPC3 positive HCC in China. The interim results of CT017 in combination with multi-tyrosine kinase inhibitors (TKIs) were disclosed at ASCO annual Congress (June 2021), which showed ORR and DCR were 16.7% and 50% respectively in HCC patients with at least 2 prior lines of systemic therapy. The median progression-free survival (mPFS) was 4.2 months.

KJ-C1807 is a next-generation autologous CAR-T 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 designed to treat patients with gastric/gastroesophageal junction cancer and pancreatic cancer.

KJ-C2112 is a next-generation autologous EGFR/EGFRvIII-bitargeted CAR-T 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 a experienced reputable principal investigator and further study KJ-C2112 in an investigator-initiated trial.

KJ-C2113 is a next-generation autologous CAR-T 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 product candidate deploying our THANK-uCAR technology with an undisclosed target for the treatment of certain solid tumors.

KJ-C2111 (CT0590) is an allogeneic CAR-T product candidate deploying our THANK-uCAR technology that targets BCMA. We are developing KJ-C2111 for the treatment of MM.

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, fly 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 candidates 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.

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 potently 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, neurotoxity 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 has not induced Grade 3 or higher CRS in the investigator-initiated trials and the Phase I clinical trials and allowed less administration of anti-IL-6 medication and other immunosuppressant mediation 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 T cells that are sourced from third-party donors. To minimize GvHD and HvGR from allogeneic T cells, we disrupt the genomic loci encoding T cell receptor and 2 microglobulin (B2M) to eliminate surface expression of the TCR or B2M, an approach that has been validated by previous research. However, as NK cells attack T cells without B2M expression, which in turn limits the expansion and persistence of the allogeneic T cells, we armor the $TCR^-/B2M^-$ 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 armoring the $TCR^-/B2M^-$ CAR-T cells with anti-NKG2A CAR resulted in improved expansion in the presence of NK cells. We are developing allogeneic CAR-T product candidates using THANK-uCAR technology, which we believe could potentially increase the expansion, persistence and efficacy of allogeneic CAR-T cells. We believe the successful application of THANK-uCAR technology would significantly lower the cost of CAR-T therapy and eventually increase patient accessibility.

To resolve the challenge with target availability, we continue to explore innovative technologies to enhance drug target availability and therefore make undruggable targets druggable.

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

As of August 15, 2021, we owned 52 issued patents and 231 patent applications in more than 19 countries and regions, including China, the United States, Europe (EPO) and Japan. This is an increase of 2 issued patent and 17 patent applications from our last disclosure as of May 29, 2021. These new patents mainly cover the areas of our THANK-uCAR technology and the new candidate product or technology. Our R&D activities continue to generate substantial IP in our areas of expertise.

Manufacturing

We have established in-house GMP-compliant manufacturing capabilities that cover end-to-end CAR-T manufacturing, including plasmids production, lentiviral vectors production and CAR-T cell product manufacturing. We have launched a 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 treatment of 200 patients. Since establishment, our Xuhui facility has achieved over 95% manufacturing success rate for all product candidates and supported our early-stage clinical trials.

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 treatment of up to 2,000 patients annually. The Jinshan 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.

With the clinical manufacturing facility in Xuhui, Shanghai and the commercial manufacturing facility in Jinshan, Shanghai, we have been manufacturing the the lentiviral vectors and CAR-T cells in house to support clinical trials in China and manufacturing the lentiviral vectors in house to support clinical trials outside of China.

To support our global expansion, we are planning for the construction of a second-phase of our Jinshan facility and building GMP-compliant commercial manufacturing facilities in the United States, which collectively will be able to expand our manufacturing capacity to support the treatment of over 10,000 patients annually.

In July 2021, we received the full building permit from local authority for our new manufacturing facility with a total GFA of approximately 3,300 sq.m. in the Research Triangle Park (RTP) area, North Carolina. CARsgen engaged with the world-leading companies in managing architect, engineering, construction, commissioning, qualification and validation. The RTP facility project adopted design-build approach that greatly shortens construction turnaround time and improves cost effectiveness. In recent public hearings, the local officials including NC Governor Cooper, Secretary of Commerce Sanders and NC Senator Hawkins from North Carolina State highly appreciated the positive impact of the CARsgen RTP project on economic development and technological innovation. CARsgen's RTP facility will support the company's ongoing clinical studies and early commercial launch in North America and Europe. Meanwhile, we have started to establish a strong CMC team in North Carolina for future facility operation. We have previously completed the technology transfer to our CDMO in the U.S., and we are currently making preparation for the technology transfer to our new manufacturing facility in RTP of Durham, North Carolina.

By building end-to-end manufacturing capabilities, we expect to significantly increase manufacturing reliability, reduce manufacturing costs, and reduce the process turnaround time or the vein-to-vein time by eliminating extra transportation time and release time due to the third-party testing. 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 US FDA to provide lentiviral vectors substances for manufacturing our CT041 and CT053 cell products in support of US clinical trials. With large scale lentiviral vectors production, we could greatly reduce the CAR-T manufacturing costs.

Commercialization

Due to the novel and comprehensive treatment process of CAR-T therapies, we started formulating our marketing strategies in a staggered approach corresponding to the expected launch timeline of our product candidates to introduce our CAR-T product candidates, once approved, to the market. The staggered approach features stepwise expansion of our future marketing efforts. For the China market, we intend to cover key Class III Grade A hospitals in tier one cities and selected tier two cities across the country that are equipped to administer CT053 CAR-T cell therapy and other treatments for hematologic malignancies in their hematology department. We also plan to broaden our footprint into oncology departments as we approach the launch of CT041 and other solid tumor product candidates. Going forward, we will also build a sales and marketing force to cover other key markets such as the United States and Europe.

In China, we are building a dedicated marketing team. By the end of 2022, we plan to cover key Class III Grade A hospitals in tier one cities and selected tier two cities across the country that are equipped to administer CT053 CAR-T cell therapy and other treatments for hematological malignancies in their hematology department. As we approach the launch of CT041 and other CAR-T product candidates for treating solid tumors, we also plan to broaden our footprint into oncology department. We aim to establish a centralized collaborative system for standard clinical management of CAR-T therapies by forging close collaborations with local key participants such as research and clinical centers, in order to achieve a whole-process management of patients for CAR-T therapies covering prior evaluation, apheresis, pre-treatment, 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 treatment centers, which may be able to re-allocate the scarce medical resources from large cities to less-developed cities or regions and provide access to patients who otherwise may not be able to receive treatment with our CAR-T product candidates. In addition, in order to ensure continuous, efficient and cost-effective supplies of CAR-T product candidates for clinical and commercial use, we aim to establish a standard validation process to expedite the installation and certification of GMP-compliant CAR-T manufacturing centers.

Going forward, we will build our sales and marketing force to enter major markets, such as the United States and Europe, in order to help more patients with solid tumors or hematologic malignancies with our CAR-T cell therapies. We have established our clinical development team in the United States and started to build our commercial team in United States and Europe to prepare for the launch of our products in those markets once approved.

Other Corporate Development

CAFA Therapeutics, 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 South Korea. Under the terms of the agreement, CARsgen will receive an upfront and additional milestone payments totaling up to $50 million USD as well as up to double digit royalties on net sales in South Korea. This collaboration with HK inno.N (KOSDAQ: 195940) showcases our commitment to establishing more external partnership with leading pharmaceutical companies to maximize the application of our technology platform and value of our product pipeline to benefit more cancer patients globally.

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

We have been continuously monitoring the situation with COVID-19 and take appropriate measures to limit the impact on our business operations. There has not been any material disruption of our ongoing clinical trials. We cannot guarantee that the COVID-19 pandemic will not further escalate or have a material adverse effect on our results of operations, financial position or prospects.

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 achievement and milestones we have achieved with our technology and pipeline product candidates, we will focus on rapidly progressing the clinical development of CT053 and CT041 in both China and overseas with an NDA and a BLA submissions expected in 2022 for China and 2023 for the U.S. 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 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 make CAR-T 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 a means to maximize the application of our technology platform and value of our product pipeline as well as develop more innovative therapies for cancer patients worldwide, ultimately creating more value for our investors and society.

III. 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 RMB234 million and RMB146 million for the six months ended June 30, 2021 and 2020, respectively. Substantially all of our operating losses resulted from research and development expenses and administrative expenses.

Loss for the periods

Net loss was RMB4,394 million for the six months ended June 30, 2021, representing an increase of RMB3,853 million from RMB541 million for the six months ended June 30, 2020. The increase was primarily due to increased fair value loss in financial instruments issued to investors, which totaled RMB4,156 million for the six months ended June 30, 2021, representing an increase of RMB3,768 million from RMB388 million for the six months ended June 30, 2020. The related financial instruments were converted to ordinary shares upon the completion of the Company's IPO in June 2021, hence no loss would be recognized after the IPO.

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 prepared 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 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.

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

	Six months ended June 30,	
	2021	**2020**
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Loss for the periods	**(4,393,846)**	(540,842)
Add:		
Fair value loss of financial instrument issued to investors	**4,155,572**	388,250
Listing fee	**26,580**	–
Share-based compensation	**1,446**	2,810
Adjusted net loss	**(210,248)**	(149,782)

	Six months ended June 30,	
	2021	**2020**
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Loss per share for the periods	**(19.68)**	(2.73)
Add：		
Fair value loss of financial instrument issued to investors per share	**18.61**	1.96
Listing fee per share	**0.12**	–
Share-based compensation per share	**0.01**	0.01
Adjusted net loss per share	**(0.94)**	(0.76)

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.

Research and Development Expenses

	Six months ended June 30,	
	2021	2020
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Employee benefit expenses	**68,879**	36,587
Testing and clinical expenses	**61,697**	57,427
Research and development consumables	**23,988**	10,395
Depreciation of property, plant and equipment	**8,435**	8,598
Depreciation of right-of-use assets	**4,421**	2,814
Amortization of intangible assets	**2,640**	2,768
Utilities	**2,079**	3,102
Travelling and transportation expenses	**1,055**	748
Short term lease and low value lease expenses	**191**	183
Professional service fees	**90**	193
Other expenses	**2,232**	2,278
Total	**175,707**	125,093

Research and development expenses increased to RMB176 million for the six months ended June 30, 2021, representing an increase of RMB51 million from RMB125 million for the six months ended June 30, 2020, primarily due to increased head count and staff cost and expenses for testing and productions in support of our clinical trials.

Administrative Expenses

	Six months ended June 30,	
	2021	2020
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Listing expenses	**26,580**	–
Employee benefit expenses	**19,335**	10,130
Professional service fees	**5,719**	2,003
Depreciation of property, plant and equipment	**4,585**	4,646
Office expenses	**2,957**	1,306
Depreciation of right-of-use assets	**2,929**	680
Auditors' remuneration	**1,102**	300
Amortization of intangible assets	**248**	138
Travelling and transportation expenses	**246**	83
Short term lease and low value lease expenses	**126**	44
Utilities	**60**	28
Other expenses	**219**	1,438
Total	**64,106**	20,796

Administrative expenses increased to RMB64 million for the six months ended June 30, 2021, representing an increase of RMB43 million from RMB21 million for the six months ended June 30, 2020, primarily due to listing expenses incurred in relation to the Company's IPO and increased headcount and staff cost.

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

	Six months ended June 30,	
	2021	2020
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Wages, salaries and bonuses	**72,779**	37,699
Pension, social security costs and housing benefits	**11,236**	2,684
Share-based compensation	**1,446**	2,810
Other welfare for employees	**2,753**	3,524
Total	**88,214**	46,717
Amount included in research and development expenses	**68,879**	36,587
Amount included in administrative expenses	**19,335**	10,130

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, social security and housing benefits during the six months ended June 30, 2021 is due to the partial waiver of welfare contributions as part of the 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:

	Six months ended June 30,	
	2021	2020
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Administrative expenses	**349**	674
Research and development expenses	**1,097**	2,136
Total	**1,446**	2,810

Fair Value Loss of Financial Instruments Issued to Investors

Fair value loss of financial instruments issued to investors increased to RMB4,156 million for the six months ended June 30, 2021, representing an increase of RMB3,768 million from RMB388 million for the six months ended June 30, 2020, primarily due to the steeper increase in the fair value of the financial instruments leading up to IPO. The financial instruments were converted to ordinary shares upon the completion of the Company's IPO in June 2021, hence no loss would be recognized after the IPO.

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

	As at	As at
	June 30,	December 31,
	2021	2020
	RMB'000	*RMB'000*
	(Unaudited)	(Audited)
Cash at banks		
– RMB	**77,044**	121,393
– HKD	**4**	–
– USD	**1,818,427**	921,576
Subtotal	**1,895,475**	1,042,969
Term deposits with original maturity between three and twelve months – USD	**1,558,176**	–
Total	**3,453,651**	1,042,969

The Group's cash and cash equivalents and term deposits with original maturity between three and twelve months as at June 30, 2021 were RMB3,454 million, representing an increase of RMB2,411 million compared to RMB1,043 million as at December 31, 2020. The increase was primarily attributable to the net proceeds from the IPO.

Borrowings and Gearing Ratio

The Group's total borrowings, including interest-bearing borrowings, as at June 30, 2021 were RMB177 million, representing an increase of RMB97 million compared to RMB80 million as at December 31, 2020.

As at June 30, 2021 and December 31, 2020, the Group's bank borrowings of approximately RMB14,194,000 and RMB16,352,000 respectively are pledged by property, plant and equipment and right-of-use assets of the Group.

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

As at June 30, 2021, the Group's unsecured borrowings are mature within six to twelve months with the interest rate ranging between 3.7% and 5.5%.

As at June 30, 2021, the Group's secured borrowings are mature within three years with the interest rate of 5.225%.

The gearing ratio (calculated by dividing the sum of borrowings and lease liabilities by total equity) of the Group as at June 30, 2021 was 9%. 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.

Lease liabilities increased to RMB123 million as at June 30, 2021 from RMB20 million as at December 31, 2020, due to newly rented offices and staff dormitories.

Foreign Exchange Exposure

We have transactional currency exposures. Certain of our bank balances, other receivables, 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.

Pledge of Shares

As at June 30, 2021, we did not have any pledging of shares by our controlling shareholders.

Significant Investments, Material Acquisitions and Disposals

As at June 30, 2021, we did not hold any significant investments. During the six months ended June 30, 2021, we did not have material acquisitions or disposals of subsidiaries, associates and joint ventures.

Capital Expenditure

For the six months ended June 30, 2021, the Group's total capital expenditure amounted to approximately RMB33 million, which was used in purchase of property, plant and equipment, and software.

Charge on Assets

As at June 30, 2021, there was no charge on assets of the Group.

Contingent Liabilities

As at June 30, 2021, the Group did not have any material contingent liabilities.

Subsequent Events

Reference is made to the announcement (the "**Announcement**") of the Company dated July 22, 2021 in relation to (i) the grant of 730,578 options to 48 option grantees pursuant to the Post-IPO Share Option Scheme; (ii) the grant of 1,600,867 RSUs to 115 grantees pursuant to the Post-IPO RSU Scheme; and (iii) the grant of 16,000 RSUs to the Connected Grantee pursuant to the 2019 Equity Incentive Plan. Due to internal administrative considerations, on August 23, 2021, the grant referred to in (ii) above pursuant to the Post-IPO RSU Scheme has been modified to a grant of the same number of RSUs to the same grantees under the 2019 Equity Incentive Plan.

Unless otherwise indicated, capitalized terms used in this sub-section shall have the same meanings as those defined in the Announcement.

Except as disclosed above, the Company is not aware of any material subsequent events after the end of the Reporting Period which requires disclosure in this announcement.

Employees and Remuneration Policies

As of June 30, 2021, we had a total of 444 employees.

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 date of this announcement, 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 date of this announcement, we had complied with all statutory social insurance fund and housing fund obligations applicable to us under PRC laws in all material aspects.

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.

The following discussion is based on, and should be read in conjunction with the financial information and the notes included elsewhere in this announcement.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

FOR THE SIX MONTHS ENDED JUNE 30, 2021

	Note	Six months ended June 30,	
		2021	2020
		RMB'000	*RMB'000*
		(Unaudited)	(Unaudited)
Administrative expenses	*5*	**(64,106)**	(20,796)
Research and development expenses	*5*	**(175,707)**	(125,093)
Other income	*3*	**4,272**	337
Other gains/(losses) - net	*4*	**1,282**	(43)
Operating loss		**(234,259)**	(145,595)
Finance costs – net	*6*	**(4,015)**	(6,997)
Fair value changes in financial instruments issued to investors		**(4,155,572)**	(388,250)
Loss before income tax		**(4,393,846)**	(540,842)
Income tax expense	*7*	**–**	–
Loss for the periods and attribute to the equity holders of the Company		**(4,393,846)**	(540,842)
Other comprehensive income/(loss) for the periods:			
Items that may be reclassified to profit or loss			
Exchange differences on translation of subsidiaries		**6,029**	(7,723)
Items that will not be reclassified to profit or loss			
Exchange differences on translation of the Company		**50,756**	(11,234)
Fair value changes relating to financial instruments issued to investors due to the Company's own credit risk		**(25,093)**	(7,063)
Other comprehensive income/(loss) for the period, net of tax		**31,692**	(26,020)
Total comprehensive loss for the periods and attribute to the equity holders of the Company		**(4,362,154)**	(566,862)
Loss per share for the loss attributable to owners of the Company			
Basic and diluted loss per share (in RMB)	*8*	**(19.68)**	(2.73)

CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

AS AT JUNE 30, 2021

	Note	**As at June 30, 2021** ***RMB'000*** **(Unaudited)**	As at December 31, 2020 *RMB'000* (Audited)
ASSETS			
Non-current assets			
Property, plant and equipment		**153,327**	129,630
Right-of-use assets		**129,916**	27,139
Intangible assets		**21,849**	23,521
Other non-current assets and prepayments		**14,828**	17,766
		319,920	198,056
Current assets			
Other receivables	*9*	**8,241**	2,418
Other current assets and prepayments		**20,130**	10,408
Term deposits with original maturity between three and twelve months		**1,558,176**	–
Cash and cash equivalents		**1,895,475**	1,042,969
		3,482,022	1,055,795
Total assets		**3,801,942**	1,253,851
EQUITY AND LIABILITIES			
Equity attributable to the equity holders of the Company			
Share capital	*10*	**1**	–
Reserves		**3,381,861**	(1,676,128)
Total equity		**3,381,862**	(1,676,128)
LIABILITIES			
Non-current liabilities			
Financial instruments issued to investors		**–**	2,745,584
Borrowings	*13*	**9,709**	11,981
Lease liabilities		**111,849**	14,016
Deferred income		**11,741**	13,167
		133,299	2,784,748
Current liabilities			
Lease liabilities		**11,463**	5,890
Accruals and other payables	*12*	**104,242**	67,379
Deferred income		**3,591**	3,591
Borrowings	*13*	**167,485**	68,371
		286,781	145,231
Total liabilities		**420,080**	2,929,979
Total equity and liabilities		**3,801,942**	1,253,851

1. GENERAL INFORMATION

CARsgen Therapeutics Holdings Limited (hereinafter the "Company") was incorporated under the law of Cayman Islands as a limited liability company on February 9, 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 condensed consolidated interim financial information 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 August 23, 2021.

2. BASIS OF PREPARATION

The unaudited interim condensed consolidated financial information for the six months ended June 30, 2021 has been prepared in accordance with International Accounting Standard ("IAS") 34 "Interim Financial Reporting". The unaudited interim condensed consolidated financial information should be read in conjunction with the Company's consolidated financial statements for the year ended December 31, 2020 and 2019 ("2020 and 2019 Consolidated Financial Statements") included in appendix I, Accountant's Report to the prospectus issued by the Company on June 7, 2021 ("Prospectus"), which have been prepared in accordance with International Financial Reporting Standards ("IFRSs").

Except for the newly effective standards, amendments and interpretations that became applicable to the Group first time in the six months ended June 30, 2021, the accounting policies applied are consistent with those of the 2020 and 2019 Consolidated Financial Statements, as set out the Accountant's Report as Appendix 1 to the Prospectus of the Company.

Taxes on income in the interim periods are accrued using the tax rate that would be applicable to expected total annual earnings.

2.1 New standards, amendments and interpretation adopted by the Group

The following amendments to standards have been adopted by the Group for the financial period beginning on January 1, 2021:

Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16	Interest Rate Benchmark Reform – Phase 2

The adoption of these standards and the new accounting policies disclosed did not have any significant impact on the Group's accounting policies and did not require retrospective adjustments.

2.2 New standards, amendments and interpretation not yet adopted by the Group

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.

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 standards 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.

3. OTHER INCOME

	Six months ended June 30,	
	2021	2020
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Government grants	**2,334**	287
Interest income on bank deposit	**1,938**	50
Total	**4,272**	337

4. OTHER GAINS/(LOSSES) – NET

	Six months ended June 30,	
	2021	2020
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Net foreign exchange gains – net	**1,476**	1
Others	**(194)**	(44)
Total	**1,282**	(43)

5. EXPENSES BY NATURE

	Six months ended June 30,	
	2021	2020
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Employee benefit expenses	**88,214**	46,717
Testing and clinical expenses	**61,697**	57,427
Listing expenses through profit & loss	**26,580**	–
Research and development consumables	**23,988**	10,395
Depreciation of property, plant and equipment	**13,020**	13,244
Utilities	**2,139**	3,130
Depreciation of right-of-use assets	**7,350**	3,494
Amortization of intangible assets	**2,888**	2,906
Professional service fees	**5,809**	2,196
Office expenses	**2,957**	1,306
Auditors' remuneration	**1,102**	300
– Audit service	**1,102**	300
– Non-audit service	**–**	–
Travelling and transportation expenses	**1,301**	831
Short term lease and low value lease expenses	**317**	227
Other expenses	**2,451**	3,716
Total	**239,813**	145,889

6. FINANCE COST-NET

	Six months ended June 30,	
	2021	2020
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Finance costs		
Interest expense on lease liabilities	**927**	189
Interest expense on loans with conversion option	**–**	4,497
Interest expense on bank borrowings	**3,088**	2,311
Total finance costs	**4,015**	6,997

7. INCOME TAX EXPENSE

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) Mainland China 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 Shanghai 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.

(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 six months ended June 30, 2021 and 2020. CARsgen USA was also subject to the state income tax in Delaware, at a rate of 8.7%, for the six months ended June 30, 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's corporation income tax

The subsidiary in Ireland is subject to income tax at a rate of 12.5% on the estimated assessable income. No provision for Ireland income tax has been provided as the subsidiary has no estimated assessable profit.

8. 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 periods.

	Six months ended June 30,	
	2021	2020
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Loss attributable to the ordinary equity holders of the company (RMB'000)	**(4,393,846)**	(540,842)
Weighted average number of ordinary shares in issue (in thousand)	**223,248**	198,140
Basic loss per share (RMB)	**(19.68)**	(2.73)

The weighted average number of ordinary shares for the six months ended June 30, 2020 for the purpose of calculating the basic loss per share had been adjusted to account for the effect of the share subdivision of the capital of the Company and the issuance of 2,476,745 ordinary shares without a corresponding change in resources.

(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 six months ended June 30, 2021 and 2020, the Company had three categories of potential ordinary shares including: loans with conversion option, financial instruments issued to investors and share-based payments. As the Group incurred losses for the six months ended June 30, 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 losses for the six months ended June 30, 2021 and 2020 are the same as basic loss per share of the respective periods.

9. OTHER RECEIVABLES

	As at June 30, 2021	As at December 31, 2020
	RMB'000	*RMB'000*
	(Unaudited)	(Audited)
Deposits	**7,747**	1,813
Others	**494**	605
Total	**8,241**	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.

10. SHARE CAPITAL

Authorized:

	Number of shares *In thousands*	Nominal value of shares *USD*	RMB equivalent value *RMB'000*
As at January 1, 2020 and June 30, 2020	50,000,000	50,000	349
As at January 1, 2021 and June 30, 2021 *(Note(a))*	200,000,000	50,000	349

Issued and fully paid:

	Number of ordinary shares at USD0.00000025 par value *In thousands*	RMB equivalent value *RMB'000*
As at January 1, 2021	198,140	–*
Issue of shares held in trust *(Note(b))*	19,623	–*
Conversion of Preferred Shares to Common Shares upon Global Offering *(Note(c))*	254,837	1
Issue of shares by Global Offering *(Note(d))*	94,747	–*
As at June 30, 2021	**567,347**	**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 USD0.00000025 par value each. Accordingly, the issued 49,534,884 shares were divided into 198,139,536 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$0.00000025 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".

11. DIVIDEND

No dividend was declared or paid by the Company or the companies now comprising the Group during the six months ended June 30, 2021 and 2020.

12. ACCRUALS AND OTHER PAYABLES

	As at June 30, 2021 ***RMB'000*** **(Unaudited)**	As at December 31, 2020 *RMB'000* (Audited)
Accrued expenses	**60,096**	33,903
Staff salaries and welfare payables	**21,977**	20,825
Listing expenses payable	**14,721**	5,190
Payables for acquisition of property, plant and equipment	**3,225**	2,244
Other taxes payable	**1,119**	1,805
Interest payables	**341**	209
Payables for research and development consumables	**103**	2,367
Others	**2,660**	836
Total	**104,242**	67,379

13. BORROWINGS

	As at June 30, 2021 ***RMB'000*** **(Audited)**	As at December 31, 2020 *RMB'000* (Audited)
Non-current		
Secured bank borrowings	**9,709**	11,981
Current		
Unsecured borrowings	**163,000**	64,000
Secured bank borrowings	**4,485**	4,371
	167,485	68,371
Total	**177,194**	80,352

	As at January 1, 2021 *RMB'000* (Unaudited)	Additions	Repayments	**As at June 30, 2021 *RMB'000* (Unaudited)**
Unsecured borrowings	64,000	145,000	(46,000)	**163,000**
Secured bank borrowings	16,352	–	(2,158)	**14,194**
Total	80,352	145,000	(48,158)	**177,194**

14. REVENUE

CAFA Therapeutics, a subsidiary of CARsgen Therapeutics, has entered into a license agreement with HK inno.N Corporation, a pharmaceutical company, during the six months ended June 30, 2021 to develop and commercialize CT032 and CT053, targeting CD19 and BCMA respectively, for the potential treatment of various cancers in South Korea. Under the terms of the agreement, CARsgen will receive an upfront payment and additional milestone payments totaling up to USD50 million as well as double-digit percentage royalties on net sales in South Korea. As at June 30, 2021, the transfer of the related documentation and technology and other efforts have not yet been commenced and hence no revenue is recognized for the six months ended June 30, 2021.

IV. CORPORATE GOVERNANCE AND OTHER INFORMATION

Interim dividend

The Board does not recommend the payment of interim dividend to the Shareholders for the six months ended June 30, 2021.

Purchase, Sale or Redemption of the Company's Listed Securities

Neither the Company nor any of its subsidiaries purchased, sold or redeemed any of the Company's listed securities from the Listing Date to June 30, 2021.

Model Code for Securities Transactions

The Company has adopted the Model Code set out in Appendix 10 to the Listing Rules. Specific enquiries have been made to all Directors and the Directors have confirmed that they have complied with the Model Code for the period from the Listing Date to June 30, 2021.

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 period from the Listing Date to June 30, 2021.

Compliance with the Corporate Governance Code

The Company has adopted and applied the principles and code provisions as set out in the Corporate Governance Code and Corporate Governance Report (the "**Corporate Governance Code**") contained in Appendix 14 to the Listing Rules. For the period from the Listing Date to June 30, 2021, the Company has complied with the mandatory code provisions in the Corporate Governance Code, except for the deviation from code provision A.2.1 as explained below.

Pursuant to code provision A.2.1 of the Corporate Governance Code, companies listed on The Stock Exchange of Hong Kong Limited (the "**Stock Exchange**") are expected to comply with, but may choose to deviate from the requirement that the roles of chairman and chief executive should be separate and should not be performed by the same individual. We do not have separate Chairman of the Board and 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. We aim to implement a high standard of corporate governance, which is crucial to safeguard the interests of our Shareholders. To accomplish this, we expect to comply with the Corporate Governance Code after the Listing except for the matter disclosed above.

Use of Proceeds from the Global Offering

The shares of the Company were listed on the Stock Exchange on June 18, 2021. The Company obtained net proceeds from the global offering amounting to approximately HK$3,008 million.

For the period from the Listing Date up to the date of this announcement, the Company has not utilized any of the net proceeds raised from the global offering. The Company intends to use the net proceeds in the same matter and proportion as set out in the Prospectus under the section headed "Future Plans and Use of Proceeds".

Audit Committee

The Audit Committee has three members comprising Mr. So Tak Young (chairman), Dr. Fan Chunhai and Mr. Guo Huaqing, with terms of reference in compliance with the Listing Rules.

The Audit Committee has considered and reviewed the accounting principles and practices adopted by the Group and has discussed matters in relation to internal controls and financial reporting with the management, including the review of the unaudited condensed consolidated interim financial results of the Group for the six months ended June 30, 2021. The Audit Committee considers that the interim financial results for the six months ended June 30, 2021 are in compliance with the relevant accounting standards, rules and regulations and appropriate disclosures have been duly made.

In addition, the Company's independent auditor, PricewaterhouseCoopers, has performed an independent review of the Group's interim financial information for the Reporting Period in accordance with International Standard on Review Engagements 2410, "Review of Interim Financial Information performed by the Independent Auditor of the Entity" issued by International Accounting Standards Board.

Legal Proceedings

As of June 30, 2021, as far as the Company is aware, the Company and its subsidiaries were not involved in any material litigation or arbitration and no material litigation or claim of material importance was pending or threatened against or by the Company.

Publication of Interim Results Announcement and Interim Report

This announcement is published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.carsgen.com).

The interim report for the Reporting Period containing all the information required by Appendix 16 to the Listing Rules will be dispatched to the Shareholders and published on the websites of the Stock Exchange and the Company in due course.

"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
"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
"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"	the Corporate Governance Code and Corporate Governance Report set out in Appendix 14 to the Listing Rules
"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
"IPO"	initial public offering
"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
"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
"QIB"	a qualified institutional buyer within the meaning of Rule 144A
"RMB" or "Renminbi"	Renminbi, the lawful currency of China
"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

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 a number of hematologic malignancies
"BLA"	biologics license application
"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
"(c)GMP"	(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"	Claudin 18.2, 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

"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
"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
"HCC"	hepatocellular carcinoma, a type of cancer arising from hepatocytes in predominantly cirrhotic liver
"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
"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"	multiple myeloma, a type of cancer that forms in the white blood cells
"NDA"	new drug application
"NHL"	non-Hodgkin's lymphoma
"NK"	natural killer cell, the human body's first line of defense due to their innate ability to rapidly seek and destroy abnormal cells
"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 where multiple ascending doses are tested on the participants to primarily assess safety, tolerability and PK/PD at different dose levels prior to commencement of Phase II clinical trial or Phase III clinical trial
"Phase II"	a study in which a drug is administered to a limited patient population to identity 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
"pivotal trial"	the final controlled trial or study to demonstrate clinical efficacy and safety evidence required before submission for drug marketing approval
"PR"	partial response
"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
"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

By Order of the Board
CARsgen Therapeutics Holdings Limited
Dr. Li Zonghai
Chairman

Hong Kong, August 23, 2021

As at the date of this announcement, the board of directors of the Company comprises Dr. Li Zonghai and Dr. Wang Huamao as executive Directors; Mr. Guo Bingsen, Mr. Guo Huaqing, Mr. Xie Ronggang and Ms. Zhao Yachao as non-executive Directors; Dr. Fan Chunhai, Dr. Yan Guangmei and Mr. So Tak Young as the independent non-executive Directors.