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, 2022

The board (the "**Board**") of directors (the "**Directors**") 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, 2022 (the "**Reporting Period**"), together with comparative figures for the same period of 2021.

FINANCIAL HIGHLIGHTS

	Six months ended June 30,	
	2022	2021
	RMB'000	*RMB'000*
Net loss	**(376,338)**	(4,393,846)
Net loss per share	**(0.69)**	(19.68)
Non-IFRS Measures		
Adjusted net loss[(1)]	**(352,888)**	(210,248)
Adjusted net loss per share[(1)]	**(0.65)**	(0.94)

	As at June 30, 2022	As at December 31, 2021
	RMB'000	*RMB'000*
Cash and cash equivalents	**600,030**	691,284
Terms deposits with original maturity between three and twelve months	**2,140,091**	2,315,654
Total	**2,740,121**	3,006,938

Our net loss was RMB376 million for the six months ended June 30, 2022, representing a decrease of RMB4,018 million from RMB4,394 million for the six months ended June 30, 2021. The decrease was primarily due to (i) the decrease of fair value loss on financial instruments issued to investors (the "**Fair Value Loss**"), which was zero for the six months ended June 30, 2022. The Fair value loss related financial instruments were converted to ordinary shares upon the Completion of the Company's initial public offering on June 18, 2021 (the "**IPO**"), hence no loss would be recognized after the IPO; and (ii) the listing fees of approximately RMB27 million (the "**Listing Fees**") for the six months ended June 30, 2021, while no listing fee was incurred during the six months ended June 30, 2022; and was partially offset by (i) the share-based compensation (together with the Fair Value Loss and the Listing Fees, collectively the "**Adjusted Items**"), which totaled RMB23 million for the six months ended June 30, 2022, representing an increase of RMB22 million from RMB1 million for the six months ended June 30, 2021; and (ii) higher research and development expenses and higher administrative expenses.

Our adjusted net loss[(1)] was RMB353 million for the six months ended June 30, 2022, representing an increase of RMB143 million from RMB210 million for the six months ended June 30, 2021. The increase was primarily due to higher research and development expenses and higher general and administrative expenses.

Cash and cash equivalents and short-term investments were RMB2,740 million as of June 30, 2022, representing a decrease of RMB267 million from RMB3,007 million as of December 31, 2021. The decrease mostly resulted from research and development expenses, administrative expenses and investment of capex.

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

BUSINESS HIGHLIGHTS

As of the date of this announcement, we have made significant progress in advancing our technology innovations, product pipeline and business operations in the U.S. and China.

CT053

CT053 is an autologous fully human chimeric antigen receptor (CAR) T-cell product candidate against B-cell maturation antigen (BCMA) for the treatment of relapsed/refractory multiple myeloma (R/R MM). We have completed patient enrollment in our pivotal Phase II trial in China. Enrollment in the pivotal Phase 2 clinical trial in North America is active. We plan to submit the new drug application (NDA) to China National Medical Products Administration (NMPA) in the third quarter of 2022 and plan to submit the biologics license application (BLA) to the U.S. Food and Drug Administration (FDA) in 2023. An update from the China investigator-initiated trials (IITs) was published in *Haematologica*.

CT041

CT041 is an autologous humanized CAR T-cell product candidate against CLDN18.2, a membrane protein highly expressed in certain cancers. As of the date of this announcement, CT041 is the world's first and the only CAR T-cell candidate for the treatment of solid tumors entering a confirmatory Phase II clinical trial. CT041 targets the treatment of CLDN18.2-positive solid tumors. Active CT041 trials include a Phase 1b/2 clinical trial for advanced gastric cancer/gastroesophageal junction cancer (GC/GEJ) and pancreatic cancer (PC) in North America (CT041-ST-02, NCT04404595), a Phase Ib clinical trial for advanced GC/GEJ and PC and a confirmatory Phase II clinical trial for advanced GC/GEJ in China (CT041-ST-01, NCT04581473), and IITs. We plan to submit an NDA to the NMPA in China in the first half of 2024 and initiate a Phase 2 clinical trial in the second half of 2022 in North America.

Updates from the Phase 1b study in the U.S. (NCT04404595) and the Phase Ib/II study in China (NCT04581473) were provided in poster presentations at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting in June 2022. An update from a China IIT was published in *Nature Medicine* in May 2022.

AB011

AB011 is a humanized monoclonal antibody product candidate against CLDN18.2 for the treatment of CLDN18.2-positive solid tumors. We have completed Phase I monotherapy cohort enrollment and initiated a trial for combination with chemotherapy for GC/GEJ and PC.

Discovery and Preclinical Development

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

We focus on four strategic pillars: (1) increasing **efficacy** against solid tumors with technologies such as CycloCAR®; (2) enhancing **safety profiles** with technologies such as sFv-ε-based T-cell therapy; (3) expanding **patient accessibility** with our differentiated allogeneic THANK-uCAR® technology; and (4) improving **target availability t**hrough LADAR®.

Platform technologies in these strategic research areas can be used to upgrade our existing product candidates and to generate future innovative pipeline product candidates.

Manufacturing Capacity

We have established in-house, vertically integrated manufacturing capabilities for the three key stages of CAR T manufacturing, including the production of plasmids, lentiviral vectors, and CAR T cells.

We have been expanding our global manufacturing capacity in China and the U.S. to support both clinical trials and the subsequent commercialization of our pipeline products. With the clinical manufacturing facility in Xuhui, Shanghai and commercial GMP manufacturing facility in Jinshan, Shanghai ("**Jinshan Manufacturing Facility**"), we manufacture CAR T-cell products in-house to support clinical trials in China and manufacture the lentiviral vectors in-house to support clinical trials globally. Our Research Triangle Park (RTP) CGMP manufacturing facility in Durham, North Carolina ("**RTP Manufacturing Facility**") will support the Company's ongoing clinical studies and early commercial launch in North America and Europe.

MANAGEMENT DISCUSSION AND ANALYSIS

I. OVERVIEW

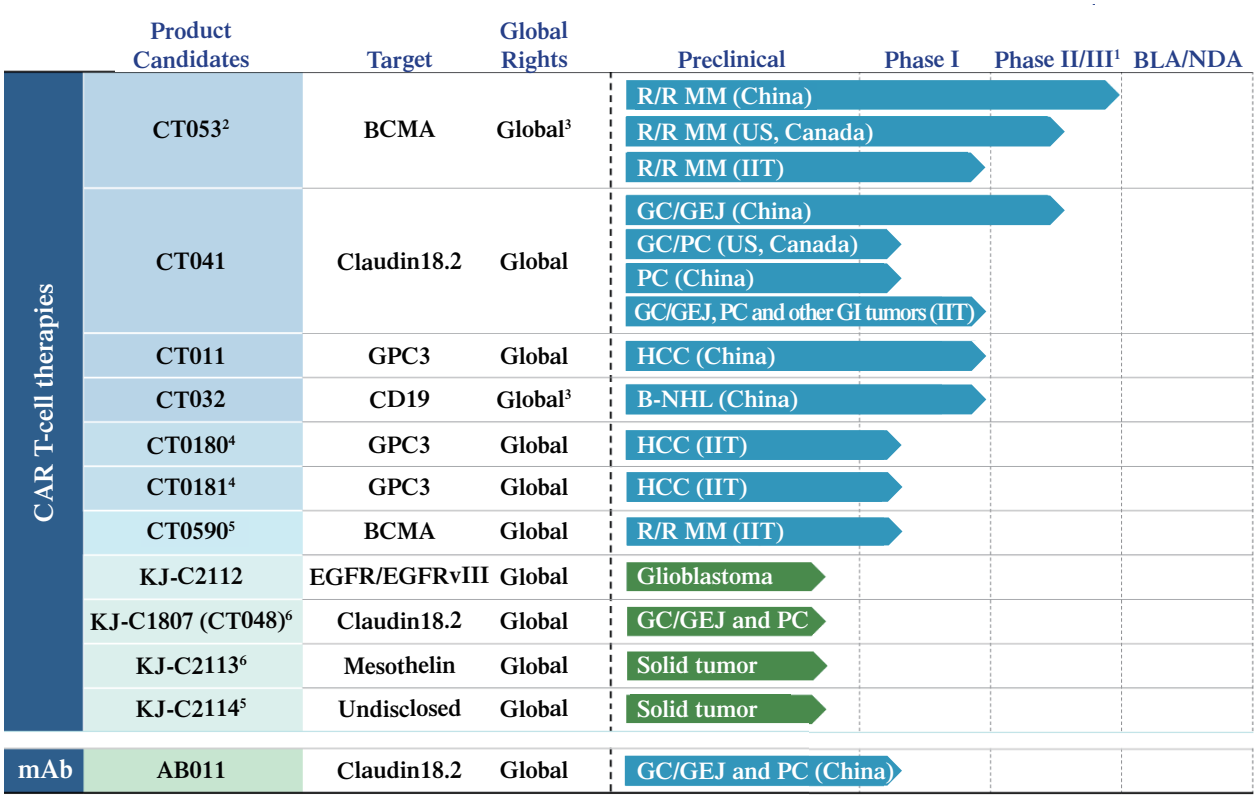
CARsgen is a biopharmaceutical company with operations in China and the U.S. mainly focusing on innovative CAR T-cell therapies for the treatment of hematologic malignancies and solid tumors. CARsgen has built an integrated platform to accelerate the cell therapy development life cycle with in-house capabilities including target discovery, antibody development, clinical development, and commercial-scale manufacturing. CARsgen has internally developed novel technologies and a product pipeline with global rights to overcome major challenges of CAR T-cell therapies, such as improving the safety profile, enhancing the efficacy in treating solid tumors, and reducing treatment associated costs. Our vision is to be a global biopharmaceutical leader that brings innovative and effective cell therapies to cancer patients worldwide and makes cancer curable.

As of the date of this announcement, we have made significant advancements in the clinical development of our pipeline products, technological innovations, and business operations in the U.S. and China.

II. BUSINESS REVIEW

Our Products and Product Pipeline

Since CARsgen's inception, our strategic business model has comprised the in-house development of innovative and differentiated biopharmaceutical products with a focus on CAR T-cell therapies. Our Core Product Candidate, CT053 for the treatment of the hematologic malignancy R/R MM, is at the most advanced development stage among the product candidates in our pipeline. In addition, solid tumor product candidates are in confirmatory Phase II (CT041), Phase I (CT011), and Phase Ib (AB011) clinical trials. The following chart summarizes the development status of each product candidate in our pipeline as of the date of this announcement. Our product candidates are developed in-house and protected by the global rights owned by CARsgen.



BCMA: B-cell maturation antigen; B-NHL: B-cell non-Hodgkin's lymphoma; EGFR/EGFRvIII: epidermal growth factor receptor, wildtype/variant III; GC: gastric cancer; GEJ: gastroesophageal junction cancer; GI: gastrointestinal; HCC: hepatocellular carcinoma; mAb: monoclonal antibody; PC: pancreatic cancer; R/R MM: relapsed/refractory multiple myeloma.

Notes:

1. Phase II/2 trials of some indications are pivotal studies.

2. Core product candidate.

3. Rights in the South Korean market have been licensed to HK Inno.N Corporation (KOSDAQ: 195940).

4. Developed with our sFv-ε-based T-cell therapy.

5. Developed with our THANK-uCAR® technology.

6. Developed with our CycloCAR® technology.

Fully Human BCMA CAR T (CT053)

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

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

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

Updated data for a total of 14 heavily pretreated patients who received CT053 infusion in the Phase I LUMMICAR STUDY 1 in China were presented at the 2021 American Society of Hematology (ASH) Annual Meeting. No dose-limiting toxicities (DLTs), no treatment-related deaths, and no Grade 3 or higher events of cytokine release syndrome (CRS) were observed. No patient developed immune effector cell-associated neurotoxicity syndrome (ICANS). At the cutoff date of July 8, 2021, with median follow up 13.6 months, the objective response rate (ORR) was 100% (14/14). Of these 14 patients, 78.6% (11/14) achieved stringent complete response (sCR) with no minimal residual disease, and 64.3% (9/14) reached complete response (CR)/sCR for more than 12 months. In addition, 92.9% (13/14) of patients achieved at least very good partial response (VGPR). The 12-month progression-free survival (PFS) rate was 85.7% (12/14). The median duration of response (mDOR) and the median PFS (mPFS) had not been reached. For the patients without extramedullary disease (EMD), the CR/sCR rate was 91.7% (11/12) and the 12-month PFS rate reached 100%, which demonstrate better treatment trends.

Updated results for our investigator-initiated trials (IITs) were published in *Haematologica*. A total of 24 heavily pretreated patients received CT053 BCMA CAR T-cell infusion. No treatment-related deaths and no Grade 3 or higher events of CRS were observed. One patient developed Grade 3 neurotoxicity (convulsion), which quickly resolved. As of June 30, 2021, with a median follow-up time of 17.4 months, the ORR was 87.5% and the CR/sCR was 79.2%. The CR/sCR rate was 70% for patients with EMD and 86% in patients without EMD. The duration of response (DOR) was 21.8 months and PFS was 18.8 months. Median overall survival (OS) was not reached.

CT053 represents a promising treatment option for patients with R/R MM, including patients with high-risk disease, and it is generally well-tolerated. An integrated analysis in patients with R/R MM and high-risk disease factors was presented at the 2021 ASH Annual Meeting. A total of 38 patients (IITs and LUMMICAR STUDY 1) received CT053 infusions. Of these, 31.6% of patients had EMD, 50.0% of patients had high-risk cytogenetics, and 28.9% of patients had International Staging System (ISS) stage III disease. Although 50% of patients had high-risk disease factors at baseline, the ORR was 92.1% (35/38), with 78.9% (30/38) of patients achieving CR/sCR and 86.8% (33/38) of patients achieving at least VGPR. Further, the mPFS was 22.7 months and mDOR was 24.0 months for all patients.

In North America, the pivotal Phase 2 CT053 trial of LUMMICAR STUDY 2 is active. As communicated with the U.S. FDA, we have added outpatient administration of CT053 to our U.S. clinical trial. We are conducting a technology transfer in order for our RTP CGMP facility to support LUMMICAR STUDY 2 in North America.

Additional data from these global clinical trials will be disclosed in academic journals or at scientific conferences.

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

We may not be able to ultimately market CT053 successfully.

Humanized CLDN18.2 CAR T (CT041)

CT041 is an autologous CAR T-cell product candidate against the protein CLDN18.2 and has the potential to be first-in-class globally. CT041 targets the treatment of CLDN18.2-positive solid tumors with a primary focus on GC/GEJ and PC. CLDN18.2 is expressed in a range of solid tumors, including GC/GEJ, PC, 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 and viable target for CAR T-cell therapy for solid tumors in which CLDN18.2 is prevalently or highly expressed. To further address the challenges of CAR T-cell therapies in treating solid tumors, we developed an innovative, patent-protected preconditioning regimen that is administered prior to infusion of CT041. This FNC regimen features the addition of low-dose nab-paclitaxel to the conventional lymphodepletion regimen comprising cyclophosphamide and fludarabine.

CT041 received Orphan Drug designation from the U.S. FDA in 2020 for the treatment of GC/GEJ and Orphan Medicinal Product designation from the EMA in 2021 for the treatment of advanced gastric cancer. CT041 was granted PRIME eligibility by the EMA for the treatment of advanced gastric cancer in 2021 and was granted RMAT Designation for the treatment of advanced GC/GEJ with CLDN18.2-positive tumors in 2022.

As of the date of this announcement, CT041 is the world's first and the only CAR T-cell candidate for the treatment of solid tumors entering a confirmatory Phase II clinical trial.

Active trials in CARsgen include a Phase 1b/2 clinical trial for advanced GC/GEJ and PC in North America (CT041-ST-02, NCT04404595), a Phase Ib clinical trial for advanced GC/GEJ and PC and a confirmatory Phase II clinical trial for advanced GC/GEJ in China (CT041-ST-01, NCT04581473), and IITs. CARsgen plans to submit an NDA to the NMPA in China in the first half of 2024. CT041 have now completed the dose escalation and initiated the dose expansion in U.S.. CARsgen also plans to initiate a Phase 2 clinical trial in the second half of 2022 in North America and to submit the BLA to the U.S. FDA in 2024.

At the 2022 ASCO Annual Meeting, the Company presented two posters with updated study results for CT041 in the Phase 1b trial in the U.S. and the Phase Ib/II trial in China.

Phase 1b trial (NCT04404595) in North America

The single-arm, open-label, Phase 1b trial (NCT04404595) is currently active in the U.S. and Canada. CLDN18.2-positive patients with GC/GEJ and two or more prior lines of systemic therapy, or PC and one or more prior line of therapy are eligible for the study.

As of May 6, 2022, we enrolled 14 patients (5 GC/GEJ, 9 PC) with a median of 3 prior lines of therapy (range 1-5) and had received 18 total cycles of CT041. These 14 patients received CT041 three dose levels (DLs) including DL1 of 2.5-3.0×10^8 cells (n=6), DL2 of 3.75-4.0×10^8 cells (n=6) and DL3 of 6.0×10^8 cells (n=2).

No DLTs or treatment-related deaths were observed. Also, no Grade 3 or greater CRS or ICANS was observed, and no gastrointestinal bleeding or acute gastric mucosal injury were reported. Only 1 patient did not have CRS. Among the 13 patients who experienced CRS, 11 patients had Grade 1 and 2 patients had Grade 2.

In the subgroup of patients with GC/GEJ, the ORR was 60% (3/5). Among the 9 PC patients, 2 patients had not had tumor response assessments by the data cutoff date, and 4 patients achieved stable disease with tumor shrinkage. mDOR and mPFS had not been reached.

Phase Ib/II study (NCT04581473) in China

The multicenter, open-label, Phase Ib/II study (NCT04581473) is evaluating the safety and efficacy of CT041 in Chinese patients with GC/GEJ. In Phase Ib, CT041 DLs of 2.5×10^8 and 3.75×10^8 cells were investigated using a 3 + 3 design. Key inclusion criteria for the Phase Ib study included patients with advanced GC/GEJ and CLDN18.2-positive tumor expression confirmed by immunohistochemistry (IHC) staining (2+/3+ in ≥ 40% of tumor cells), who were refractory to or intolerant of at least 2 prior treatments. HER2-positive patients should have received standard anti-HER2 therapy.

As of December 22, 2021, 14 eligible patients with GC/GEJ were enrolled in Phase Ib, among whom 57.1% had ≥ 3 organs metastatic involvement and 92.9% had peritoneal dissemination. Most of the patients (85.7%) had received 2 prior treatments or a triple combination of fluoropyrimidine, oxaliplatin and paclitaxel. About a third (35.7%) of the patients had been exposed to a PD-1/PD-L1 inhibitor.

All patients received at least one infusion (11 received 2.5×10^8 cells and 3 received 3.75×10^8 cells) of CT041 and 7 patients received two infusions. For the 7 patients who received two infusions, the median interval between infusions was 132 days (range 49-252 days).

No patients had DLTs or adverse events leading to death. Thirteen patients had Grade 2 CRS, and only one patient had Grade 4 CRS, which was related to their disease burden, who fully recovered after corticosteroid treatment. No ICANS or gastrointestinal mucosal injury was reported.

Thirteen patients were evaluable for response and one patient withdrew from the study before any tumor assessment was performed. Eight of 14 (57.1%) patients achieved partial response (PR) at the first tumor assessment after the first CT041 infusion. Based on the investigators' assessment, the ORR and disease control rate (DCR) were 57.1% and 78.6%, respectively. While the median follow-up time was 8.8 months, the mPFS and median OS were 5.6 months and 10.8 months, respectively.

Investigator-initiated trial

The interim results of the investigator-initiated trial of CT041 were reported in the *Nature Medicine* article titled "Claudin18.2-specific CAR T cells in gastrointestinal cancers: Phase I trial interim results", and were also orally presented at the European Society for Medical Oncology Congress 2021 ("**ESMO Congress 2021**"). As of April 8, 2021, 49 patients were infused. The first 37 patients who received CT041 infusion and completed at least 12 weeks of evaluation were included in this interim analysis, including 28 cases of GC/GEJ, 5 cases of PC and 4 cases of other digestive system tumors. Approximately 83.8% of patients had received at least 2 prior lines of therapies and 50% of them had at least three organ sites involved.

For the 28 patients with GC/GEJ, 67.9% of the patients had peritoneal metastases, 42.9% had anti-PD-1/PD-L1 antibody exposure, and 35.7% had multikinase inhibitor exposure.

CT041 was generally well-tolerated with no Grade 3 or higher CRS and no neurotoxicity reported. No treatment-related death and no ICANS were reported.

Within the 28 patients with GC/GEJ, 18 received at least 2 prior lines of therapies and were treated at a dose of 2.5×10^8 CAR T cells (recommended Phase II dose), among whom 8 (44%) patients had been exposed to an anti-PD-1/PD-L1 antibody. These 18 patients achieved an ORR of 61.1%, DCR of 83.3%, median PFS of 5.6 months, a DOR rate at 6 months of 57.1%. PFS, OS and follow-up duration were calculated from the CT041 infusion date.

For the 28 patients with GC/GEJ, a subgroup analysis revealed that ORR reached 50% or above in patients with different baseline characteristics, such as expression level of CLDN18.2 and previous anti-PD-1/PD-L1 antibody treatment. See the following table for details:

Table 1. CT041 Investigator-initiated trial – Phase I subgroup interim results

Baseline disease characteristics	No. of patients with GC/GEJ (n = 28)	No. of patients with partial response	Subgroup ORR
CLDN18.2 expression			
High expression	16	10	63%
Low/middle expression	12	6	50%
PD-1/PD-L1 exposure			
Not exposed	16	10	63%
Exposed	12	6	50%
WHO classification			
Signet ring cell carcinoma	12	7	58%
Other	16	9	56%
Lauren classification			
Intestinal	10	7	70%
Non-intestinal	18	9	50%

Excerpted and adapted from the subgroup analysis in CARsgen's *Nature Medicine* paper.

CT041 also showed preliminary efficacy in five evaluable patients with PC who failed at least 2 prior lines of systemic treatment.

CT041 has demonstrated promising therapeutic efficacy and safety in the ongoing investigator-initiated trial, which is led by Dr. Lin SHEN at the Beijing Cancer Hospital, in China for CLDN18.2 positive GC/GEJ and PC.

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

We may not be able to ultimately market CT041 successfully.

Humanized GPC3 CAR T (CT011)

CT011 is an autologous CAR T-cell product candidate with proof-of-concept clinical data for the treatment of hepatocellular carcinoma (HCC) and has the potential to be the first-in-class globally. Our co-founder, CEO and Chief Scientific Officer, Dr. Zonghai 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-cell therapies to treat HCC. Our investigator-initiated trial in China enrolled 13 patients with advanced GPC3+ HCC and demonstrated that CT011 therapy was generally tolerable in patients who have been heavily pretreated. The OS rates at 6 months, 1 year and 3 years were 50.3%, 42.0% and 10.5%, respectively, with a median OS of 278 days. We have completed enrollment of a Phase I trial in China.

A case report of long-term complete response of advanced hepatocellular carcinoma using CT011 was published in Frontiers in Immunology in August 2022. To the best of our knowledge, this is the first reported case of complete response after the combination therapy of CAR T cells with tyrosine kinase inhibitors.

Humanized CD19 CAR T (CT032)

CT032 is an autologous CAR T-cell product candidate against CD19 being developed for the treatment of B-cell NHL. CT032 incorporates a humanized CD19-specific single-chain fragment variant, which we expect to reduce the toxicity of CT032 and reduce immunogenicity, as compared to currently commercialized CD19-specific CAR T-cell products which use murine anti-CD19 scFv 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 GC/GEJ and PC 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 investigational new drug (IND) clearance in the world for a mAb targeting CLDN18.2. We are conducting a Phase I clinical trial of AB011 for the treatment of CLDN18.2 positive solid tumors in China to evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy of AB011 injection.

In the second quarter of 2021 we received supplemental application approval by the Center for Drug Evaluation (CDE) regarding the addition of chemotherapy combination cohort with AB011 in Phase Ib, and we have subsequently initiated the combination cohort of AB011 with chemotherapy. We completed Phase I monotherapy cohort enrollment and initiated combination with chemotherapy. During the combination treatment phase, the first two patients with advanced gastric cancer were assessed to be in PR at week 6 after the first dose.

IND-Enabling or Preclinical Stage Product Candidates

In addition to the above clinical-stage product candidates currently in IND trials, we have internally developed seven IND-enabling or preclinical product candidates as described below. Three of these products, CT0180, CT0181 and CT0590, are already in the IIT clinical stage.

CT0180 is an autologous T-cell product engineered to express a fusion protein of GPC3-targeted antibody and T-cell receptor. An IIT trial has been initiated in China to evaluate the efficacy and safety of CT0180 in the treatment of hepatocellular carcinoma.

CT0181 is an autologous T-cell product engineered with a GPC3-targeted antibody-fused T-cell receptor co-expressing the interleukin (IL)-7 cytokine. An IIT trial has been initiated in China to evaluate the efficacy and safety of CT0181 in the treatment of hepatocellular carcinoma.

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

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

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

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

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

Continuous Discovery and Technology Development

Despite the approval of some CAR T-cell products for the last-line treatment of hematologic malignancies, significant challenges still remain, such as limited efficacies against solid tumors, undesirable safety concerns, and high manufacturing and treatment costs. We strive to explore and develop innovative technology platforms to address these challenges to generate better cell therapy products to global cancer patients.

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

We continue to dedicate ourselves to advancing innovative CAR T technologies to address the major challenges of the industry. Our four strategic pillars include:

(1) **Efficacy**: To enhance efficacy against solid tumors, we continue to develop next-generation CAR T technologies, such as CycloCAR®. CycloCAR® features the co-expression of cytokine IL-7 and chemokine CCL21 in CAR T cells to potentially improve clinical efficacy and reduce the requirement of lymphodepletion conditioning. Our preclinical studies showed that IL-7 enhanced the proliferation and survival of CAR T cells and inhibited the apoptosis of CAR T cells, and CCL21 could drive infiltration of T cells and dendritic cells into tumor sites. The preclinical CycloCAR T cells improved 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). Our studies demonstrated that, independent of lymphodepletion chemotherapy, CycloCAR T cells exerted potent antitumor effects that were facilitated by infiltration of T cells and dendritic cells into tumor tissues, CycloCAR T cells experienced increased survival, and a potential anti-angiogenesis effect. We are using CycloCAR® to develop CAR T-cell therapies against several 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.

(2) **Safety**: To minimize safety concerns, we continue to develop innovative technologies that can help reduce the risk of CRS, neurotoxicity and on-target off-tumor toxicities and to improve applicability of adoptive cell therapies. We leverage our in-house 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 levels of cytokine release. As an evidence of our antibody engineering capabilities, we have developed CT053, which did not induce Grade 3 or higher CRS in the IITs or in the Phase I clinical trials and reduced the need for anti-IL-6 medication and other immunosuppressant mediation (data as of the respective data cutoff dates for the ongoing IITs and clinical trials).

To improve the applicability of adoptive cell therapies, we developed the sFv-ε-based T-cell therapy powered by a full T-cell receptor (TCR) complex comprising a GPC3-targeted scFv and a CD3ε subunit, which can form a functional TCR complex with other TCR subunits (TCRα, TCRβ, CD3γ, CD3δ and CD3ζ) and redirect T cells to kill tumor cells in an MHC-independent manner. Our preclinical studies showed that sFv-ε-based T-cell therapies could effectively recognize and kill carcinoma cells and significantly inhibit tumor growth in mouse xenograft models with reduced cytokine release in vitro and in vivo, which could improve the safety and applicability of adoptive cell therapies. In addition, the co-expressed IL-7 is a cytokine that could enhance the proliferation and survival of T cells. Our preclinical studies showed that sFv-ε-based T-cell therapies displayed superior antitumor efficacy, T-cell persistence, and immunological memory in solid tumors xenografts with low cytokine release.

(3) **Patient accessibility**: To reduce the cost and increase the accessibility of CAR T-cell therapies, we continue to develop our market-differentiating allogeneic THANK-uCAR® technology. THANK-uCAR® is our proprietary technology to generate allogeneic CAR T cells with improved expansion and persistence by modifying donor-derived T cells. To minimize graft versus host disease (GvHD) and host versus graft response (HvGR) from allogeneic T cells, we disrupt the genomic loci encoding TCR and β2 microglobulin (B2M) to eliminate surface expression of the TCR or the human leukocyte antigen (HLA), an approach that has been validated by previous research. However, natural killer (NK) cells attack T cells without HLA expression, which then limits the expansion and persistence of the allogeneic CAR T cells. To protect the allogeneic CAR T cells from the patient's NK cells, we arm these TCR-/HLA- CAR T cells with a CAR that recognizes NKG2A to hinder the NKG2A-positive NK cell rejection of the CAR T cells and therefore allow the THANK-uCAR T cells to resist the attack by NK cells. Our in vitro and in vivo studies demonstrated that the armoring the TCR-/HLA- CAR T cells with the anti-NKG2A CAR resulted in improved expansion in the presence of NK cells. We are developing allogeneic CAR T-cell product candidates using THANK-uCAR® technology, which we believe could potentially increase CAR T cell expansion, persistence and efficacy. We believe the successful application of THANK-uCAR® technology would significantly lower the cost of CAR T-cell therapy and increase patient accessibility.

(4) **Target availability**: In the development of cancer therapies, the expression of tumor-associated antigens in normal tissues poses a significant challenge, as this expression pattern leads to on-target off-tumor toxicities. To resolve the challenge with target availability, we continue to explore innovative technologies to enhance drug target availability and therefore turn undruggable antigens into promising targets. We developed LADAR® technology (local action driven by artificial receptor), in which an artificial receptor is triggered by a LADAR Ligand to induce the transcription of the gene(s) of interest (eg, the tumor antigen-targeted CAR, plus any cytokines or other therapeutic mediators). Through the LADAR® artificial receptor, the antitumor CAR transcription is only triggered when the LADAR binds to a LADAR Ligand, making it possible to precisely control when and where immune cells act against cancer cells.

The LADAR-CAR signaling circuits require both antigens for LADAR® and CAR recognition to kill target cells, thus reducing on-target off-tumor effects when these two antigens are not simultaneously expressed in the same normal tissues. In our in vitro studies, the LADAR® system induced strong therapeutic gene expression in response to antigen engagement and, importantly, negligible leakage expression in resting cells. LADAR-CAR T cells executed killing function only if both antigens were present.

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

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

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

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

As of June 30, 2022, we had more than 300 patents of which 70 patents had been issued globally including China, the United States, Europe and Japan. This status is an increase of 7 issued patents and 21 patent applications from the end of 2021. Our R&D activities would continue to generate substantial intellectual property in our areas of expertise.

Manufacturing

We have established in-house GMP-compliant manufacturing capabilities to support vertically integrated CAR T manufacturing, including plasmids, lentiviral vectors, and CAR T-cell production. The vertically integrated production contributes to increased efficiency and enhanced control, resulting in improved drug product consistency and faster turnaround times for patients, especially for patients with rapidly progressing solid tumors. The integrated manufacturing will also significantly reduce costs and improve margins for more advantageous commercialization.

We have been expanding our manufacturing capacity in China and the U.S. to support both the clinical trials and the subsequent commercialization of our pipeline products.

Our clinical manufacturing facility in Xuhui, Shanghai with a total gross floor area (GFA) of approximately 3,000 sq.m. and an annual CAR T production capacity to support the CAR T-cell treatment of 200 patients has been used for clinical manufacturing of CAR T-cell products in supporting multiple clinical studies of our leading assets. Since establishment, our Xuhui facility has achieved over 95% manufacturing success rate for all product candidates.

We have also completed the construction of our commercial-scale manufacturing facility located in Jinshan, Shanghai with a total GFA of approximately 7,600 sq.m. and an estimated manufacturing capacity to support CAR T-cell treatment of up to 2,000 patients annually. The Jinshan Manufacturing Facility passed the on-site inspection conducted by the Shanghai Medical Products Administration (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 can produce the lentiviral vectors and CAR T cells in-house to support clinical trials and CAR T-cell commercialization in China. We also provide the lentiviral vectors to clinical trials outside of China.

We have made significant progress in expanding CARsgen's manufacturing capacity outside China by launching a state-of-the-art GMP Manufacturing Facility in Research Triangle Park, Durham, North Carolina. We successfully passed the official inspections and received the Certificate of Compliance from the City-County Inspections Department of Durham. We have commenced commissioning, qualification, and validation of RTP Manufacturing Facility through the RMAT consultation with the FDA. Concurrently, we have been executing the technology transfer to RTP Manufacturing Facility, advancing to the clinical manufacturing of CT041 and CT053 products.

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

By building vertically integrated manufacturing capabilities in-house, we expect to significantly increase manufacturing sustainability, reduce manufacturing costs, and shorten the vein-to-vein time. In addition, we have an in-house GMP-compliant manufacturing facility capable of high yield production of lentiviral vectors. To accelerate the clinical production at the RTP Manufacturing Facility, CARsgen Jinshan Manufacturing Facility will provide the lentiviral vector to support CAR T-cell production for CT053 and CT041 clinical studies in North America. With large scale lentiviral vectors production, we could greatly reduce the CAR T manufacturing costs.

Commercialization

To better prepare for the commercialization of our innovative CAR T-cell products, we have started to formulate our marketing strategies in a staggered approach corresponding to the expected launch timeline of our product candidates. The staggered approach features stepwise expansion of our future marketing efforts. We have established a marketing team for the pre-launch activities of CT053 and CT041.

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

Expansion and Retention of Talent

As of June 30, 2022, we had a total of 601 employees. We have also strengthened the leadership team: we hired Dr. Raffaele BAFFA as the Chief Medical Officer of the Company, and Mr. Richard DALY as the President of CARsgen Therapeutics Corporation. Biographical details of the senior management team are provided on the Company's website at **www.CARsgen.com**.

Other Corporate Development

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

Impact of COVID-19

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

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

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

Industry Overview

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

Future and Outlook

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

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 RMB368 million and RMB234 million for the six months ended June 30, 2022 and 2021, respectively. Substantially all of our operating losses resulted from research and development expenses and administrative expenses.

Loss for the periods

Our net loss was RMB376 million for the six months ended June 30, 2022, representing a decrease of RMB4,018 million from RMB4,394 million for the six months ended June 30, 2021. The decrease was primarily due to (i) the decrease of fair value loss on financial instruments issued to investors (the "**Fair Value Loss**"), which was zero for the six months ended June 30, 2022. The Fair value loss related financial instruments were converted to ordinary shares upon the Completion of the Company's initial public offering on June 18, 2021 (the "**IPO**"), hence no loss would be recognized after the IPO; and (ii) the listing fees of approximately RMB27 million (the "**Listing Fees**") for the six months ended June 30, 2021, while no listing fee was incurred during the six months ended June 30, 2022; and was partially offset by (i) the share-based compensation (together with the Fair Value Loss and the Listing Fees, collectively the "**Adjusted Items**"), which totaled RMB23 million for the six months ended June 30, 2022, representing an increase of RMB22 million from RMB1 million for the six months ended June 30, 2021; and (ii) higher research and development expenses and higher administrative expenses.

Based on our financial performance for the six months ended June 30, 2022, and reasonable estimate of expenses to be incurred during the second half of 2022, we expect our net loss for the year ended December 31, 2022 to record a decrease of approximately 73% to 83% on a year-on-year basis. The above preliminary estimate is subject to risks and uncertainties, and the actual results may differ materially from such statements. Such statements do not constitute substantial commitments to investors. Investors are hereby reminded of risks which may result from inappropriate reliance upon or utilization of the information given above.

Non-IFRS Measures

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

Adjusted net loss for the periods and adjusted net loss per share for the periods represent the net loss and net loss per share respectively excluding the effect of certain non-cash items and 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,	
	2022	2021
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Loss for the periods	**(376,338)**	(4,393,846)
Add:		
Fair value loss of financial instrument issued to investors	**–**	4,155,572
Listing fee	**–**	26,580
Share-based compensation	**23,450**	1,446
Adjusted net loss	**(352,888)**	(210,248)

	Six months ended June 30,	
	2022	2021
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Loss per share for the periods	**(0.69)**	(19.68)
Add:		
Fair value loss of financial instrument issued to investors per share	**–**	18.61
Listing fee per share	**–**	0.12
Share-based compensation per share	**0.04**	0.01
Adjusted net loss per share	**(0.65)**	(0.94)

Based on our financial performance for the six months ended June 30, 2022, and reasonable estimate of expenses to be incurred during the second half of 2022, we expect our adjusted net loss for the year ended December 31, 2022 to record a decrease of approximately 51%-71% on a year-on-year basis. The above preliminary estimates are subject to risks and uncertainties, and the actual results may differ materially from such statements. Such statements do not constitute substantial commitments to investors. Investors are hereby reminded of risks which may result from inappropriate reliance upon or utilization of the information given above.

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,	
	2022	2021
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Employee benefit expenses	**144,371**	68,879
Testing and clinical expenses	**108,336**	61,697
Research and development consumables	**24,200**	23,988
Depreciation of property, plant and equipment	**13,984**	8,435
Depreciation of right-of-use assets	**11,443**	4,421
Utilities	**6,820**	2,079
Amortization of intangible assets	**2,681**	2,640
Travelling and transportation expenses	**1,628**	1,055
Professional service fees	**770**	90
Short-term lease and low-value lease expenses	**325**	191
Other expenses	**1,746**	2,232
Total	**316,304**	175,707

Research and development expenses increased to RMB316 million for the six months ended June 30, 2022, representing an increase of RMB140 million from RMB176 million for the six months ended June 30, 2021, 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,	
	2022	2021
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Employee benefit expenses	**35,295**	19,335
Professional service fees	**9,548**	5,719
Depreciation of property, plant and equipment	**5,154**	4,585
Office expenses	**4,798**	2,957
Depreciation of right-of-use assets	**1,458**	2,929
Auditors' remuneration	**1,422**	1,102
– audit service	**1,422**	1,102
– non-audit service	**–**	–
Travelling and transportation expenses	**1,010**	246
Utilities	**803**	60
Amortization of intangible assets	**472**	248
Short-term lease and low-value lease expenses	**178**	126
Listing expenses	**–**	26,580
Other expenses	**2,843**	219
Total	**62,981**	64,106

Administrative expenses are RMB63 million for the six months ended June 30, 2022, representing a decrease of RMB1 million from RMB64 million for the six months ended June 30, 2021, primarily due to increased headcount and staff cost and no Listing fee in this period.

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,	
	2022	2021
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Wages and salaries	**132,622**	72,779
Pension costs	**9,757**	5,242
Share-based compensation	**23,450**	1,446
Other employee benefits	**13,837**	8,747
Total	**179,666**	88,214
Amount included in research and development expenses	**144,371**	68,879
Amount included in administrative expenses	**35,295**	19,335

The increase of employee benefit expenses is mainly due to higher headcount, the related increase in staff salary and benefit costs as well as higher share-based compensation due to new grants and higher stock prices post IPO.

Share-based payments

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

	Six months ended June 30,	
	2022	2021
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Administrative expenses	**3,736**	349
Research and development expenses	**19,714**	1,097
Total	**23,450**	1,446

Fair Value Loss of Financial Instruments Issued to Investors

The fair value loss of financial instruments issued to investors decrease to zero for the six months ended June 30, 2022, from RMB4,156 million for the six months ended December 31, 2021, primarily due to the financial instruments were converted to ordinary shares upon the Company's IPO in June 2021, hence no loss would be recognized after the IPO.

Liquidity and Capital Resources

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

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

	For the six months ended June 30,	
	2022	2021
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Net cash used in operating activities	**(310,464)**	(185,608)
Net cash generated from/(used in) investing activities	**148,003**	(1,591,147)
Net cash (used in)/generated from financing activities	**(8,955)**	2,640,680
Net (decrease)/increase in cash and cash equivalents	**(171,416)**	863,925
Cash and cash equivalents at beginning of the period	**691,284**	1,042,969
Exchange gain/(loss) on cash and cash equivalents	**80,162**	(11,419)
Cash and cash equivalents at end of the period	**600,030**	1,895,475

Net Cash Used in Operating Activities

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

Our net cash used in operating activities were RMB310 million and RMB186 million for the six months ended June 30, 2022 and 2021, respectively. We are currently a pre-revenue and pre-income company. We believe our pipeline products have promising global market potential in the future. We intend to continue investing in our research and development efforts and aim to obtain marketing approvals for our product candidates as soon as feasible. As we launch and commercialize our product candidates, we expect to generate operating income and improve our net operating cash outflow position.

Net Cash Generated from/Used in Investing Activities

Our cash generated in investing activities mainly reflects our net cash receipts from short term deposits and cash used for our purchase of property, plant and equipment. For the six months ended June 30, 2022, our net cash generated from investing activities was RMB148 million, which was primarily attributable to net cash receipts from investment of term deposit and offset by cash used for purchase of equipment. For the six months ended June 30, 2021, our net cash used in investing activities was RMB1,591 million, which was primarily attributable to net cash payment for investment of term deposit and purchase of equipment.

Net Cash Generated from Financing Activities

For the six months ended June 30, 2022, our net cash used in financing activities was RMB9 million, primarily attributable to payment of principals and interest of lease liabilities and payment of interest on bank borrowings. For the six months ended June 30, 2021, our net cash generated from financing activities was RMB2,641 million, which was primarily attributable to proceeds from our IPO and bank borrowings.

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

	As at June 30, 2022 ***RMB'000*** **(Unaudited)**	As at December 31, 2021 *RMB'000* (Audited)
Cash at banks		
– RMB	**57,075**	33,773
– HKD	**4,134**	–
– USD	**538,821**	657,511
Subtotal	**600,030**	**691,284**
Term deposits with original maturity between three and twelve months		
– RMB	**26,000**	–
– USD	**2,114,091**	2,315,654
Total	**2,740,121**	3,006,938

The Group's cash and cash equivalents and term deposits with original maturity between three and twelve months as at June 30, 2022 were RMB2,740 million, representing an decrease of RMB267 million compared to RMB3,007 million as at December 31, 2021. The decrease mostly resulted from our research and development expenses, administrative expenses and investment of capex.

Borrowing and Gearing Ratio

The Group's total borrowings, including interest-bearing borrowings, as at June 30, 2022 were RMB228 million, representing an increase of RMB1 million compared to RMB227 million as at December 31, 2021.

As at June 30, 2022 and December 31, 2021, the Group's bank borrowings of approximately RMB9,705,000 and RMB11,979,000 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, 2022, the Group's unsecured borrowings are mature within six to twelve months with the interest rate ranging between 3.5000% and 5.5000%.

As at June 30, 2022, the Group's secured borrowings are mature within three years with the interest rate of 5.2250%.

The gearing ratio (calculated by dividing the sum of borrowings and lease liabilities by total equity) of the Group as at June 30, 2022 was 12.3245%, representing an increase of 1.0438% compared to 11.2807% as at December 31, 2021.

Lease Liabilities

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

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

Our lease liabilities increased to RMB116 million as at June 30, 2022 from RMB111 million as at December 31, 2021, due to newly rented offices and staff dormitories.

CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

FOR THE SIX MONTHS ENDED JUNE 30, 2022

	Note	Six months ended June 30,	
		2022	2021
		RMB'000	*RMB'000*
		(Unaudited)	(Unaudited)
Administrative expenses	*5*	**(62,981)**	(64,106)
Research and development expenses	*5*	**(316,304)**	(175,707)
Other income	*3*	**10,388**	4,272
Other gains – net	*4*	**1,205**	1,282
Operating loss		**(367,692)**	(234,259)
Finance income		**726**	–
Finance costs		**(9,372)**	(4,015)
Finance costs – net	*6*	**(8,646)**	(4,015)
Fair value changes in financial instruments issued to investors		**–**	(4,155,572)
Loss before income tax		**(376,338)**	(4,393,846)
Income tax expense	*7*	**–**	–
Loss for the periods and attribute to the equity holders of the Company		**(376,338)**	(4,393,846)
Other comprehensive income for the periods:			
Items that may be reclassified to profit or loss			
Exchange differences on translation of subsidiaries		**(72,376)**	6,029
Items that will not be reclassified to profit or loss			
Exchange differences on translation of the Company		**215,132**	50,756
Fair value changes relating to financial instruments issued to investors due to the Company's own credit risk		**–**	(25,093)
Other comprehensive income for the periods, net of tax		**142,756**	31,692
Total comprehensive loss for the periods and attribute to the equity holders of the Company		**(233,582)**	(4,362,154)
Loss per share for the loss attributable to owners of the Company			
Basic and diluted loss per share (in RMB)	*8*	**(0.69)**	(19.68)

CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

AS AT JUNE 30, 2022

	Note	**As at June 30, 2022** ***RMB'000*** **(Unaudited)**	As at December 31, 2021 *RMB'000* (Audited)
ASSETS			
Non-current assets			
Property, plant and equipment		**373,412**	300,898
Right-of-use assets		**84,487**	85,291
Intangible assets		**18,181**	20,133
Other non-current assets and prepayments		**4,780**	28,460
		480,860	434,782
Current assets			
Other receivables	*9*	**28,243**	41,885
Other current assets and prepayments		**30,547**	22,030
Term deposits with original maturity between three and twelve months		**2,140,091**	2,315,654
Cash and cash equivalents		**600,030**	691,284
		2,798,911	3,070,853
Total assets		**3,279,771**	3,505,635
EQUITY AND LIABILITIES			
Equity attributable to the equity holders of the Company			
Share capital	*10*	**1**	1
Reserves		**2,790,650**	2,996,659
Total equity		**2,790,651**	2,996,660
LIABILITIES			
Non-current liabilities			
Borrowings	*12*	**4,981**	7,375
Lease liabilities		**99,748**	97,312
Deferred income		**14,364**	15,116
		119,093	119,803
Current liabilities			
Lease liabilities		**15,954**	14,027
Accruals and other payables	*13*	**122,551**	138,025
Current income tax payable		**700**	7,645
Deferred income		**7,571**	10,144
Borrowings	*12*	**223,251**	219,331
		370,027	389,172
Total liabilities		**489,120**	508,975
Total equity and liabilities		**3,279,771**	3,505,635

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, 2022.

2. BASIS OF PREPARATION

This condensed interim financial information for the six months ended June 30, 2022 has been prepared in accordance with International Accounting Standard ("IAS") 34 "Interim Financial Reporting" issued by the International Accounting Standards Board ("IASB"). This Condensed Interim Financial Information should be read in conjunction with the annual financial statements for the year ended December 31, 2021 ("2021 Annual Financial Statements"), which have been prepared in accordance with International Financial Reporting Standards ("IFRSs") issued by the IASB.

Except for the newly effective standards, amendments and interpretations that became applicable to the Group first time in the six months ended June 30, 2022, the accounting policies applied are consistent with 2021 Annual Financial Statement.

The consolidated financial statements have been prepared under the historical cost convention.

The consolidated financial statements are presented in thousands of Renminbi ("RMB'000"), unless otherwise stated.

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, 2022:

- Property, Plant and Equipment: Proceeds before intended use – Amendments to IAS 16
- Reference to the Conceptual Framework – Amendments to IFRS 3
- Onerous Contracts – Cost of Fulfilling a Contract – Amendments to IAS 37
- Annual Improvements to IFRS Standards 2018 – 2020

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 adjustment.

2.2. New standards, amendments and interpretation not yet adopted

Certain new accounting standard, amendments and interpretation have been published but are not mandatory for the financial year beginning January 1, 2021 and have not been early adopted by the Group. These new accounting standard, amendments and interpretation are not expected to have a material impact on the Group's financial statements when they become effective.

3. OTHER INCOME

	Six months ended June 30,	
	2022	2021
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Government grants (i)	**4,419**	2,334
Interest income on bank deposit	**5,969**	1,938
Total	**10,388**	4,272

(i) The government grants mainly represent subsidies received from the government in relation to the support on certain research and development projects. There are no unfulfilled conditions or other contingencies attached to these grants.

4. OTHER GAINS – NET

	Six months ended June 30,	
	2022	2021
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Net foreign exchange gains – net	**2,313**	1,476
Others	**(1,108)**	(194)
Total	**1,205**	1,282

5. EXPENSE BY NATURE

	Six months ended June 30,	
	2022	2021
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Employee benefit expenses	**179,666**	88,214
Testing and clinical expenses	**108,336**	61,697
Research and development consumables	**24,200**	23,988
Depreciation of property, plant and equipment	**19,138**	13,020
Depreciation of right-of-use assets	**12,901**	7,350
Professional service fees	**10,318**	5,809
Utilities	**7,623**	2,139
Office expenses	**4,798**	2,957
Amortization of intangible assets	**3,153**	2,888
Travelling and transportation expenses	**2,638**	1,301
Auditors' remuneration	**1,422**	1,102
– Audit service	**1,422**	1,102
– Non-audit service	**–**	–
Short-term lease and low-value lease expenses	**503**	317
Listing expenses through statement of profit and loss	**–**	26,580
Other expenses	**4,589**	2,451
Total	**379,285**	239,813

6. FINANCE COSTS – NET

	Six months ended June 30,	
	2022	2021
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Finance income		
Interest income	**(726)**	–
Finance costs		
Interest expense on lease liabilities	**2,532**	927
Interest expense on bank borrowings	**6,840**	3,088
Total finance costs	**9,372**	4,015
Total finance costs – net	**8,646**	4,015

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 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) 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, 2022 and 2021. CARsgen USA was also subject to the state income tax for the six months ended June 30, 2022 and 2021.

No provision for US corporate income tax was provided for as there's no assessable profit.

(e) British Virgin Islands income tax

Under the current laws of BVI, the subsidiary incorporated in BVI is not subject to tax on income or capital gains. In addition, upon payments of dividends by our BVI subsidiaries to us, no BVI withholding tax is imposed.

(f) Ireland corporation income tax

Subsidiary in Ireland is subject to income tax at a rate of 12.5% on the estimated assessable income and 33% on the capital gains. No provision for Ireland income tax has been provided as the subsidiary has no estimated assessable profit for the six months ended June 30, 2022 and 2021.

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,	
	2022	2021
	(Unaudited)	(Unaudited)
Loss attributable to the ordinary equity holders of the company (RMB'000)	**(376,338)**	(4,393,846)
Weighted average number of ordinary shares in issue (in thousands)	**549,356**	223,248
Basic loss per share (RMB)	**(0.69)**	(19.68)

(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, 2022, the Company had outstanding potential ordinary share in relation to share-based payments. As the Group incurred losses for the six months ended June 30, 2022 and 2021, the potential ordinary shares were not included in the calculation of diluted loss per share as their inclusion would be anti-dilutive. Accordingly, diluted loss per share for the six months ended June 30, 2022 and 2021 are the same as basic loss per share of the respective periods.

9. OTHER RECEIVABLES

	As at June 30, 2022	As at December 31, 2021
	RMB'000	*RMB'000*
	(Unaudited)	(Audited)
Lease incentive receivables	**17,700**	32,660
Deposits	**5,728**	5,298
Others	**4,815**	3,927
Total	**28,243**	41,885

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, 2021 and June 30, 2021	200,000,000	50,000	349
As at January 1, 2022 and June 30, 2022	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, 2022	567,537	1
Share option scheme *(Note(a))*	2,272	–*
Issue of shares held in trust *(Note(b))*	469	–*
As at June 30, 2022	**570,278**	**1**

* The amounts are less than RMB1,000.

Note(a): During six months ended June 30, 2022, the Company issued 2,272,326 ordinary shares and 118,395 treasury shares at HKD4,996,000 (equivalent to RMB4,123,000 approximately) in total at the price ranging from nil to HKD10.92 per share as certain employees of the Group exercised their options under employee share-based payment.

Note(b): On April 28, 2022, the Company allotted and issued 468,299 shares to Carfe Unity Limited, which was 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 Carfe Unity Limited were accounted as "Reserve-Treasury shares held in trust".

11. DIVIDEND

No dividend was declared or paid by the Company during the six months ended June 30, 2022 and 2021.

12. BORROWINGS

	As at June 30, 2022 ***RMB'000*** **(Unaudited)**	As at December 31, 2021 *RMB'000* (Audited)
Non-current		
Secured bank borrowings	**4,981**	7,375
Current		
Unsecured bank borrowings	**218,527**	214,727
Secured bank borrowings	**4,724**	4,604
	223,251	219,331
Total	**228,232**	226,706

	As at December 31, 2021 *RMB'000* (Audited)	**Additions**	**Repayments**	**As at June 30, 2022** ***RMB'000*** **(Unaudited)**
Unsecured bank borrowings	214,727	103,800	(100,000)	**218,527**
Secured bank borrowings	11,979	–	(2,274)	**9,705**
Total	226,706	103,800	(102,274)	**228,232**

13. ACCRUALS AND OTHER PAYABLES

	As at June 30, 2022 ***RMB'000*** **(Unaudited)**	As at December 31, 2021 *RMB'000* (Audited)
Accrued expenses	**71,338**	45,520
Payables for acquisition of property, plant and equipment	**1,841**	37,969
Payables for research and development consumables	**656**	340
Staff salaries and welfare payables	**43,750**	45,837
Other taxes payable	**1,666**	2,620
Interest payables	**716**	393
Others	**2,584**	5,346
Total	**122,551**	138,025

IV. CORPORATE GOVERNANCE AND OTHER INFORMATION

Interim Dividend

The Board does not recommend the payment of interim dividend to the Shareholders for the Reporting Period.

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 for the Reporting Period.

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 Reporting Period.

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

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 contained in Appendix 14 to the Listing Rules. For the Reporting Period, the Company has complied with the code provisions in Part 2 of the Corporate Governance Code, except for the deviation from code provision C.2.1 as explained below.

Pursuant to code provision C.2.1 of the Corporate Governance Code, companies listed on 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 – Dr. Zonghai LI ("**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, 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.

The Board will continue to review and monitor the code of corporate governance practices of the Company with an aim to maintaining a high standard of corporate governance.

Use of Proceeds from the IPO

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

- approximately HK$902.4 million (US$115.7 million) (or approximately 30% of the net proceeds) to fund further development of our Core Product Candidate, BCMA CAR-T (CT053)

- approximately HK$932.5 million (US$119.6 million) (or approximately 31% of the net proceeds) to fund ongoing and planned research and development of our other pipeline product candidates

- approximately HK$601.6 million (US$77.2 million) (or approximately 20% of the net proceeds) for developing full-scale manufacturing and commercialization capabilities

- approximately HK$300.8 million (US$38.6 million) (or approximately 10% of the net proceeds) for continued upgrading of CAR-T technologies and early-stage research and development activities

- approximately HK$270.7 million (US$34.7 million) (or approximately 9% of the net proceeds) will be used for our working capital and other general corporate purposes.

The net proceeds from the Global Offering have been utilized in accordance with the purposes set out in the Prospectus. The table below sets out the applications of the net proceeds and actual usage up to June 30, 2022:

Use of proceeds		**Planned allocation of Net Proceeds** *(HKD million)*	**Planned allocation of Net Proceeds** *(RMB million)*	**Utilized amount (as at June 30, 2022)** *(RMB million)*	**Remaining amount (as at June 30, 2022)** *(RMB million)*
Further development of our Core Product Candidate, BCMA CAR-T (CT053)	30%	902.4	771.7	172.9	598.8
Ongoing and planned research and development of our other pipeline product candidates	31%	932.5	797.5	214.7	582.8
Developing full-scale manufacturing and commercialization capabilities	20%	601.6	514.5	258.4	256.1
Upgrading of CAR-T technologies and early-stage research and development activities	10%	300.8	257.2	37.4	219.8
Working capital and other general corporate purposes	9%	270.7	231.5	43.5	188.0
Total	**100%**	**3,008.0**	**2,572.4**	**726.9**	**1,845.5**

The unutilized amount of net proceeds is expected to be used by 2024.

Audit Committee

The Audit Committee has three members comprising Mr. Tak Young SO (chairman), Dr. Chunhai FAN and Mr. Huaqing GUO, 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, 2022. The Audit Committee considers that the interim financial results for the six months ended June 30, 2022 are in compliance with the relevant accounting standards, rules and regulations and appropriate disclosures have been duly made.

Legal Proceedings

As of June 30, 2022, 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.

Subsequent Event

Save as disclosed in this announcement, the Group has no significant events occured after the Reporting Period which require additional disclosures or adjustments as at the date of this announcement.

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.

DEFINITION	
"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 this announcement 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 set out in Appendix 14 to the Listing Rules
"Director(s)"	the director(s) of the Company
"EMA"	European Medicines Agency
"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
"Health Canada"	the department of Canada's government with responsibility for national public health
"HK$" or "Hong Kong dollars" or "HKD"	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
"RMB" or "Renminbi"	Renminbi, the lawful currency of China
"Shareholder(s)"	holder(s) of shares of the Company
"Stock Exchange"	The Stock Exchange of Hong Kong Limited
"United States" or "U.S."	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 OF TECHNICAL TERMS

"ADCC"	antibody-dependent cellular 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
"ASCO"	American Society of Clinical Oncology
"ASH"	American Society of Hematology
"B2M"	beta 2 microglobulin
"BCMA"	B-cell maturation antigen, a protein that is highly expressed in several 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
"CGMP"	current good manufacturing practices
"chemokine"	a specific type of cytokine that attracts immune cells to a target
"chemotherapy"	a category of cancer treatment that uses one or more anti-cancer chemotherapeutic agents as part of its standardized regimen
"CLDN18.2"	Claudin18.2, an attractive target in the treatment of certain solid tumors such as gastric cancer, gastroesophageal junction 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
"CR"	complete response, the disappearance of all signs of cancer in response to treatment
"CRS"	cytokine release syndrome, a systemic inflammatory response that arises as a complication of some diseases or infections, and is also an adverse effect of some monoclonal antibody drugs, as well as adoptive T-cell therapies
"CTA"	Clinical Trial Application
"CycloCAR®"	a next-generation CAR T-cell technology under development by the Company, which features co-expression of cytokine IL-7 and chemokine CCL21 in the CAR T cells to potentially improve clinical efficacy and reduce the requirement for lymphodepletion conditioning
"cytokine"	small proteins involved in immune system cell signaling, including controlling the growth and activity of immune system cells and blood cells. Their release has an effect on the behavior of cells around them
"cytotoxic"	toxic to living cells
"DCR"	disease control rate, the percentage of patients who have achieved complete response, partial response or stable disease to a therapeutic intervention
"DL(s)"	dose level(s)
"DLT(s)"	dose-limiting toxicity(ies)
"DOR"	duration of response
"EGFR"	epidermal growth factor receptor
"EGFRvIII"	variant III of epidermal growth factor receptor
"GC/GEJ"	gastric cancer or gastroesophageal junction cancer

"GFA"	gross floor area
"GPC3"	Glypican-3, an oncofetal antigen expressed in a variety of tumors including certain liver and lung cancers
"Grade"	term used to refer to the severity of adverse events
"GvHD"	graft versus host disease
"HCC"	hepatocellular carcinoma, a type of cancer arising from hepatocytes in predominantly cirrhotic liver
"HLA"	human leukocyte antigen
"HvGR"	host versus graft response
"ICANS"	immune effector cell-associated neurotoxicity syndrome
"IIT(s)" or "investigator-initiated trial(s)"	clinical trial(s) sponsored and conducted by independent investigators
"IND"	investigational new drug or investigational new drug application, also known as clinical trial application in China
"ISS"	International Staging System
"LADAR®"	Local Action Driven by Artificial Receptor technology, with similar mechanism of synNotch system, in which the intracellular transcription of the gene of interest is controlled by a chimeric regulatory antigen receptor
"mAb"	monoclonal antibodies, or antibodies that are made by identical immune cells that are all clones belonging to a unique parent cell
"mesothelin"	cell-surface protein whose expression is mostly restricted to mesothelial cell layers lining the pleura, pericardium and peritoneum
"MM" or "R/R MM"	multiple myeloma, a type of cancer that forms in the white blood cells; cancer that relapses or does not respond to treatment is called relapsed and/or refractory multiple myeloma
"NDA"	new drug application
"neurotoxicity"	possible adverse side effect of T-cell therapies that leads to a state of confusion, aphasia, encephalopathy, tremor, muscular weakness, and somnolence
"NHL"	non-Hodgkin's lymphoma

"NK cell"	natural killer cell, the human body's first line of defense due to their innate ability to rapidly seek and destroy abnormal cells
"NKG2A"	also named KLRC1, killer cell lectin-like receptor subfamily C, member 1
"ORR"	objective response rate
"OS"	overall survival
"PC"	pancreatic cancer
"PFS"	progression-free survival, the length of time during and after the treatment of a disease, such as cancer, that a patient lives without tumor progression or death
"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 II"	a study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the drug for specific targeted disease, and to determine dosage tolerance and optimal dosage
"Phase Ib"	a phase of clinical trials that primarily assesses safety, tolerability and pharmacokinetics/pharmacodynamics at multiple ascending dose levels prior to commencement of a Phase II or Phase III clinical trial
"pivotal trial" or "confirmatory trial"	the controlled trial or study intended to demonstrate the required clinical efficacy and safety evidence before submission for drug marketing approval
"PR"	partial response

"PRIME"	PRIority MEdicine. A scheme launched by the EMA to offer early and proactive support to medicine developers to optimize the generation of robust data on medicine's benefits and risks, and accelerate assessment of medicines applications, for medicines that target an unmet medical need with advantages over existing treatments
"RMAT"	Regenerative Medicine Advanced Therapy, 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
"RTP"	Research Triangle Park, the location for CARsgen's U.S. CGMP manufacturing facility in Durham, North Carolina
"sFv-ε"	single-chain fragment variable (scFv) linked to CD3ε
"solid tumor"	an abnormal mass of tissue that usually does not contain cysts or liquid areas
"TCR"	T-cell receptor
"TCR-/HLA-"	the genetic deletion of T-cell receptor and human leukocyte antigen
"THANK-uCAR®"	the Company's proprietary technology to generate CAR T cells with improved expansion and persistence from T cells that are sourced from third-party donors
"VGPR"	very good partial response

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

Hong Kong, August 23, 2022

As at the date of this announcement, the board of directors of the Company comprises Dr. Zonghai LI, Dr. Huamao WANG and Dr. Hua JIANG as executive Directors; Mr. Bingsen GUO, Mr. Huaqing GUO and Mr. Ronggang XIE as non-executive Directors; Dr. Chunhai FAN, Dr. Guangmei YAN and Mr. Tak Young SO as the independent non-executive Directors.

In the case of inconsistency, the English text of this announcement shall prevail over the Chinese text.