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## 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, 2023

The board (the “Board”) of directors (the “Director(s)”) 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, 2023 (the “Reporting Period”), together with comparative figures for the same period of 2022.

#### FINANCIAL HIGHLIGHTS

	<b>Six months ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
	<b>RMB'000</b>	<b>RMB'000</b>
Net loss	<b>(404,472)</b>	(376,338)
Net loss per share (RMB)	<b>(0.73)</b>	(0.69)
<b>Non-IFRS Measures</b>		
Adjusted net loss <sup>(1)</sup>	<b>(385,726)</b>	(352,888)
Adjusted net loss per share <sup>(1)</sup> (RMB)	<b>(0.70)</b>	(0.65)
	<b>As at</b>	<b>As at</b>
	<b>June 30,</b>	<b>December 31,</b>
	<b>2023</b>	<b>2022</b>
	<b>RMB'000</b>	<b>RMB'000</b>
Cash and cash equivalents	<b>1,683,921</b>	2,268,036
Terms deposits with original maturity between three and twelve months	<b>490,087</b>	—
<b>Total</b>	<b>2,174,008</b>	2,268,036

Our net loss was RMB404 million for the six months ended June 30, 2023, representing an increase of RMB28 million from RMB376 million for the six months ended June 30, 2022. The increase was primarily due to higher research and development expenses and the turnaround from net foreign exchange gains for the six months ended June 30, 2022 to net foreign exchange losses for the six months ended June 30, 2023.

Our adjusted net loss<sup>(1)</sup> was RMB386 million for the six months ended June 30, 2023, representing an increase of RMB33 million from RMB353 million for the six months ended June 30, 2022. The increase was primarily due to higher research and development expenses and the turnaround from net foreign exchange gains for the six months ended June 30, 2022 to net foreign exchange losses for the six months ended June 30, 2023.

Cash and cash equivalents and term deposits with original maturity between three and twelve months were RMB2,174 million as of June 30, 2023, representing a decrease of RMB94 million from RMB2,268 million as of December 31, 2022. 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.

## **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 United States of America (U.S.) and the People’s Republic of China.

### **Zevorcabtagene Autoleucel (Zevor-cel, R&D code: CT053)**

Zevor-cel is an autologous fully human CAR T-cell product candidate against B-cell maturation antigen (BCMA) for the treatment of relapsed/refractory multiple myeloma (R/R MM). In October 2022, China National Medical Products Administration (NMPA) accepted the New Drug Application (NDA) and has granted the priority review for zevor-cel. Zevor-cel is expected to be approved by the NMPA for the treatment of R/R MM at the end of 2023 or the beginning of 2024. The enrollment in the Phase 2 clinical trial in the United States and Canada is underway.

In January 2023, CARsgen and Huadong Medicine (Hangzhou) Co., Ltd., a wholly-owned subsidiary of Huadong Medicine Co., Ltd. (Stock Code: SZ.000963) (“**Huadong Medicine**”) entered into a collaboration agreement for the commercialization of CARsgen’s lead drug candidate, zevor-cel, in mainland China. Since reaching the agreement, teams from CARsgen and Huadong Medicine have been working together closely to implement this collaboration and prepare for the approval and commercialization of zevor-cel in China.

## CT041

CT041 is an autologous humanized CAR T-cell product candidate against Claudin18.2, a membrane protein highly expressed in certain cancers. As of the date of this announcement, CT041, based on our information, is the world's first CAR T-cell candidate for the treatment of solid tumors that has entered a Phase II clinical trial. In April 2023, CT041 has achieved IND clearance from the NMPA for the postoperative adjuvant therapy of Claudin18.2 positive pancreatic cancer (PC). In May 2023, a Phase 2 clinical trial of CT041 in the U.S. has been initiated for the treatment of Claudin18.2 positive advanced gastric cancer/gastroesophageal junction cancer (GC/GEJ) in patients who have failed at least 2 prior lines of systemic therapies. Active CT041 trials include a Phase 1b/2 clinical trial for advanced gastric cancer (GC) and PC in the United States and Canada (CT041-ST-02, NCT04404595), a Phase Ib clinical trial for advanced gastric cancer/gastroesophageal junction cancer (GC/GEJ) and PC (CT041-ST-01, NCT04581473), a confirmatory Phase II clinical trial for advanced GC/GEJ in China (CT041-ST-01, NCT04581473), and an investigator-initiated trial (NCT03874897).

### 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**") has commenced operations of GMP production of autologous CAR T-cell products. The RTP Manufacturing Facility will provide CARsgen additional manufacturing capacity of autologous CAR T-cell products for 700 patients annually to support clinical studies and early commercial launch in the United States, Canada, and Europe.

## MANAGEMENT DISCUSSION AND ANALYSIS

### I. OVERVIEW

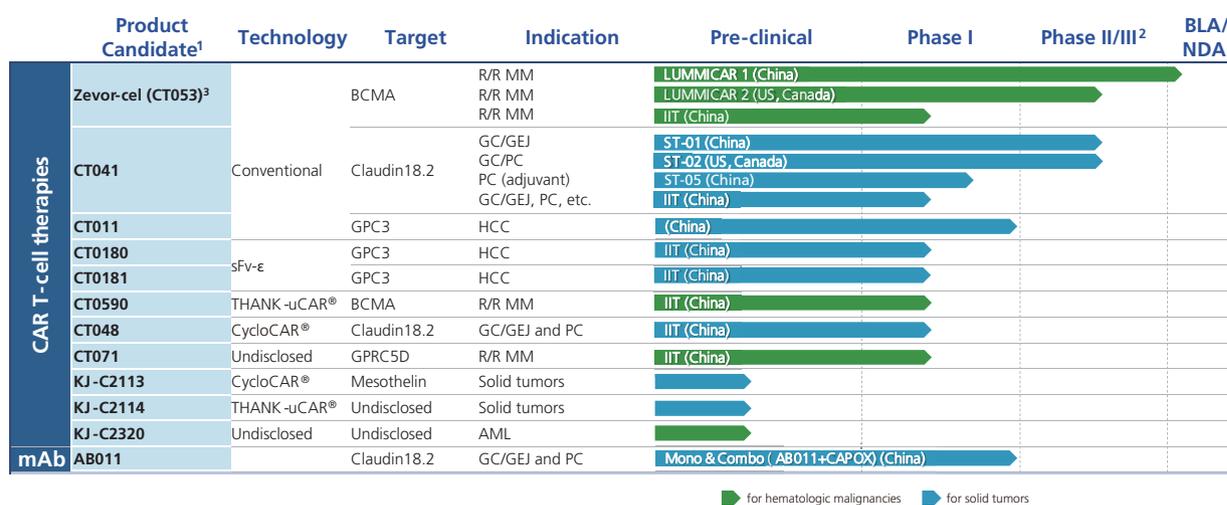
CARsgen is a biopharmaceutical company with operations in China and the U.S. focused on innovative CAR T-cell therapies for the treatment of hematologic malignancies and solid tumors. CARsgen has built an integrated platform to accelerate the cell therapy development life cycle with in-house capabilities 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.

In the first half of 2023, we continued to make steady advancements in the clinical development of our differentiated product pipeline, technology innovations, manufacturing capabilities, and business development.

## II. BUSINESS REVIEW

### Our Products and Product Pipeline

Since CARsgen’s inception, we have been focusing our efforts on in-house development of innovative and differentiated CAR T-cell therapies. Our Core Product Candidate, zevor-cel for the treatment of R/R MM, is at the most advanced development stage among the product candidates in our pipeline. In addition, our 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 with global rights owned by CARsgen.



R/R MM: relapsed/refractory multiple myeloma; GC: gastric cancer; GEJ: gastroesophageal junction cancer; PC: pancreatic cancer; HCC: hepatocellular carcinoma; AML: acute myeloid leukemia

Notes:

1. All product candidates are self-developed with global rights.
2. Phase II trials of some indications are pivotal studies.
3. Core Product Candidate. Commercial rights in mainland China have been granted to Huadong Medicine. Rights in the South Korean market have been licensed out to HK Inno.N Corporation (KOSDAQ: 195940).

## ***Zevorcabtagene Autoleucel (Zevor-cel, R&D code: CT053) – Fully Human BCMA-targeted CAR T***

Zevor-cel is a 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 low immunogenicity and increased stability that overcomes T-cell exhaustion by reducing the self-activation of CAR T cells in the absence of tumor-associated targets.

CARsgen developed zevor-cel in-house with our integrated research and development platform. Zevor-cel received Regenerative Medicine Advanced Therapy (RMAT) for the treatment of R/R MM from the FDA in October 2019, PRIority MEDicines (PRIME) eligibility for the treatment of R/R MM from the EMA in September 2019, Breakthrough Therapy designation for the treatment of R/R MM from the NMPA in December 2020. In addition, zevor-cel received Orphan Drug designation for the treatment of multiple myeloma from the U.S. FDA in 2019, Orphan Medicinal Product designation for the treatment of multiple myeloma from the European Medicines Agency (EMA) in 2020, and priority review from NMPA in October 2022.

The Phase 2 trial (LUMMICAR STUDY 2, NCT03915184) for R/R MM is being conducted by CARsgen in the United States and Canada. After a recent development meeting with FDA Center for Biologics Evaluation and Research (CBER), CARsgen plans to complete enrollment of approximately 100 patients in a Phase 2 clinical trial by the end of 2023. CARsgen plans to submit a BLA to the U.S. FDA in the first half of 2025. Updated data for a total of 17 patients who received zevor-cel infusion in the Phase 1b/2 trial in U.S. were presented orally at the 7th Annual CAR-TCR Summit in September 2022.

CARsgen is conducting a pivotal Phase II study (LUMMICAR STUDY 1, NCT03975907) in China for R/R MM. NMPA has accepted the NDA submission for zevor-cel in October 2022. Zevor-cel is expected to be approved by the NMPA for the treatment of R/R MM at the end of 2023 or the beginning of 2024. At the 64th ASH Annual Meeting in December 2022, CARsgen presented one poster, titled ‘Phase II Study of Fully Human BCMA-Targeted CAR T Cells (Zevorcabtagene Autoleucel) in Patients with Relapsed/Refractory Multiple Myeloma’, highlighting the updated study results for zevor-cel in the Phase I/II trial in China. A poster titled ‘Sustainable Efficacy and Safety Results from LUMMICAR STUDY 1: A Phase 1/2 Study of Fully Human B-Cell Maturation Antigen-Specific CAR T Cells (CT053) in Chinese Subjects with Relapsed and/or Refractory Multiple Myeloma’, which included the sustainable efficacy and safety results from the Phase I study of zevor-cel in China, was previously presented at the 63rd ASH Annual Meeting in December 2021.

Updated results for the investigator-initiated trials (NCT03302403, NCT03380039, NCT03716856) were published in *Haematologica* in August 2022 article titled ‘A novel BCMA CAR-T-cell therapy with optimized human scFv for treatment of relapsed/refractory multiple myeloma: results from Phase I clinical trials’.

Additional data from these global clinical trials will be disclosed in academic journals or conferences. CARsgen plans to conduct additional clinical trials to develop zevor-cel as a treatment for earlier lines of multiple myeloma.

**We may not be able to ultimately develop and market zevor-cel successfully.**

## ***CT041 – Humanized Claudin18.2-targeted CAR T***

CT041 is an autologous CAR T-cell product candidate against the protein Claudin18.2 and has the potential to be first-in-class globally. CT041 targets the treatment of Claudin18.2-positive solid tumors with a primary focus on GC/GEJ and PC. Claudin18.2 is expressed in a range of solid tumors, including GC/GEJ, PC, biliary tract cancer (BTC), colorectal, lung, and ovarian cancers. Leveraging our in-depth understanding of CAR T-cell therapy, as well as our integrated antibody platform, we were the first in the world to successfully identify, validate, and report Claudin18.2 as a solid tumor-associated antigen and viable target for CAR T-cell therapy for solid tumors in which Claudin18.2 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 lymphodepletion regimen (FNC) 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 was granted RMAT designation by U.S. FDA for the treatment of advanced GC/GEJ with Claudin18.2-positive tumors in January 2022 and was granted PRIME eligibility by the EMA for the treatment of advanced gastric cancer in November 2021. CT041 received Orphan Drug designation from the U.S. FDA in September 2020 for the treatment of GC/GEJ and Orphan Medicinal Product designation from the EMA in January 2021 for the treatment of advanced gastric cancer.

As of the date of this announcement, CT041, based on our information, is the world's first CAR T-cell candidate for the treatment of solid tumors that has entered a Phase II clinical trial.

The Phase 1b/2 clinical trial for advanced GC and PC (CT041-ST-02, NCT04404595) is currently active in the U.S. and Canada. A Phase 2 clinical trial of CT041 in the U.S. has been initiated in May 2023. CARsgen plans to submit the BLA of CT041 for the treatment of advanced GC to the U.S. FDA in 2025. At the 2022 ASCO Annual Meeting, CARsgen presented a poster entitled 'Multicenter Phase 1b Trial of Salvage CT041 Claudin18.2-specific Chimeric Antigen Receptor T Cell Therapy for Patients with Advanced Gastric and Pancreatic Adenocarcinoma' with updated study results for CT041 in the Phase 1b trial in the U.S..

In China, CARsgen is conducting a confirmatory Phase II clinical trial for advanced GC/GEJ (CT041-ST-01, NCT04581473). CARsgen plans to submit an NDA of CT041 for the treatment of advanced GC to the NMPA in China in 2024. In April 2023, CT041 has achieved IND clearance from the NMPA for the postoperative adjuvant therapy of Claudin18.2 positive PC (CT041-ST-05, NCT05911217). The updated results from the Phase Ib/II CT041 study in China were presented at the 2022 ASCO Annual Meeting with the poster titled 'Safety, Tolerability and Preliminary Efficacy Results in Patients with Advanced Gastric/Gastroesophageal Junction Adenocarcinoma from a Phase Ib/II Study of Claudin18.2 CAR T-cell Therapy'.

The results of the investigator-initiated trial of CT041 (NCT03874897) were reported in the *Nature Medicine* article titled “Claudin18.2-specific CAR T cells in gastrointestinal cancers: Phase I trial interim results” in May 2022.

Additional data from these global clinical trials will be disclosed in academic journals or at scientific conferences. CARsgen plans to conduct additional clinical trials to develop CT041 as an earlier line of treatment for GC/GEJ.

**We may not be able to ultimately develop and market CT041 successfully.**

### ***CT011 – Humanized GPC3-targeted CAR T***

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. 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 titled ‘Long term complete response of advanced hepatocellular carcinoma to glypican-3 specific chimeric antigen receptor T-Cells plus sorafenib, a case report’ was published in *Frontiers in Immunology* in August 2022.

**We may not be able to ultimately develop and market CT011 successfully.**

### ***AB011 – Anti-Claudin18.2 mAb***

AB011 is a humanized monoclonal antibody product candidate that targets Claudin18.2, 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 Claudin18.2 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 Claudin18.2 positive gastric cancer mouse models.

AB011 is the first monoclonal antibody against Claudin18.2 that received IND clearance in China. We are conducting a Phase I clinical trial of AB011 for the treatment of Claudin18.2 positive solid tumors in China to evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy of AB011 infusion. We completed Phase I monotherapy and the combination with chemotherapy cohorts enrollment. AB011 in combination with atezolizumab monoclonal antibody and chemotherapy (capecitabine and oxaliplatin) achieved IND clearance from the NMPA for first-line treatment Claudin18.2 positive unresectable locally advanced, recurrent or metastatic gastric cancer/gastroesophageal junction cancer.

This multicenter, open-label, two-stage, Phase I study (AB011-ST-01, NCT04400383) is conducted to evaluate the safety and preliminary efficacy in patients with advanced solid tumors as monotherapy (Stage 1) and AB011 plus chemotherapy (Stage 2). The updated results were presented in a poster titled ‘A Multicenter, Phase 1 Study of AB011, a Recombinant Humanized Anti-Claudin18.2 Monoclonal Antibody, as Monotherapy and Combined with Capecitabine and Oxaliplatin (CAPOX) in Patients with Advanced Solid Tumors’ at ASCO GI in January 2023.

**We may not be able to ultimately develop and market AB011 successfully.**

### **IND-Enabling or Preclinical Stage Product Candidates**

In addition to the above clinical-stage product candidates currently in clinical phase, we have internally developed eight IND-enabling or preclinical product candidates as described below. Five of these products, CT0180, CT0181, CT0590, CT048 and CT071 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 has been initiated in China to evaluate the safety and efficacy of CT0180 in the treatment of hepatocellular carcinoma.

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

CT0590 is an allogeneic CAR T-cell product candidate deploying our THANK-uCAR<sup>®</sup> technology that targets BCMA for the treatment of R/R MM. An IIT has been initiated in China to evaluate the safety and efficacy of CT0590 for the treatment of R/R MM.

CT048 is a next-generation autologous CAR T-cell product candidate developed with our CycloCAR<sup>®</sup> technology to treat patients with Claudin18.2-positive GC/GEJ and PC. We anticipate that by co-expressing cytokine IL-7 and chemokine CCL21, CT048 potentially has a greater clinical efficacy and reduced requirement for lymphodepletion conditioning. An IIT has been initiated in China to evaluate the safety and efficacy of CT048 for the treatment of GC/GEJ and PC.

CT071 is a CAR T-cell product candidate developed with an undisclosed proprietary technology of CARsgen targeting G protein-coupled receptor, class C, group 5, member D (GPRC5D) for the treatment of R/R MM. An IIT has been initiated in China to evaluate the safety and efficacy of CT071 for the treatment of R/R MM.

KJ-C2113 is a next-generation autologous CAR T-cell product candidate developed with our CycloCAR<sup>®</sup> 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.

KJ-C2320 is a CAR T-cell product candidate deploying an undisclosed proprietary technology of CARsgen with an undisclosed target for the treatment of acute myeloid leukemia.

## **Continuous Discovery and Technology Development**

Despite the approval of some CAR T-cell products for the last-line treatment of hematologic malignancies, significant challenges 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 develop a product candidate efficiently and effectively 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 Claudin18.2, 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 evidence of our antibody engineering capabilities, we have developed zevor-cel, 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 medication (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- $\epsilon$ -based T-cell therapy powered by a full T-cell receptor (TCR) complex comprising a GPC3-targeted scFv and a CD3 $\epsilon$  subunit, which can form a functional TCR complex with other TCR subunits (TCR $\alpha$ , TCR $\beta$ , CD3 $\gamma$ , CD3 $\delta$  and CD3 $\zeta$ ) and redirect T cells to kill tumor cells in an MHC-independent manner. Our preclinical studies showed that sFv- $\epsilon$ -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- $\epsilon$ -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<sup>®</sup> technology. THANK-uCAR<sup>®</sup> 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  $\beta$ 2 microglobulin (B2M) to eliminate surface expression of the TCR or the human leukocyte antigen (HLA), an approach that has been validated by previous research. However, 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 arming 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<sup>®</sup> technology, which we believe could potentially increase CAR T cell expansion, persistence and efficacy. We believe the successful application of THANK-uCAR<sup>®</sup> 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<sup>®</sup> 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 (e.g., the tumor antigen-targeted CAR, plus any cytokines or other therapeutic mediators). Through the LADAR<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> system, such as LADAR-cytokine circuits. We believe that the establishment of LADAR<sup>®</sup> 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, 2023, we had more than 300 patents of which 101 patents had been issued globally including China, the United States, Europe, and Japan. This status is an increase of 9 issued patents and 24 patent applications from the end of 2022. 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 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. The RTP Manufacturing Facility, which the technology transfer has been completed, is now in full operation.

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. CARsgen has started building a world-class Chemistry, Manufacturing and Controls (CMC) team for the RTP Manufacturing Facility operations. The RTP Manufacturing Facility now is supporting CARsgen's ongoing clinical studies of zevor-cel and CT041 and also will support early commercial launch in the United States, Canada and Europe.

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 zevor-cel and CT041 clinical studies in the United States and Canada. With large scale lentiviral vectors production, we could greatly reduce the CAR T manufacturing costs.

## **Commercialization and External Collaboration**

In formulating our strategies for the commercialization of our innovative CAR T-cell products, we have been carefully evaluating the different available options while considering the company's strategic development goals at different stages, the resources, the capabilities, and the financial implications. For the commercialization of zevor-cel in China, we have conducted thorough analysis for the two options of commercialization by ourselves or partnering with a company with established commercial network and capabilities.

### ***Collaboration for zevor-cel commercialization in mainland China with Huadong Medicine***

In January 2023, CARsgen and Huadong Medicine (Hangzhou) Co., Ltd., a wholly-owned subsidiary of Huadong Medicine entered into a collaboration agreement for the commercialization of zevor-cel in mainland China. Under the terms of the Agreement, CARsgen will receive an upfront payment of RMB200 million and is eligible to receive regulatory and commercial milestone payments up to RMB1,025 million. CARsgen will continue to be responsible for the development, regulatory approval, and manufacturing of zevor-cel in mainland China.

Huadong Medicine's extensive commercialization experience in mainland China along with their strategic goal of being a leader in the oncology therapeutic area created the opportunity for a strong, strategic and mutually beneficial partnership between our two companies. We believe that the partnership with Huadong Medicine, through leveraging the respective strengths of the two companies, can significantly maximize the commercial successes of zevor-cel in the market while reduce the risk and associated cost. Since reaching the agreement, teams from CARsgen and Huadong Medicine have been working together closely to implement this collaboration and prepare for the approval and commercialization of zevor-cel in China.

### ***License Agreement for zevor-cel in the Republic of Korea with HK Inno.N Corporation***

CARsgen has entered into a licensing agreement with HK Inno.N Corporation (KOSDAQ: 195940), a fully-integrated pharmaceutical company, to develop and commercialize CT032 and zevor-cel, 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.

## **Expansion and Retention of Talent**

As of June 30, 2023, we had a total of 525 employees.

CARsgen continuously invests in talent development. New employees from various subsidiaries and departments completed new hire orientation training. The training expedited the new employee's integration into CARsgen. Performance management workshops were organized, mainly targeting management personnel. Through case discussions and other activities, the participants deepened their understanding and insights into strategic goal decomposition, cross-department goal alignment, and setting challenging objectives. CARsgen also accelerated the development of talents with global experience and perspective offering job rotations and overseas assignments.

## **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 three 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 zevor-cel and CT041, and innovative technology platforms, including CycloCAR<sup>®</sup>, THANK-uCAR<sup>®</sup> and LADAR<sup>®</sup>, 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 achieved, we will continue to focus on rapid clinical development of zevor-cel and CT041 both in China and overseas. We will advance the clinical development to earlier line of treatment and continue to develop 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 RMB409 million and RMB368 million for the six months ended June 30, 2023 and 2022, respectively. Substantially all of our operating losses resulted from research and development expenses, administrative expenses and the turnaround from net foreign exchange gains for the six months ended June 30, 2022 to net foreign exchange losses for the six months ended June 30, 2023.

#### Loss for the Periods

Net loss was RMB404 million for the six months ended June 30, 2023, representing an increase of RMB28 million from RMB376 million for the six months ended June 30, 2022. The increase was primarily due to higher research and development expenses and the turnaround from net foreign exchange gains for the six months ended June 30, 2022 to net foreign exchange losses for the six months ended June 30, 2023.

#### *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 a non-cash item, namely the 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:

	<b>Six months ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
	<b>RMB'000</b>	<b>RMB'000</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
<b>Loss for the periods</b>	<b>(404,472)</b>	<b>(376,338)</b>
Add:		
Share-based compensation	<b>18,746</b>	<b>23,450</b>
<b>Adjusted net loss</b>	<b><u>(385,726)</u></b>	<b><u>(352,888)</u></b>

	<b>Six months ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
	<b>RMB</b>	<b>RMB</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
<b>Loss per share for the periods</b>	<b>(0.73)</b>	<b>(0.69)</b>
Add:		
Share-based compensation per share	<u><b>0.03</b></u>	<u>0.04</u>
<b>Adjusted net loss per share</b>	<u><u><b>(0.70)</b></u></u>	<u><u>(0.65)</u></u>

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. 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**

	<b>Six months ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
	<b>RMB'000</b>	<b>RMB'000</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
Employee benefit expenses	<b>137,294</b>	144,371
Testing and clinical expenses	<b>101,474</b>	108,336
Research and development consumables	<b>28,691</b>	24,200
Depreciation of property, plant and equipment	<b>28,386</b>	13,984
Utilities	<b>9,238</b>	6,820
Depreciation of right-of-use assets	<b>8,318</b>	11,443
Amortization of intangible assets	<b>2,999</b>	2,681
Travelling and transportation expenses	<b>2,994</b>	1,628
Professional service fees	<b>1,532</b>	770
Short-term lease and low-value lease expenses	<b>516</b>	325
Other expenses	<u><b>1,871</b></u>	<u>1,746</u>
<b>Total</b>	<u><u><b>323,313</b></u></u>	<u><u>316,304</u></u>

Research and development expenses increased to RMB323 million for the six months ended June 30, 2023, representing an increase of RMB7 million from RMB316 million for the six months ended June 30, 2022, primarily due to increased depreciation of property, plant and equipment for testing and productions in support of our clinical trials.

### Administrative Expenses

	<b>Six months ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
Employee benefit expenses	<b>35,819</b>	35,295
Professional service fees	<b>9,047</b>	9,548
Office expenses	<b>5,212</b>	4,798
Depreciation of property, plant and equipment	<b>2,414</b>	5,154
Travelling and transportation expenses	<b>1,944</b>	1,010
Auditors' remuneration	<b>1,815</b>	1,422
– audit service	<b>1,630</b>	1,422
– non-audit service	<b>185</b>	–
Depreciation of right-of-use assets	<b>1,278</b>	1,458
Amortization of intangible assets	<b>660</b>	472
Utilities	<b>542</b>	803
Short-term lease and low-value lease expenses	<b>292</b>	178
Other expenses	<b>3,291</b>	2,843
	<hr/>	<hr/>
<b>Total</b>	<b><u>62,314</u></b>	<b><u>62,981</u></b>

Administrative expenses are RMB62 million for the six months ended June 30, 2023, representing a decrease of RMB1 million from RMB63 million for the six months ended June 30, 2022.

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***

	<b>Six months ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
Wages and salaries	<b>126,320</b>	132,622
Pension costs	<b>10,637</b>	9,757
Share-based compensation	<b>18,746</b>	23,450
Other employee benefits	<b>17,410</b>	13,837
	<hr/>	<hr/>
<b>Total</b>	<b>173,113</b>	179,666
	<hr/> <hr/>	<hr/> <hr/>
Amount included in research and development expenses	<b>137,294</b>	144,371
Amount included in administrative expenses	<b>35,819</b>	35,295
	<hr/> <hr/>	<hr/> <hr/>

The decrease of employee benefit expenses is mainly due to lower headcount and the related decrease in staff salary and benefit costs which was partially offset by the annual growth of salaries.

### ***Share-based payments***

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

	<b>Six months ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
Administrative expenses	<b>3,144</b>	3,736
Research and development expenses	<b>15,602</b>	19,714
	<hr/>	<hr/>
<b>Total</b>	<b>18,746</b>	23,450
	<hr/> <hr/>	<hr/> <hr/>

## 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,	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Net cash used in operating activities	(141,845)	(310,464)
Net cash (used in)/generated from investing activities	(404,526)	148,003
Net cash used in financing activities	(7,504)	(8,955)
	<hr/>	<hr/>
Net decrease in cash and cash equivalents	(553,875)	(171,416)
Cash and cash equivalents at beginning of the period	2,268,036	691,284
Exchange (loss)/gain on cash and cash equivalents	(30,240)	80,162
	<hr/>	<hr/>
Cash and cash equivalents at end of the period	<u>1,683,921</u>	<u>600,030</u>

### 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 RMB142 million and RMB310 million for the six months ended June 30, 2023 and 2022, respectively. During the Reporting Period, we received about RMB200 million (including VAT) from Huadong Medicine according to the collaboration agreement for the commercialization of zevor-cel in mainland China.

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 Used in/Generated from Investing Activities

Our cash used in investing activities mainly reflects our cash used for our purchase of term deposits with original maturity between three and twelve months, property, plant and equipment and our cash generated from investing activities mainly reflects our net cash receipts from term deposits with original maturity between three and twelve months. For the six months ended June 30, 2023, our net cash used in investing activities was RMB405 million, which was primarily attributable to cash payment for investment of term deposit and purchase of 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.

## Net Cash Used in Financing Activities

For the six months ended June 30, 2023, our net cash used in financing activities was RMB8 million, primarily attributable to payment of principals and interest of lease liabilities and payment of principals of bank borrowings. For the six months ended June 30, 2022, our net cash used in financing activities was RMB9 million, which was primarily attributable to payment of principals and interest of lease liabilities and payment of interest on bank borrowing.

## Cash and Cash Equivalents and Term Deposits with Original Maturity Between Three and Twelve Months

	As at June 30, 2023 <i>RMB'000</i> (Unaudited)	As at December 31, 2022 <i>RMB'000</i> (Audited)
Cash at banks		
– RMB	926,679	906,855
– USD	745,983	1,357,360
– HKD	11,259	3,821
	<u>1,683,921</u>	<u>2,268,036</u>
<b>Subtotal</b>	<b><u>1,683,921</u></b>	<b><u>2,268,036</u></b>
Term deposits with original maturity between three and twelve months		
– USD	490,087	–
	<u>490,087</u>	<u>–</u>
<b>Total</b>	<b><u>2,174,008</u></b>	<b><u>2,268,036</u></b>

The Group's cash and cash equivalents and term deposits with original maturity between three and twelve months as at June 30, 2023 were RMB2,174 million, representing a decrease of RMB94 million compared to RMB2,268 million as at December 31, 2022. 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, 2023 were RMB5 million, representing a decrease of RMB2 million compared to RMB7 million as at December 31, 2022.

As at June 30, 2023 and December 31, 2022, the Group's bank borrowings of approximately RMB5 million and RMB7 million 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, 2023, the Group's secured borrowings are mature within one year with the interest rate of 5.2250% (2022: 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, 2023 was 5.04%, representing an increase of 0.21% compared to 4.83% as at December 31, 2022.

## **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 decreased to RMB106 million as at June 30, 2023 from RMB112 million as at December 31, 2022, mainly due to some staff dormitories were expired.

## **Significant Investments, Material Acquisitions and Disposals**

As at June 30, 2023, we did not hold any significant investments. During the six months ended June 30, 2023, we did not have material acquisitions or disposals of subsidiaries, associates and joint ventures.

## **Foreign Exchange Risk**

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

## **Capital Expenditure**

For the six months ended June 30, 2023, the Group's total capital expenditure amounted to approximately RMB9 million, which was used in purchase of property, plant and equipment, and software.

## **Charge on Assets**

As at June 30, 2023 and December 31, 2022, the Group's building with carrying values of RMB30 million and RMB31 million respectively were pledged for certain of the Group's borrowings. As at June 30, 2023 and December 31, 2022, the Group's land use rights with carrying values of RMB7 million and RMB7 million respectively were pledged as collateral for the Group's borrowings.

## **Contingent Liability**

As at June 30, 2023, the Group did not have any material contingent liabilities.

## **Employees and Remuneration Policies**

As of June 30, 2023, we had a total of 525 employees.

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

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

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

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

### **Future Investment Plans and Expected Funding**

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

**CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME**  
**FOR THE SIX MONTHS ENDED JUNE 30, 2023**

	<i>Note</i>	<b>Six months ended June 30,</b>	
		<b>2023</b>	<b>2022</b>
		<b>RMB'000</b>	<b>RMB'000</b>
		<b>(Unaudited)</b>	<b>(Unaudited)</b>
Administrative expenses	5	(62,314)	(62,981)
Research and development expenses	5	(323,313)	(316,304)
Other income	3	41,605	10,388
Other (losses)/gains – net	4	(65,208)	1,205
<b>Operating loss</b>		<b>(409,230)</b>	<b>(367,692)</b>
Finance income		7,299	726
Finance costs		(2,541)	(9,372)
Finance income/(costs) – net	6	4,758	(8,646)
<b>Loss before income tax</b>		<b>(404,472)</b>	<b>(376,338)</b>
Income tax expense	7	–	–
<b>Loss for the period and attribute to the equity holders of the Company</b>		<b>(404,472)</b>	<b>(376,338)</b>
<b>Other comprehensive income for the period:</b>			
<i>Items that may be reclassified to profit or loss</i>			
Exchange differences on translation of subsidiaries		7,710	(72,376)
<i>Items that will not be reclassified to profit or loss</i>			
Exchange differences on translation of the Company		106,005	215,132
<b>Other comprehensive income for the period, net of tax</b>		<b>113,715</b>	<b>142,756</b>
<b>Total comprehensive loss for the period and attribute to the equity holders of the Company</b>		<b>(290,757)</b>	<b>(233,582)</b>
<b>Loss per share for the loss attributable to the equity holders of the Company</b>			
Basic and diluted loss per share (in RMB)	8	(0.73)	(0.69)

**CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION**  
*AS AT JUNE 30, 2023*

	<i>Note</i>	As at <b>June 30, 2023</b> <i>RMB'000</i> (Unaudited)	As at December 31, 2022 <i>RMB'000</i> (Audited)
<b>ASSETS</b>			
<b>Non-current assets</b>			
Property, plant and equipment		347,382	363,850
Right-of-use assets		70,286	77,533
Intangible assets		9,285	14,476
Other non-current assets and prepayments		4,915	6,321
		<u>431,868</u>	<u>462,180</u>
<b>Current assets</b>			
Other receivables	9	20,509	11,834
Other current assets and prepayments		18,572	20,769
Term deposits with original maturity between three and twelve months		490,087	–
Cash and cash equivalents		1,683,921	2,268,036
		<u>2,213,089</u>	<u>2,300,639</u>
<b>Total assets</b>		<u><b>2,644,957</b></u>	<u><b>2,762,819</b></u>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity attributable to the equity holders of the Company</b>			
Share capital	10	1	1
Reserves		2,205,593	2,473,173
<b>Total equity</b>		<u><b>2,205,594</b></u>	<u><b>2,473,174</b></u>
<b>LIABILITIES</b>			
<b>Non-current liabilities</b>			
Borrowings	12	–	2,523
Lease liabilities		89,879	94,938
Deferred income		15,677	21,180
		<u>105,556</u>	<u>118,641</u>
<b>Current liabilities</b>			
Lease liabilities		16,230	17,134
Accruals and other payables	13	116,688	141,114
Current income tax payable		1,391	1,341
Contract liabilities	14	188,679	–
Deferred income		5,840	6,565
Borrowings	12	4,979	4,850
		<u>333,807</u>	<u>171,004</u>
<b>Total liabilities</b>		<u><b>439,363</b></u>	<u><b>289,645</b></u>
<b>Total equity and liabilities</b>		<u><b>2,644,957</b></u>	<u><b>2,762,819</b></u>

## 1. GENERAL INFORMATION

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

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

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

The condensed consolidated interim financial information were approved and authorized for issue by the board of directors of the Company on August 22, 2023.

## 2. BASIS OF PREPARATION

This condensed interim financial information for the six months ended June 30, 2023 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, 2022 (“2022 Annual Financial Statements”), which have been prepared in accordance with International Financial Reporting Standards (“IFRS”) 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, 2023, the accounting policies applied are consistent with 2022 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 new standards and amendments have been adopted by the Group for the financial period beginning on January 1, 2023:

- Insurance Contracts – IFRS 17
- Definition of Accounting Estimates – Amendments to IAS 8
- Deferred Tax related to Assets and Liabilities arising from a Single Transaction – Amendments to IAS 12
- Disclosure of Accounting Policies – Amendments to IAS 1 and IFRS Practice Statement 2

The adoption of these new standards and amendments did not have material impact on the Group’s financial position or operating result and did not require retrospective adjustment.

## 2.2. New standards, amendments and interpretation not yet adopted

Standards	Key requirements	Effective for annual periods beginning on or after
Amendments to IAS 1	Non-current Liabilities with Covenants	January 1, 2024
Amendments to IFRS 16	Lease Liability in Sale and Leaseback	January 1, 2024
Amendments to IFRS 10 and IAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture	To be determined

Certain new accounting standard, amendments and interpretation have been published but are not mandatory for the financial year beginning January 1, 2023 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,	
	2023 <i>RMB'000</i> (Unaudited)	2022 <i>RMB'000</i> (Unaudited)
Government grants ( <i>Note(a)</i> )	10,869	4,419
Interest income on term deposits with original maturity between three and twelve months	<u>30,736</u>	<u>5,969</u>
<b>Total</b>	<b><u><u>41,605</u></u></b>	<b><u><u>10,388</u></u></b>

*Note(a):* 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 (LOSSES)/GAINS – NET

	Six months ended June 30,	
	2023 <i>RMB'000</i> (Unaudited)	2022 <i>RMB'000</i> (Unaudited)
Foreign exchange (losses)/gains – net	(65,259)	2,313
Others	<u>51</u>	<u>(1,108)</u>
<b>Total</b>	<b><u><u>(65,208)</u></u></b>	<b><u><u>1,205</u></u></b>

## 5. EXPENSE BY NATURE

	Six months ended June 30,	
	2023 RMB'000 (Unaudited)	2022 RMB'000 (Unaudited)
Employee benefit expenses	173,113	179,666
Testing and clinical expenses	101,474	108,336
Depreciation of property, plant and equipment	30,800	19,138
Research and development consumables	28,691	24,200
Professional service fees	10,579	10,318
Utilities	9,780	7,623
Depreciation of right-of-use assets	9,596	12,901
Office expenses	5,263	4,798
Travelling and transportation expenses	4,938	2,638
Amortization of intangible assets	3,659	3,153
Auditors' remuneration	1,815	1,422
– Audit service	1,630	1,422
– Non-audit service	185	–
Short-term lease and low-value lease expenses	808	503
Other expenses	5,111	4,589
<b>Total</b>	<b>385,627</b>	<b>379,285</b>

## 6. FINANCE INCOME/(COSTS) – NET

	Six months ended June 30,	
	2023 RMB'000 (Unaudited)	2022 RMB'000 (Unaudited)
<b>Finance income</b>		
Interest income	7,299	726
<b>Finance costs</b>		
Interest expense on lease liabilities	(2,344)	(2,532)
Interest expense on bank borrowings	(197)	(6,840)
Total finance costs	(2,541)	(9,372)
<b>Total finance income/(costs) – net</b>	<b>4,758</b>	<b>(8,646)</b>

## 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 Co., Ltd. ("CARsgen Therapeutics (Shanghai)") which obtained its High and New Technology Enterprises status in year 2020 and hence is entitled to a preferential tax rate of 15% for a three-year period commencing 2020.

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

#### **(d) The US corporate income tax**

CARsgen Therapeutics Corporation ("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, 2023 and 2022. CARsgen USA was also subject to the state income tax for the six months ended June 30, 2023 and 2022.

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

#### **(e) British Virgin Islands income tax**

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

#### **(f) Ireland's corporation income tax and related capital gains 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, 2023 and 2022.

## 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,	
	2023 (Unaudited)	2022 (Unaudited)
Loss attributable to the ordinary equity holders of the company ( <i>RMB'000</i> )	(404,472)	(376,338)
Weighted average number of ordinary shares in issue ( <i>in thousand</i> )	555,475	549,356
Basic loss per share ( <i>RMB</i> )	<u>(0.73)</u>	<u>(0.69)</u>

### (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, 2023, 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, 2023 and 2022, 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, 2023 and 2022 are the same as basic loss per share of the respective periods.

## 9. OTHER RECEIVABLES

	As at June 30, 2023 <i>RMB'000</i> (Unaudited)	As at December 31, 2022 <i>RMB'000</i> (Audited)
Interest receivable	13,815	739
Deposits – current	6,671	6,309
Others	23	4,786
<b>Total</b>	<u><b>20,509</b></u>	<u><b>11,834</b></u>

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 <i>In thousands</i>	Nominal value of shares in total <i>USD</i>
As at January 1, 2022 and June 30, 2022	200,000,000	50,000
As at January 1, 2023 and June 30, 2023	200,000,000	50,000

### Issued and fully paid:

	Number of ordinary shares at USD0.00000025 par value <i>In thousands</i>	RMB equivalent value <i>RMB'000</i>
As at January 1, 2022	567,537	1
Issue of shares to employees under Employee Stock Option Scheme	2,272	—*
Issue of shares held in trust	469	—*
As at June 30, 2022	570,278	1
As at January 1, 2023	572,625	1
Issue of shares to employees under Employee Stock Option Scheme ( <i>Note(a)</i> )	686	—*
Issue of shares held in trust ( <i>Note(b)</i> )	2,013	—*
As at June 30, 2023	575,324	1

\* The amounts are less than RMB1,000.

*Note(a):* During the six months ended June 30, 2023, the Company issued 685,834 ordinary shares at HKD4,913,000 (equivalent to RMB4,431,000 approximately) in total with price ranging from nil to HKD10.81 per share to employees under Employee Stock Option Scheme.

*Note(b):* On June 21, 2023, the Company allotted and issued 2,012,554 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, 2023 and 2022.

## 12. BORROWINGS

	As at <b>June 30,</b> <b>2023</b> <i>RMB'000</i> (Unaudited)	As at December 31, 2022 <i>RMB'000</i> (Audited)
<i>Non-current</i>		
Secured bank borrowings	—	2,523
<i>Current</i>		
Secured bank borrowings	4,979	4,850
	<b>4,979</b>	<b>4,850</b>
<b>Total</b>	<b>4,979</b>	<b>7,373</b>

	As at December 31, 2022 <i>RMB'000</i> (Audited)	Additions	Repayments	As at <b>June 30,</b> <b>2023</b> <i>RMB'000</i> (Unaudited)
Secured bank borrowings	7,373	—	(2,394)	4,979
<b>Total</b>	<b>7,373</b>	<b>—</b>	<b>(2,394)</b>	<b>4,979</b>

## 13. ACCRUALS AND OTHER PAYABLES

	As at <b>June 30,</b> <b>2023</b> <i>RMB'000</i> (Unaudited)	As at December 31, 2022 <i>RMB'000</i> (Audited)
Accrued expenses	74,049	81,536
Staff salaries and welfare payables	37,091	51,017
Other taxes payable	915	4,094
Payables for acquisition of property, plant and equipment	614	1,529
Interest payables	33	49
Payables for research and development consumables	—	503
Others	3,986	2,386
<b>Total</b>	<b>116,688</b>	<b>141,114</b>

#### 14. CONTRACT LIABILITIES

The Group has recognised the following liabilities related to contracts with customers:

	<b>As at June 30, 2023 RMB'000 (Unaudited)</b>	As at December 31, 2022 RMB'000 (Audited)
Contract liabilities – Exclusive distribution rights of CT053	<b><u>188,679</u></b>	<u>–</u>

As at January 16, 2023, CARsgen Life Sciences Co., Ltd. (“CARsgen Life Science”), a wholly-owned subsidiary of the Company and Huadong Medicine (Hangzhou) Co., Ltd., a wholly-owned subsidiary of Huadong Medicine Co., Ltd. entered into a collaboration agreement (the “Agreement”) with total upfront and milestone payments up to RMB1,225 million. Pursuant to the Agreement, Huadong Medicine Co., Ltd. is granted the exclusive right to commercialize CARsgen’s drug candidate, zevorcabtagene autoleucl (CT053) in mainland China. During the six months ended June 30, 2023, CARsgen Life Sciences received an upfront payment of RMB200 million (RMB188,679,000 excluding VAT) under the Agreement. CARsgen Life Sciences will continue to be responsible for the development, regulatory approval, and manufacturing of CT053 in mainland China. The upfront fee is restricted by the term in the contract with Huadong Medicine.

## **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 recognizes the importance of good corporate governance for enhancing the management of the Company as well as preserving the interests of the shareholders as a whole. The Company has adopted corporate governance practices based on the principles and code provisions as set out in Part 2 of the CG Code as contained in Appendix 14 to the Listing Rules as its own code of corporate governance practices.

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

Pursuant to code provision C.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 and 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 as mentioned above, Dr. LI is the Director best suited to identify strategic opportunities and focus of the Board due to his extensive understanding of our business as our CEO. Our Board also believes that the combined role of chairman of the Board and CEO can promote the effective execution of strategic initiatives and facilitate the flow of information between management and the Board. Our Board will continue to review and consider splitting the roles of chairman of the Board and the CEO at a time when it is appropriate by taking into account the circumstances of our Group as a whole.

### **Subsequent Event**

On July 4, 2023, Ms. Xiangke ZHAO was appointed as an independent non-executive Director and the chairman of the Audit Committee with effect from July 4, 2023. Following the appointment of Ms. Xiangke ZHAO, the Company re-complied with relevant requirements under Rules 3.10(1), 3.10(2), 3.10A and 3.21 of the Listing Rules. For more details, please refer to the announcement of the Company dated July 4, 2023.

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

### **Legal Proceedings**

As of June 30, 2023, 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.

### **Use of Proceeds from the Global Offering**

The Company’s Shares were listed on the Stock Exchange on June 18, 2021 with a total of 94,747,000 offer shares issued and the net proceeds raised from the Global Offering were approximately HK\$3,008 million. The net proceeds from the Global Offering (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, 2023:

Use of proceeds	Planned allocation of Net Proceeds (HKD million)	Planned allocation of Net Proceeds (RMB million)	Utilized amount (as at December 31, 2022) (RMB million)	Utilized for the six months ended June 30, 2023 (RMB million)	Utilized amount (as at June 30, 2023) (RMB million)	Remaining amount (as at June 30, 2023) (RMB million)
Further development of our Core Product Candidate, BCMA CAR-T (CT053)	902.4	832.0	302.3	148.0	450.3	381.7
Ongoing and planned research and development of our other pipeline product candidates	932.5	859.8	324.6	113.5	438.1	421.7
Developing full-scale manufacturing and commercialization capabilities	601.6	554.7	278.5	13.4	291.9	262.8
Upgrading of CAR-T technologies and early – stage research and development activities	300.8	277.3	68.0	37.4	105.4	171.9
Working capital and other general corporate purposes	270.7	249.6	93.9	70.7	164.6	85.0
<b>Total</b>	<b>3,008.0</b>	<b>2,773.4</b>	<b>1,067.3</b>	<b>383.0</b>	<b>1,450.3</b>	<b>1,323.1</b>

The unutilized amount of net proceeds is expected to be fully utilized by 2026.

The above RMB amounts were converted using the June 30, 2023 rate of HK\$1 to RMB0.922.

## **Audit Committee**

As at the date of this announcement, the Audit Committee has three members comprising Ms. Xiangke ZHAO (chairman), Mr. Huaqing GUO and Dr. Huabing LI, 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, 2023. The Audit Committee considers that the interim financial results for the six months ended June 30, 2023 are in compliance with the relevant accounting standards, rules and regulations and appropriate disclosures have been duly made.

## **Publication of Interim Results Announcement and Interim Report**

This announcement is published on the websites of the Stock Exchange ([www.hkexnews.hk](http://www.hkexnews.hk)) and the Company ([www.carsgen.com](http://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
“CARsgen Therapeutics (Shanghai)”	CARsgen Therapeutics Co., Ltd (科濟生物醫藥(上海)有限公司), a company incorporated in the PRC with limited liability on October 30, 2014, and one of our consolidated affiliated entities
“China” or “PRC”	the People’s Republic of China, which for the purpose of the Prospectus and for geographical reference only, excludes Hong Kong, Macao and Taiwan
“Company”, “our Company”, “the Company”, “CARsgen Therapeutics” or “CARsgen”	CARsgen Therapeutics Holdings Limited (科濟藥業控股有限公司), an exempted company incorporated in the Cayman Islands with limited liability on February 9, 2018
“Core Product Candidate”	has the meaning ascribed to it in Chapter 18A of the Listing Rules and in this context, refers to CT053
“Corporate Governance Code” or “CG Code”	the Corporate Governance Code set out in Appendix 14 to the Listing Rules
“Director(s)”	the director(s) of the Company
“Global Offering”	the initial public offering of the Shares on the terms and subject to the conditions as described in the Prospectus
“Group”, “our Group”, “we”, “us” or “our”	our Company, its subsidiaries and consolidated affiliated entities from time to time or, where the context so requires, in respect of the period prior to our Company becoming the holding company of its present subsidiaries and consolidated affiliated entities, such subsidiaries and consolidated affiliated entities as if they were subsidiaries and consolidated affiliated entities of our Company at the relevant time
“HK\$” or “Hong Kong dollars”	Hong Kong dollars, the lawful currency of Hong Kong

“Hong Kong” or “HK”	the Hong Kong Special Administrative Region of the People’s Republic of China
“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
“Prospectus”	the prospectus issued by the Company on June 7, 2021 in connection with the Global Offering
“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.” or “US”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“US\$” or “U.S. dollars” or “USD”	United States dollars, the lawful currency of the United States

## GLOSSARY

“ADCC”	antibody-dependent cellular cytotoxicity is an immune mechanism through which Fc receptor-bearing effector cells recognize and kill antibody-coated target cells expressing tumor- or pathogen-derived antigens on their surface
“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
“ASCO GI”	American Society of Clinical Oncology Gastrointestinal Cancers Symposium
“ASH”	American Society of Hematology
“BCMA”	B-cell maturation antigen, a protein that is highly expressed in multiple myeloma with limited expression on normal tissues other than plasma cells
“BLA”	biologics license application
“B2M”	beta 2 microglobulin
“CAR(s)”	chimeric antigen receptor(s)
“CAR-T” or “CAR T”	chimeric antigen receptor T cell
“CD19”	a cell surface protein expressed on the surface of almost all B cell leukemia and lymphoma
“CDC”	complement-dependent cytotoxicity, an effector function of IgG and IgM antibodies
“CGMP”	current good manufacturing practices
“chemotherapy”	a category of cancer treatment that uses one or more anti-cancer chemotherapeutic agents as part of its standardized regimen
“CMC”	chemistry, manufacturing, and controls processes in the development, licensure, manufacturing, and ongoing marketing of pharmaceutical products
“cohort”	a group of patients as part of a clinical study who share a common characteristic or experience within a defined period and who are monitored over time
“combination therapy”	treatment in which a patient is given two or more therapeutic agents for the treatment of a single disease

“CRS”	cytokine release syndrome, a form of systemic inflammatory response syndrome that arises as a complication of some diseases or infections, and is also an adverse effect of some monoclonal antibody drugs, as well as adoptive T cell therapies
“CycloCAR®”	a next-generation CAR-T technology under development by the Company, which features co-expression of cytokines IL-7 and chemokine CCL21 in the CAR T-cells to potentially improve clinical efficacy and reduced requirement for lymphodepletion conditioning
“cytokine”	a broad and loose category of small proteins that are important in cell signaling. Their release affects the growth of all blood cells and other cells that help the body’s immune and inflammation responses
“EMA”	European Medicines Agency
“FDA” or “U.S. FDA” or “US FDA”	United States Food and Drug Administration
“GMP”	Good Manufacturing Practice
“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
“IIT” or “investigator-initiated trial”	clinical trial sponsored and conducted by independent investigators
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China
“LADAR®”	Local Action Driven by Artificial Receptor technology, with similar mechanism of synNotch system, in which the intracellular transcription of the gene of interest is controlled by a chimeric regulatory antigen receptor
“mAb” or “monoclonal antibody”	antibodies that are made by identical immune cells which are all clones belonging to a unique parent cell

“mesothelin”	cell-surface protein whose expression is mostly restricted to mesothelial cell layers lining the pleura, pericardium and peritoneum
“MM” or “R/R MM”	multiple myeloma, a type of cancer that forms in the white blood cells; cancer that relapses or does not respond to treatment is called relapsed and/or refractory multiple myeloma
“NDA”	new drug application
“NK cell”	natural killer cell, the human body’s first line of defense due to their innate ability to rapidly seek and destroy abnormal cells
“NKG2A”	also named KLRC1, killer cell lectin-like receptor subfamily C, member 1
“neurotoxicity”	possible adverse side effect of T cell therapies that leads to a state of confusion, aphasia, encephalopathy, tremor, muscular weakness, and somnolence
“Phase I”	a study in which a drug is introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage, tolerance, absorption, metabolism, distribution, excretion, and if possible, to gain an early indication of its effectiveness
“Phase Ib”	a phase of clinical trials that primarily assesses safety, tolerability and pharmacokinetics/pharmacodynamics at multiple ascending dose levels prior to commencement of a Phase II or Phase III clinical trial
“Phase II”	a study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the drug for specific targeted disease, and to determine dosage tolerance and optimal dosage
“confirmatory trial” or “pivotal trial”	the trial or study intended to demonstrate the required clinical efficacy and safety evidence before submission for drug marketing approval
“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
“regenerative medicine advanced therapy” or “RMAT”	a special status granted by the FDA to regenerative medicine therapies, including cell therapies, intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition

“solid tumor”	an abnormal mass of tissue that usually does not contain cysts or liquid areas
“TCR”	T cell receptor
“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

## CAUTIONARY LANGUAGE REGARDING FORWARD-LOOKING STATEMENTS

All statements in this announcement that are not historical fact or that do not relate to present facts or current conditions are forward-looking statements. Such forward-looking statements express the Group’s current views, projections, beliefs and expectations with respect to future events as of the date of this announcement. Such forward-looking statements are based on a number of assumptions and factors beyond the Group’s control. As a result, they are subject to significant risks and uncertainties, and actual events or results may differ materially from these forward-looking statements and the forward-looking events discussed in this announcement might not occur. Such risks and uncertainties include, but are not limited to, those detailed under the heading “Principal Risks and Uncertainties” in our most recent annual report and interim report and other announcements and reports made available on our corporate website, <https://www.carsgen.com>. No representation or warranty is given as to the achievement or reasonableness of, and no reliance should be placed on, any projections, targets, estimates or forecasts contained in this announcement.

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

Hong Kong, August 22, 2023

*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. Guangmei YAN, Dr. Huabing LI and Ms. Xiangke ZHAO as the independent non-executive Directors.*

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