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 ANNUAL RESULTS FOR THE YEAR ENDED DECEMBER 31, 2023

The board (the "**Board**") of directors (the "**Directors**") of CARsgen Therapeutics Holdings Limited (the "**Company**", "**CARsgen Therapeutics**" or "**CARsgen**") is pleased to announce the audited consolidated results of the Company, its subsidiaries and consolidated affiliated entities (collectively, the "**Group**") for the year ended December 31, 2023 (the "**Reporting Period**"), together with the audited comparative figures for the year ended December 31, 2022.

FINANCIAL HIGHLIGHTS

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Net loss	**(747,794)**	(892,247)
Net loss per share (RMB)	**(1.34)**	(1.62)
Non-IFRSs Measures		
Adjusted net loss[(1)]	**(733,336)**	(848,252)
Adjusted net loss per share (RMB)[(1)]	**(1.31)**	(1.54)

	As at December 31,	
	2023	2022
	RMB'000	*RMB'000*
Cash and bank balances	**1,849,752**	2,268,036
Total	**1,849,752**	2,268,036

Our net loss was RMB748 million for the year ended December 31, 2023, representing a decrease of RMB144 million from RMB892 million for the year ended December 31, 2022. The decrease was primarily due to (i) the decrease in share-based compensation ("**Adjusted Items**"), which totaled RMB14 million for the year ended December 31, 2023, representing a decrease of RMB30 million from RMB44 million for the year ended December 31, 2022; (ii) lower research and development expenses and lower administrative expenses; and (iii) foreign exchange losses of RMB30 million for the year ended December 31, 2023, representing a net impact of RMB67 million from foreign exchange losses of RMB97 million for the year ended December 31, 2022.

Our adjusted net loss(1) was RMB733 million for the year ended December 31, 2023, representing a decrease of RMB115 million from RMB848 million for the year ended December 31, 2022. The decrease was primarily due to lower research and development expenses, lower general and administrative expenses and foreign exchange losses.

Cash and bank balances were RMB1,850 million as of December 31, 2023, representing a decrease of RMB418 million from RMB2,268 million as of December 31, 2022. The decrease mostly resulted from payments of research and development expenses, administrative expenses and capital expenditure on long-term assets. During the Reporting Period, we received RMB200 million (including VAT) from Huadong Medicine according to the collaboration agreement for the commercialization of zevor-cel in mainland China.

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

BUSINESS HIGHLIGHTS

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

Zevorcabtagene autoleucel (CT053)

Zevorcabtagene autoleucel 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).

As informed by the NMPA on March 1, 2024, zevorcabtagene autoleucel was granted conditional approval on February 23, 2024 for the treatment of adult patients with relapsed or refractory multiple myeloma who have progressed after at least 3 prior lines of therapy (including a proteasome inhibitor and an immunomodulatory agent). Over 100 patients have been enrolled in the Phase 2 trial (NCT03915184) for R/R MM in North America. The study has been placed on clinical hold by the FDA due to CMC observations related to our Research Triangle Park (RTP) Manufacturing Facility in Durham, North Carolina.

An update from the Phase I study in China (NCT03975907) with 3 years term follow-up was presented as a poster at the 2023 American Society of Hematology ("**ASH**") Annual Meeting in December 2023.

Satricabtagene autoleucel (CT041)

Satricabtagene autoleucel is an autologous humanized CAR T-cell product candidate against Claudin18.2 (CLDN18.2), a membrane protein highly expressed in certain cancers. As of the date of this announcement, satricabtagene autoleucel, based on our information, is the world's first CAR T-cell candidate for the treatment of solid tumors entering a Phase II clinical trial.

In April 2023, satricabtagene autoleucel IND was approved by the National Medical Products Administration (NMPA) for the postoperative adjuvant therapy of Claudin18.2 positive pancreatic cancer (PC) (CT041-ST-05, NCT05911217). In May 2023, the Phase 2 part of the Phase 1b/2 clinical trial (NCT04404595) in the U.S. and Canada was 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. The study is currently under a clinical hold by the FDA due to CMC observations related to our RTP Manufacturing Facility.

Updates from the Phase 1b study in the U.S. (NCT04404595) were presented as a poster at the 2024 American Society of Clinical Oncology Gastrointestinal Cancers Symposium ("**ASCO GI**").

CT011

CT011 is an autologous CAR T-cell product candidate against Glypican-3 (GPC3). In January 2024, CT011 IND was approved by the NMPA for GPC3-positive stage IIIa hepatocellular carcinoma at high risk of recurrence after surgical resection.

CT071

CT071 is an autologous fully human CAR T-cell therapy candidate against G protein-coupled receptor class C group 5 member D (GPRC5D) developed utilizing CARsgen's proprietary CARcelerate™ platform for the treatment of R/R MM and relapsed/refractory primary plasma cell leukemia (R/R pPCL). The IND was cleared by the FDA on November 30, 2023 for R/R MM and R/R pPCL. An investigator-initiated trial (IIT) is ongoing in China to assess the safety and efficacy of CT071 in treating R/R MM and relapsed/refractory plasma cell leukemia (R/R PCL) (NCT05838131).

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 expanded our global manufacturing capacity in China and the U.S. to support both clinical trials and subsequent commercialization of our pipeline. 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, which 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.

In December 2023, during its inspection, FDA found that certain procedures related to the manufacturing of the CAR T products were not conducted in accordance with Current Good Manufacturing Practices (CGMP) or other procedural controls and requirements associated with the manufacturing facility, and a clinical hold was subsequently initiated for zevorcabtagene autoleucel, satricabtagene autoleucel and CT071. We have already been conducting a comprehensive review and improvement on the CGMP and are working closely with the FDA to address the findings to ensure the smooth progress and production quality for clinical trials and launching applications. A response with Corrective and Preventive Actions (CAPAs) plan with a timetable was submitted to FDA on December 28, 2023. We are continuing to address any observations identified by FDA and will submit a complete response once ready. Then, the FDA has 30 days to determine if the clinical hold can be lifted. We are committed to working closely with the FDA to address the findings to ensure the smooth progress and production quality for clinical trials and launching applications.

Commercialization and External Collaboration

In January 2023, CARsgen and Huadong Medicine (Hangzhou) Co., Ltd., a wholly-owned subsidiary of Huadong Medicine Co., Ltd. (SZ. 000963) entered into a collaboration agreement for the commercialization of CARsgen's lead drug candidate, zevorcabtagene autoleucel, in mainland China.

In August 2023, CARsgen and Moderna, Inc. (Nasdaq: MRNA, "**Moderna**") have initiated a collaboration agreement to investigate satricabtagene autoleucel in combination with Moderna's investigational Claudin18.2 mRNA cancer vaccine.

I. MANAGEMENT DISCUSSION AND ANALYSIS

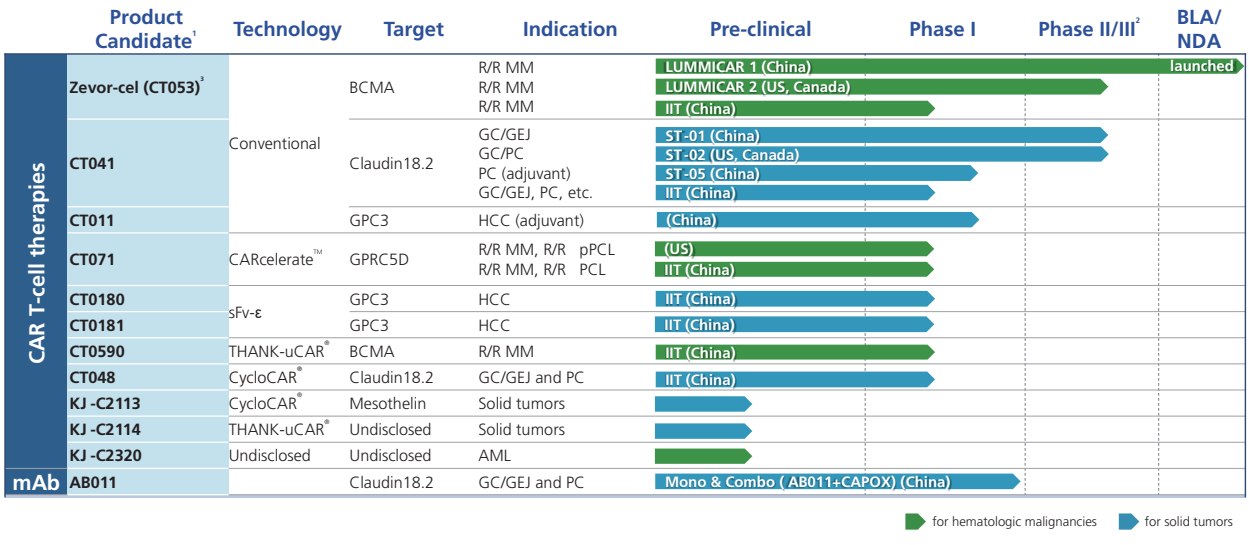
1. OVERVIEW

CARsgen is a biopharmaceutical company with operations in China and the U.S. and is focused on innovative CAR T-cell therapies for the treatment of hematologic malignancies and solid tumors. CARsgen has established a comprehensive CAR T-cell research and development platform, encompassing target discovery, innovative CAR T-cell development, clinical trials, and commercial-scale production. CARsgen has internally developed novel technologies and a product pipeline with global rights to address major challenges of CAR T-cell therapies, such as improving the safety profile, enhancing the efficacy in treating solid tumors, and reducing treatment costs. CARsgen's mission is to become a global biopharmaceutical leader that brings innovative and differentiated cell therapies to cancer patients worldwide and makes cancer curable.

2. BUSINESS REVIEW

Our Products and Product Pipeline

Since CARsgen's inception, our strategic business model has been centered around the in-house development of innovative and differentiated biopharmaceutical products, with a primary focus on CAR T-cell therapies. Our leading product candidate, zevorcabtagene autoleucel for the treatment of the hematologic malignancy R/R MM, is at the most advanced development stage among the product candidates in our pipeline. Another hematologic malignancy product candidate (CT071) is in Phase 1 clinical trial. In addition, solid tumor product candidates are in confirmatory Phase II (CT041), Phase I (CT011), and Pre-IND stages. The following chart summarizes the development status of each product candidate in our pipeline as of the date of this announcement. Our product candidates are developed in-house and protected by the global rights owned by CARsgen.



R/R MM: relapsed/refractory multiple myeloma; GC: gastric cancer; GEJ: gastroesophageal junction cancer; PC: pancreatic cancer; HCC: hepatocellular carcinoma; R/R pPCL: relapsed/refractory primary plasma cell leukemia; 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 (SZ: 000963). Rights in the South Korean market have been licensed out to HK Inno.N Corporation (KOSDAQ: 195940).

Zevorcabtagene autoleucel (CT053) – Fully Human BCMA CAR T

Zevorcabtagene autoleucel 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 which helps overcome the challenge of T-cell exhaustion by reducing the self-activation of CAR T cells in the absence of tumor-associated targets.

CARsgen developed zevorcabtagene autoleucel in-house with our integrated research and development platform. Zevorcabtagene autoleucel received Orphan Drug designation for the treatment of multiple myeloma from the U.S. FDA in 2019 and Orphan Medicinal Product designation for the treatment of multiple myeloma from the European Medicines Agency (EMA) in 2020. Also, zevorcabtagene autoleucel received Regenerative Medicine Advanced Therapy (RMAT) designation 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 2020, and received the priority review from NMPA in October 2022.

As informed by the NMPA on March 1, 2024, zevorcabtagene autoleucel was granted conditional approval on February 23, 2024 for the treatment of adult patients with relapsed or refractory multiple myeloma who have progressed after at least 3 prior lines of therapy (including a proteasome inhibitor and an immunomodulatory agent). Over 100 patients have been enrolled in the Phase 2 trial (NCT03915184) for R/R MM in North America. The study has been placed on clinical hold by the FDA due to CMC observations related to our RTP Manufacturing Facility based in Durham, North Carolina. Updated data for a total of 17 patients who received zevorcabtagene autoleucel infusion in the Phase 1b/2 trial in U.S. were presented orally at the 7th Annual CAR-TCR Summit in September 2022.

At the 65th ASH Annual Meeting in December, 2023, CARsgen presented a poster titled 'Three-Year Follow-up on Efficacy and Safety Results from Phase I Lummicar Study 1 of Zevorcabtagene Autoleucel in Chinese Patients with Relapsed or Refractory Multiple Myeloma', highlighting the 3-year follow-up on efficacy and safety results from the Phase I portion of Phase I/II registrational study in China (LUMMICAR-1, NCT03975907).

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 clinical trials will be disclosed in academic journals or at scientific conferences in due course. CARsgen plans to conduct additional clinical trials to develop zevorcabtagene autoleucel as a treatment option in earlier lines of multiple myeloma.

Warning under Rule 18A.08(3) of the Listing Rules: There is no assurance that zevorcabtagene autoleucel will ultimately be successfully developed and marketed (outside China) by the Company. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

Satricabtagene autoleucel – Humanized Claudin18.2 CAR T

Satricabtagene autoleucel is an autologous CAR T-cell product candidate against the protein Claudin18.2 and has the potential to be first-in-class globally. Satricabtagene autoleucel 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, colorectal, lung, and ovarian cancers. Leveraging our in-depth understanding in CAR T-cell therapy, as well as our integrated antibody platform, we were the first in the world to successfully identify, validate and report 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 preconditioning regimen that is administered prior to infusion of satricabtagene autoleucel. This regimen features the addition of low-dose nab-paclitaxel to the conventional lymphodepletion regimen comprising cyclophosphamide and fludarabine (FNC).

Satricabtagene autoleucel 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. Satricabtagene autoleucel was granted PRIME eligibility by the EMA for the treatment of advanced gastric cancer in November 2021 and was granted RMAT Designation for the treatment of advanced GC/GEJ with Claudin18.2-positive tumors in January 2022.

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

In May 2023, the Phase 2 part of the satricabtagene autoleucel Phase 1b/2 clinical trial was initiated in the U.S. and Canada for advanced GC/GEJ trial (CT041-ST-02, NCT04404595). The study is currently under a clinical hold by the FDA due to CMC observations related to our RTP Manufacturing Facility. At the 2024 ASCO GI meeting, CARsgen presented a poster entitled 'CLDN18.2 chimeric antigen receptor T cell therapy for patients with advanced gastric and pancreatic adenocarcinoma: Results of ELIMYN18.2 phase 1b clinical trial' with updated study results for satricabtagene autoleucel in the Phase 1b trial in the U.S..

Trials of satricabtagene autoleucel conducted in CARsgen in China include investigator-initiated trials (NCT03874897), a Phase Ib clinical trial for advanced GC/GEJ and PC and a confirmatory Phase II clinical trial for advanced GC/GEJ in China (CT041-ST-01, NCT04581473), and a Phase I clinical trial for PC adjuvant therapy in China (CT041-ST-05, NCT05911217). The updated results from the Phase Ib/II satricabtagene autoleucel study in China were presented at the 2022 ASCO Annual Meeting with the poster titled 'Multicenter Phase 1b Trial of Salvage CT041 Claudin18.2 – specific Chimeric Antigen Receptor T Cell Therapy for Patients with Advanced Gastric and Pancreatic Adenocarcinoma'. CARsgen plans to submit an NDA to the NMPA in China at the end of 2024.

The results of the investigator-initiated trial of satricabtagene autoleucel (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.

Two metastatic pancreatic cancer patients administrated with satricabtagene autoleucel after the failure of standard therapy (NCT04581473 and NCT03874897) were reported in *Journal of Hematology & Oncology* article titled "CT041 CAR T cell therapy for Claudin18.2-positive metastatic pancreatic cancer".

An article titled "Metastatic gastric cancer target lesion complete response with Claudin18.2-CAR T cells" was published in *Journal for ImmunoTherapy of Cancer* reporting a patient with metastatic GC, who had progressed on four lines of combined systemic chemotherapy and immunotherapy after receiving two satricabtagene autoleucel infusions achieved target lesion complete response and sustained an 8-month overall partial response with only minimal ascites.

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 satricabtagene autoleucel as an earlier line of treatment for GC/GEJ and PC.

Warning under Rule 18A.08(3) of the Listing Rules: There is no assurance that satricabtagene autoleucel will ultimately be successfully developed and marketed by the Company. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

CT011 – Humanized GPC3 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.

In January 2024, CT011 achieved IND clearance from the NMPA for patients with GPC3-positive stage IIIa hepatocellular carcinoma at high risk of recurrence after surgical resection.

In July 2023, an article titled "Combined local therapy and CAR-GPC3 T-cell therapy in advanced hepatocellular carcinoma: a proof-of-concept treatment strategy" was published in *Cancer Communication (London, England)* demonstrating patients who received local therapy followed by sequential infusions of CAR-GPC3 T-cells achieved disease-free survival exceeding 7 years.

Warning under Rule 18A.08(3) of the Listing Rules: There is no assurance that CT011 will ultimately be successfully developed and marketed by the Company. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

CT071 – GPRC5D CAR T

CT071 is an autologous CAR T-cell therapy candidate targeting GPRC5D developed utilizing CARsgen's proprietary CARcelerate™ platform of for the treatment of R/R MM and R/R pPCL. It incorporates a fully-human single-chain variable fragment (scFV) developed by CARsgen.

CARsgen's proprietary CARcelerate™ platform may shorten CT071's manufacturing time to around 30 hours and therefore, resulting CAR-T cells are younger and possibly more potent compared to conventional manufacturing. The improved manufacturing efficiency aims to expedite the availability of the product to the patients, enhance the supply capacity and reduce the manufacturing costs.

CT071 IND was cleared by the FDA in November 2023 for the treatment of patients with R/R MM and R/R pPCL. The Phase 1 clinical trial of CT071 in the U.S. is currently on clinical hold by the FDA due to CMC observations at our RTP Manufacturing Facility. An investigator-initiated trial (IIT) is already under way in China to assess the safety and efficacy of CT071 in treating R/R MM and R/R PCL (NCT05838131). Preliminary clinical data from the IIT shows an acceptable safety profile with preliminary efficacy.

Warning under Rule 18A.08(3) of the Listing Rules: There is no assurance that CT071 will ultimately be successfully developed and marketed by the Company. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

IND-Enabling or Preclinical Stage Product Candidates

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

CT0180 is an autologous T-cell product engineered to express a fusion protein of GPC3-targeted antibody and T-cell receptor. An IIT trial has been initiated in China to evaluate the efficacy and safety of CT0180 in the treatment of hepatocellular carcinoma. The results from the IIT in China were presented at the 2023 ASCO Annual Meeting with the poster titled 'Phase 1 trial of Chimeric Anti-GPC3 scFv-CD3ε Engineered T Cells (CT0180) in Patients with Advanced Hepatocellular Carcinoma'.

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

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

CT048 (KJ-C1807) is a next-generation autologous CAR T-cell product candidate developed with our CycloCAR® technology being developed to treat patients with GC/GEJ and PC targeting Claudin18.2. 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. CARsgen has initiated an IIT trial to evaluate the efficacy and safety of CT048 for the treatment of GC/GEJ and PC.

KJ-C2112 is a next-generation autologous CAR T-cell product candidate for the treatment of patients with EGFR/EGFRvIII-overexpressing glioblastoma. Preclinical studies have demonstrated the efficacy of KJ-C2112. We plan to collaborate with an experienced principal investigator and study KJ-C2112 in an investigator-initiated trial.

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

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

Continuous Discovery and Technology Development

Despite the approval of some CAR T-cell products for the last-line treatment of hematologic malignancies, significant challenges 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 for global cancer patients.

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

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

To improve the manufacturing efficiency, we developed a proprietary platform that can shorten the manufacturing time for the CAR T cells to around 30 hours, as compared to the conventional CAR T manufacturing process. The CARcelerate™ platform produces CAR T cells that are younger and more likely to remain in a 'naïve' state and less likely to be exhausted. As such, these CAR T cells from the CARcelerate™ platform are expected to exhibit more potent tumor killing activity. The improved manufacturing efficiency is expected to enhance the supply capacity, reduce the manufacturing costs, and expedite the availability of the product to the patients. We are using CARcelerate™ to manufacture an autologous CAR T-cell therapy candidate targeting GPRC5D, CT071, for the treatment of patients with R/R MM or R/R pPCL.

(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.

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

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

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

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

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

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

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

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

As of December 31, 2023, we had more than 300 patents of which 104 patents had been issued globally including China, the United States, Europe and Japan. This status is an increase of 22 issued patents and 29 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.The integrated manufacturing is also expected to significantly reduce costs and improve margins for more advantageous commercialization. To further improve the manufacture efficiency, we developed a proprietary platform CARcelerate™ that can shorten the manufacturing time for the CAR T cells to around 30 hours, as compared to the conventional CAR T manufacturing process. The CARcelerate™ platform produces CAR T cells that are younger and are more likely to remain in a 'naïve' state and less likely to be exhausted; as such, these CAR T cells from the CARcelerate™ platform are expected to exhibit more potent tumor killing activity.

We have expanded our manufacturing capacity in China and the U.S. to support both the clinical trials and the subsequent commercialization of our products. A total of three production sites have been put into full operation, with the one in Xuhui, Shanghai, supporting clinical development and the ones located in Jinshan, Shanghai, and Research Triangle Park, Durham, North Carolina, United States supporting both clinical development and commercialization manufacture.

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. Our clinical manufacturing facility in Xuhui, Shanghai with a total gross floor area (GFA) of approximately 3,000 sq.m. and an annual CAR T production capacity to support the CAR T-cell treatment of 200 patients has been used for clinical manufacturing of CAR T-cell products in supporting multiple clinical studies of our leading assets. Since establishment, our Xuhui facility has achieved over 95% manufacturing success rate for all product candidates. We have also completed the construction of our commercial-scale manufacturing facility located in Jinshan, Shanghai with a total GFA of approximately 7,600 sq.m. and an estimated manufacturing capacity to support CAR T-cell treatment of up to 2,000 patients annually. The Jinshan Manufacturing Facility passed the on-site inspection conducted by the Shanghai Medical Products Administration (SHMPA) and obtained the first Manufacture License for Pharmaceutical Products ("**Manufacturing License**") issued in China for CAR T-cell therapy.

The RTP Manufacturing Facility, with a total GFA of approximately 3,300 sq.m, was put into full operation in September 2022 with technology transfer completed and provides CARsgen with additional manufacturing capacity of autologous CAR T-cell products for 700 patients annually. In December 2023, during its inspection, FDA found that certain procedures related to the manufacturing of the CAR T products were not conducted in accordance with Current Good Manufacturing Practices (CGMP) or other procedural controls and requirements associated with the manufacturing facility, and a clinical hold was subsequently initiated for zevorcabtagene autoleucel, satricabtagene autoleucel and CT071. We have already been conducting a comprehensive review and improvement on the CGMP and is working closely with the FDA to address the findings to ensure the smooth progress and production quality for clinical trials and launching applications. A response with Corrective and Preventive Actions (CAPAs) plan with a timetable was submitted to FDA on December 28, 2023. We are continuing to address any observations identified by FDA and will submit a complete response once ready. Then, the FDA has 30 days to determine if the clinical hold can be lifted. We are committed to working closely with the FDA to address the findings to ensure smooth progress and production quality for clinical trials and launching applications.

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 zevorcabtagene autoleucel and satricabtagene autoleucel clinical studies in the United States and Canada. With large scale lentiviral vectors production, we expect to reduce the CAR T manufacturing costs noticeably.

Commercialization and External Collaboration

In formulating our strategies for the commercialization and development 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.

Collaboration to evaluate satricabtagene autoleucel in combination with an mRNA cancer vaccine with MODERNA, INC.

CARsgen and Moderna, Inc. (Nasdaq: MRNA, "**Moderna**") have initiated a collaboration agreement (the "**Agreement**") to investigate CARsgen's Claudin18.2 CAR T-cell product candidate (satricabtagene autoleucel) in combination with Moderna's investigational Claudin18.2 mRNA cancer vaccine.

Moderna is developing an investigational off-the-shelf mRNA cancer vaccine that encodes for the Claudin18.2 protein, a tumor associated antigen. Pursuant to the Agreement, the collaboration contemplates conducting preclinical studies and a Phase I clinical trial to evaluate satricabtagene autoleucel in combination with Moderna's Claudin18.2 mRNA cancer vaccine. Since reaching the agreement, CARsgen has collaborated with Moderna in conducting a series of in vitro and in vivo studies to evaluate the combination of satricabtagene autoleucel and Claudin18.2 mRNA cancer vaccine.

Collaboration for zevorcabtagene autoleucel commercialization in mainland China with Huadong Medicine

In January 2023, CARsgen and Huadong Medicine (Hangzhou) Co., Ltd., a wholly-owned subsidiary of Huadong Medicine Co., Ltd. (SZ. 000963) entered into a collaboration agreement for the commercialization of zevorcabtagene autoleucel in mainland China. Under the terms of the agreement, CARsgen received 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 zevorcabtagene autoleucel 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 zevorcabtagene autoleucel 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 zevorcabtagene autoleucel in China.

License Agreement for zevorcabtagene autoleucel 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 zevorcabtagene autoleucel, 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 December 31, 2023, we had a total of 516 employees.

CARsgen continuously invests in talent development. New employees from various subsidiaries and departments completed new hire orientation training and new employees have buddies assigned to. The training and buddies 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 accelerated the development of talents with global experience and perspective offering English training, job rotations and overseas assignments. CARsgen also supports new managers' role transition and leadership development by offering trainings and organized experience sharing salon.

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 five 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 zevorcabtagene autoleucel, CT071, satricabtagene autoleucel, and innovative technology platforms, including CycloCAR®, THANK-uCAR®, LADAR® and CARcelerate™, we are committed to increasing the efficiency and developing the innovative therapies to fulfill these unmet medical needs.

Future and Outlook

With the mission of "making cancer curable", we will continue to develop innovative product candidates for the treatment of cancer patients worldwide. Building on the milestones we have achieved, we will focus on rapid clinical development of zevorcabtagene autoleucel and satricabtagene autoleucel in both China and overseas, CT071 in overseas and CT011 in China. 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 complete the rectification according to the requirements given by the FDA as fast as we can and continue to expand our manufacturing capacity in China and the United States to support the clinical trials and future commercialization of our product candidates and to make CAR T-cell treatments more accessible and affordable. We will continue to establish additional external partnerships with leading research institutes and pharmaceutical companies on technology and product licenses as means to maximize the application of our technology platform and the value of our product pipeline, bringing more innovative cell therapy products to cancer patients worldwide and ultimately creating more value for our investors and the society.

3. FINANCIAL REVIEW

Overview

We have no products approved for commercial sale and have not generated any revenue from product sales. We have never been profitable and have incurred operating losses in every year since inception, with operating losses of RMB768 million and RMB881 million for the years ended December 31, 2023 and 2022, respectively. Substantially all of our operating losses resulted from research and development expenses and administrative expenses.

Loss for the years

Our net loss was RMB748 million for the year ended December 31, 2023, representing a decrease of RMB144 million from RMB892 million for the year ended December 31, 2022. The decrease was primarily due to (i) the decrease in share-based compensation ("**Adjusted Items**"), which totaled RMB14 million for the year ended December 31, 2023, representing a decrease of RMB30 million from RMB44 million for the year ended December 31, 2022; (ii) lower research and development expenses and lower administrative expenses; and (iii) foreign exchange losses of RMB30 million for the year ended December 31, 2023, representing a net impact of RMB67 million from foreign exchange losses of RMB97 million for the year ended December 31, 2022.

Non-IFRSs Measures

To supplement the Group's consolidated net loss and net loss per share which are presented in accordance with the IFRSs, 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 IFRSs.

Adjusted net loss for the years and adjusted net loss per share for the years represent the net loss and net loss per share respectively excluding the effect of share-based compensation. The terms adjusted net loss and adjusted net loss per share are not defined under the IFRSs.

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

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Loss for the years	**(747,794)**	(892,247)
Add:		
Share-based compensation	**14,458**	43,995
Adjusted net loss	**(733,336)**	(848,252)

	Year ended December 31,	
	2023	2022
	RMB	*RMB*
	(Audited)	(Audited)
Loss per share for the years	**(1.34)**	(1.62)
Add:		
Share-based compensation per share	**0.03**	0.08
Adjusted net loss per share	**(1.31)**	(1.54)

The Company believes that the adjusted non-IFRSs 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-IFRSs 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-IFRSs measures is not intended to be considered in isolation or as a substitute for the financial information prepared and presented in accordance with the IFRSs. 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 IFRSs, and these non-IFRSs measures may not be comparable to similarly-titled measures represented by other companies.

Research and Development Expenses

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Employee benefit expenses	**253,480**	273,297
Testing and clinical expenses	**249,638**	252,470
Depreciation of property, plant and equipment	**55,817**	47,208
Research and development consumables	**54,632**	51,494
Utilities	**19,178**	19,070
Depreciation of right-of-use assets	**12,266**	20,160
Amortization of intangible assets	**6,144**	5,846
Travelling and transportation expenses	**5,793**	4,952
Office expenses	**1,861**	2,392
Short term lease and low value lease expenses	**1,623**	814
Professional service expenses	**270**	1,191
Other expenses	**957**	1,407
Total	**661,659**	680,301

Research and development expenses decreased to RMB662 million for the year ended December 31, 2023, representing a decrease of RMB18 million from RMB680 million for the year ended December 31, 2022, primarily due to lower employee benefit expenses.

Administrative Expenses

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Employee benefit expenses	**71,857**	79,931
Professional service expenses	**20,356**	23,216
Office expenses	**7,841**	13,041
Depreciation of property, plant and equipment	**6,411**	4,411
Depreciation of right-of-use assets	**5,499**	2,837
Auditors' remuneration	**4,191**	3,445
– audit service	**4,191**	3,260
– non-audit service	**–**	185
Short term lease and low value lease expenses	**3,847**	723
Travelling and transportation expenses	**3,112**	2,036
Utilities	**1,399**	991
Amortization of intangible assets	**1,258**	1,071
Other expenses	**5,918**	4,093
Total	**131,689**	135,795

Administrative expenses decreased to RMB132 million for the year ended December 31, 2023, representing a decrease of RMB4 million from RMB136 million for the year ended December 31, 2022, primarily due to lower employee benefit expenses.

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

Employee benefit expenses

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Wages and salaries	**276,243**	250,072
Pension costs	**20,582**	21,472
Share-based compensation	**14,458**	43,995
Other employee benefits	**14,054**	37,689
Total	**325,337**	353,228
Amount included in Research and Development Expenses	**253,480**	273,297
Amount included in Administrative Expenses	**71,857**	79,931

The decrease of employee benefit expenses is mainly due to lower share-based compensation and other employee benefits.

Share-based payments

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

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Research and development expenses	**13,910**	36,310
Administrative expenses	**548**	7,685
Total	**14,458**	43,995

The decrease of share-based compensation expenses is mainly due to the forfeiture of immature restricted shares and stock options of departing employees.

4. LIQUIDITY AND CAPITAL RESOURCES

Management monitors and maintains a level of cash and bank balances 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 years indicated:

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Net cash used in operating activities	**(454,935)**	(643,048)
Net cash generated from investing activities	**39,251**	2,386,990
Net cash used in financing activities	**(22,142)**	(236,514)
Net (decrease)/increase in cash and cash equivalents	**(437,826)**	1,507,428
Cash and cash equivalents at beginning of the years	**2,268,036**	691,284
Exchange gains on cash and cash equivalents	**19,542**	69,324
Cash and cash equivalents at end of the years	**1,849,752**	2,268,036

Net Cash Used in Operating Activities

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

Our operating activities used RMB455 million and RMB643 million for the year ended December 31, 2023 and 2022, respectively. During the Reporting Period, we received 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-income company. We believe our pipeline products have promising global market potential in the future. We intend to continue investing in our research and development efforts and aim to obtain marketing approvals for our product candidates as soon as feasible. As we launch and commercialize our product candidates, we expect to generate operating income and improve our net operating cash outflow position.

Net Cash Generated from Investing Activities

Our cash generated from investing activities mainly reflects our cash generated from redemption of investment of term deposit and partially offset by purchase of property, plant and equipment.

For the year ended December 31, 2023, our net cash generated from investing activities was RMB39 million, which was primarily redemption of investment of term deposit and partially offset by purchase of property, plant and equipment. For the year ended December 31, 2022, our net cash generated from investing activities was RMB2,387 million, which was primarily redemption of investment of term deposit and partially offset by purchase of property, plant and equipment.

Net Cash Used in Financing Activities

During the Reporting Period, our cash outflow from financing activities was primarily due to payments of lease expenses and repayments of bank borrowings.

For the year ended December 31, 2023, our net cash used in financing activities was RMB22 million, primarily attributable to payment of lease expenses of RMB23 million, net repayments of bank borrowings of RMB5 million and payment of interest expenses of RMB0.3 million. For the year ended December 31, 2022, our net cash used in financing activities was RMB237 million, primarily attributable to net repayments of bank borrowings of RMB219 million and payment of interest expenses of RMB10 million.

Cash and Bank Balances

	As at December 31, 2023 ***RMB'000*** **(Audited)**	As at December 31, 2022 *RMB'000* (Audited)
Cash at banks		
– USD	**1,058,394**	1,357,360
– RMB	**779,122**	906,855
– HKD	**12,236**	3,821
Total	**1,849,752**	2,268,036

The Group's total cash and bank balances as at December 31, 2023 were RMB1,850 million, representing a decrease of RMB418 million compared to RMB2,268 million as at December 31, 2022. The decrease was primarily attributable to payments of research and development expenses, and administrative expenses.

Borrowing and Gearing Ratio

The Group's total borrowings, including interest-bearing borrowings, as at December 31, 2023 were RMB3 million, representing a decrease of RMB4 million compared to RMB7 million as at December 31, 2022.

As at December 31, 2023 and December 31, 2022, the Group's bank borrowings of approximately RMB3 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 December 31, 2023, the maturity of the Group's secured borrowings is 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 December 31, 2023 and 2022 were 4.73% and 4.83%, respectively.

Lease liabilities

The Group leases offices and dormitory. Lease on offices and dormitory 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 entities.

Our lease liabilities decreased to RMB83 million as at December 31, 2023 from RMB112 million as at December 31, 2022.

5. OTHER FINANCIAL INFORMATION

Significant Investments, Material Acquisitions and Disposals

As at December 31, 2023, we did not hold any significant investments. During the year ended December 31, 2023, we did not have any material acquisitions or disposals of subsidiaries, associates and joint ventures.

Foreign Exchange Risk

The Group has entities operating in the United States of America and in the People's Republic of China and there are certain cash and bank balances, other receivables, accruals and other payables denominated in a currency that is not the functional currency of the relevant group entities. As at December 31, 2023, the Group had no foreign exchange hedging instruments. The Group constantly reviews the economic situation and its foreign exchange risk profile, and will consider appropriate hedging measures, as may be necessary.

As at December 31, 2023 and 2022, if the USD strengthened/weakened by 5% against the RMB with all other variables held constant, net loss for the years would have increased/decreased approximately RMB90 million and RMB78 million respectively.

Capital Expenditure

For the year ended December 31, 2023, the Group's total capital expenditure amounted to approximately RMB10 million, which was mostly used in purchase of property, plant and equipment, and software.

Charge on Assets

As at December 31, 2023 and 2022, the Group's building with carrying values of RMB29 million and RMB31 million respectively were pledged for certain of the Group's borrowings.

As at December 31, 2023 and 2022, the Group's land use right with carrying values of RMB6.5 million and RMB6.6 million respectively was pledged as collateral for the Group's borrowings.

Contingent Liability

As at December 31, 2023, the Group did not have any material contingent liabilities.

Employees and Remuneration Policies

During the Reporting Period, we have scaled down our team from about 539 employees as at December 31, 2022 to 516 employees as at December 31, 2023. As at December 31, 2023, we had a total of 516 employees, with 61% of them are female.

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

During the Reporting Period, 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 shareholders' interest. The Group will continue to grow through self-development, mergers and acquisitions, and other means. We will employ a combination of financing channels to finance capital expenditures, including but not limited to internal funds, capital markets and bank loans. Currently, the bank credit lines available to the Group are adequate.

II. ANNUAL RESULTS

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

Year ended December 31, 2023

	Notes	**2023** ***RMB'000***	2022 *RMB'000*
Administrative expenses		**(131,689)**	(135,795)
Research and development expenses		**(661,659)**	(680,301)
Other income	*3*	**56,536**	35,595
Other losses – net	*4*	**(30,837)**	(100,796)
Operating loss		**(767,649)**	(881,297)
Finance income		**24,926**	5,866
Finance costs		**(4,664)**	(15,521)
Finance income/(costs) – net	*6*	**20,262**	(9,655)
Loss before income tax		**(747,387)**	(890,952)
Income tax expense	*7*	**(407)**	(1,295)
Loss for the year and attributable to the ordinary equity holders of the parent		**(747,794)**	(892,247)
Other comprehensive (loss)/income for the year:			
Items that may be reclassified to profit or loss			
Exchange differences on translation of subsidiaries		**(33,065)**	(63,456)
Items that will not be reclassified to profit or loss			
Exchange differences on translation of the Company		**88,317**	377,717
Other comprehensive income for the year, net of tax		**55,252**	314,261
Total comprehensive loss for the year attributable to the ordinary equity holders of the parent		**(692,542)**	(577,986)
Loss per share attributable to ordinary equity holders of the parent			
Basic and diluted loss per share (in RMB)	*9*	**(1.34)**	(1.62)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

December 31, 2023

	Notes	**2023** ***RMB'000***	2022 *RMB'000*
NON-CURRENT ASSETS			
Property, plant and equipment		**311,952**	363,850
Right-of-use assets		**49,438**	77,533
Intangible assets		**8,660**	14,476
Other non-current assets and prepayments		**14,076**	6,321
Total non-current assets		**384,126**	462,180
CURRENT ASSETS			
Inventories		**683**	–
Other receivables		**9,792**	11,834
Other current assets and prepayments		**12,861**	20,769
Cash and bank balances		**1,849,752**	2,268,036
Total current assets		**1,873,088**	2,300,639
CURRENT LIABILITIES			
Accruals and other payables	*10*	**158,008**	141,114
Borrowings		**2,522**	4,850
Lease liabilities		**12,230**	17,134
Income tax payable		**–**	1,341
Deferred income		**13,220**	6,565
Contract liabilities		**10,237**	–
Total current liabilities		**196,217**	171,004
NET CURRENT ASSETS		**1,676,871**	2,129,635
TOTAL ASSETS LESS CURRENT LIABILITIES		**2,060,997**	2,591,815
NON-CURRENT LIABILITIES			
Borrowings		**–**	2,523
Lease liabilities		**70,468**	94,938
Deferred income		**10,387**	21,180
Contract liabilities		**178,442**	–
Total non-current liabilities		**259,297**	118,641
Net assets		**1,801,700**	2,473,174
EQUITY			
Equity attributable to owners of the parent			
Share capital		**1**	1
Reserves		**1,801,699**	2,473,173
Total equity		**1,801,700**	2,473,174

NOTES TO THE FINANCIAL STATEMENTS

1. CORPORATE AND GROUP INFORMATION

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

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

The consolidated financial statements are presented in thousands of Renminbi ("RMB"), unless otherwise stated, and were approved and authorized for issue by the Board of Directors of the Company on March 26, 2024.

2. BASIS OF PREPARATION AND ACCOUNTING POLICIES

These financial statements have been prepared in accordance with IFRSs, which include all standards and interpretations approved by the IASB, and the disclosure requirements of the Hong Kong Companies Ordinance. They have been prepared under the historical cost convention, except for wealth management products which have been measured at fair value. These financial statements are presented in RMB and all values are rounded to the nearest thousand (RMB'000) except when otherwise indicated.

The Group has adopted the following new and revised IFRSs for the first time for the current year's financial statements.

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

Except as described below, the application of the new and revised IFRSs in the current year has had no material impact on the Group's financial position and performance for the current and prior years.

Amendments to IAS 12 *Deferred Tax related to Assets and Liabilities arising from a Single Transaction* narrow the scope of the initial recognition exception in IAS 12 so that it no longer applies to transactions that give rise to equal taxable and deductible temporary differences, such as leases and decommissioning obligations. Therefore, entities are required to recognise a deferred tax asset (provided that sufficient taxable profit is available) and a deferred tax liability for temporary differences arising from these transactions.

Prior to the initial application of these amendments, the Group applied the initial recognition exception and did not recognise a deferred tax asset and a deferred tax liability for temporary differences for transactions related to leases. The Group has applied the amendments on temporary differences related to leases as at January 1, 2022. Upon initial application of these amendments, the Group recognised (i) a deferred tax asset amounting to RMB18,754,000 for all deductible temporary differences associated with lease liabilities (provided that sufficient taxable profit is available), and (ii) a deferred tax liability amounting to RMB18,754,000 for all taxable temporary differences associated with right-of-use assets at January 1, 2022. The adoption of amendments to IAS 12 had no cumulative effect on the Group's financial statements.

3. OTHER INCOME

	2023 *RMB'000*	2022 *RMB'000*
Government grants (i)	**8,671**	13,815
Interest income on term deposits with original maturity between three and twelve months	**47,865**	21,700
Others	**–**	80
Total	**56,536**	35,595

(i) The government grants mainly represent subsidies received from the government to support on certain research and development projects that are relating to both expenses and assets. Government grants were released to profit or loss either over the periods that the expenses for which it is intended to compensate are expensed, or over the expected useful life of the relevant asset, when all attaching conditions and requirements are compliant with.

4. OTHER LOSSES – NET

	2023 *RMB'000*	2022 *RMB'000*
Foreign exchange losses – net	**(30,467)**	(97,351)
Others	**(370)**	(3,445)
Total	**(30,837)**	(100,796)

5. LOSS BEFORE TAX

	2023 *RMB'000*	2022 *RMB'000*
Employee benefit expenses	**325,337**	353,228
Testing and clinical expenses	**249,638**	252,470
Depreciation of property, plant and equipment	**62,228**	51,619
Research and development consumables	**54,632**	51,494
Professional service expenses	**20,626**	24,407
Utilities	**20,577**	20,061
Depreciation of right-of-use assets	**17,765**	22,997
Office expenses	**9,702**	15,433
Travelling and transportation expenses	**8,905**	6,988
Amortization of intangible assets	**7,402**	6,917
Short term lease and low value lease expenses	**5,470**	1,537
Auditors' remuneration	**4,191**	3,445
– Audit service	**4,191**	3,260
– Non-audit service	**–**	185
Other expenses	**6,875**	5,500
Total	**793,348**	816,096
Administrative expenses	**131,689**	135,795
Research and development expenses	**661,659**	680,301
Total	**793,348**	816,096

6. FINANCE INCOME/(COSTS) – NET

	2023	2022
	RMB'000	*RMB'000*
Finance Income		
Interest income	**24,926**	5,866
Finance costs		
Interest expense on lease liabilities	**(4,388)**	(4,980)
Interest expense on bank borrowings	**(276)**	(10,541)
Total finance cost	**(4,664)**	(15,521)
Total finance income/(costs) – net	**20,262**	(9,655)

7. INCOME TAX EXPENSE

	2023	2022
	RMB'000	*RMB'000*
Current income tax		
– PRC Corporate Tax	**–**	–
– Ireland Capital Gains Tax	**407**	1,295
Deferred income tax	**–**	–
	407	1,295

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% (2022: 16.5%) as the Company has no estimated assessable profit.

(c) PRC corporate income tax

Subsidiaries in Mainland China are subject to income tax at a rate of 25%(2022: 25%) pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the "CIT Law"), with the exception of CARsgen Therapeutics obtained its High and New Technology Enterprises status in year 2023 and hence is entitled to a preferential tax rate of 15% (2022: 15%) for a three-year period commencing 2023.

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

(d) The US corporate income tax

CARsgen USA, which was incorporated in Delaware, the United States on May 4, 2016, was subject to statutory U.S. Federal corporate income tax at a rate of 21% (2022: 21%) for the years ended December 31, 2023. CARsgen USA was also subject to the state income tax during for the years ended December 31, 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 corporation income tax and Ireland capital gains tax

Subsidiary in Ireland is subject to income tax at a rate of 12.5% (2022: 12.5%) on the estimated assessable profit and 33% (2022: 33%) on the capital gains. Provision for Ireland capital gain tax has been provided as the subsidiary has realized capital gain for the years ended December 31, 2023 and 2022.

8. DIVIDEND

No dividend was declared or paid by the Group during the years ended December 31, 2023 (2022:nil).

9. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic loss per share amount is based on the loss attributable to ordinary equity holders of the parent and the weighted average number of ordinary shares in issue (excluding shares reserved for share incentive scheme) during the reporting period.

No adjustment has been made to the basic loss per share amounts presented for the reporting period in respect of a dilution as the impact of restricted share units had an anti-dilutive effect on the basic loss per share amounts presented.

The calculation of the basic and diluted loss are based on:

	2023	2022
	RMB'000	*RMB'000*
Loss attributable to the ordinary equity holders of the parent *(RMB'000)*	**(747,794)**	(892,247)
Weighted average number of ordinary shares in issue during the year, used in the basic loss per share calculation *('000)*	**556,125**	551,626
Basic and diluted loss per share *(RMB)*	**(1.34)**	(1.62)

10. ACCRUALS AND OTHER PAYABLES

	2023	2022
	RMB'000	*RMB'000*
Accrued expenses (i)	**111,103**	81,536
Staff salaries and welfare payables	**36,800**	51,017
Other taxes payable	**2,621**	4,094
Payables for acquisition of property, plant and equipment	**1,029**	1,529
Payables for research and development consumables	**512**	503
Interest payables	**33**	49
Others	**5,910**	2,386
Total	**158,008**	141,114

(i) Accrued expenses were mainly expenses incurred for the research and development activities.

11. EVENTS AFTER THE REPORTING PERIOD

On March 1, 2024, the Company announced that the National Medical Products Administration ("**NMPA**") of China has approved the New Drug Application ("**NDA**") of zevorcabtagene autoleucel, for the treatment of adult patients with relapsed or refractory multiple myeloma who have progressed after at least 3 prior lines of therapy. According to the contract with Huadong Medicine Co., Ltd., the Company has received the first commercial milestone payments of RMB75 million as at the date of this announcement.

III. CORPORATE GOVERNANCE RELATED INFORMATION

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

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

Model Code for Securities Transactions

The Company has adopted the Insider Dealing Policy (the "**Policy**"), with terms no less exacting than the Model Code as set out in Appendix C3 to the Listing Rules as its own securities dealing policy to regulate all dealings by Directors and employees who, because of his/her office or employment, is likely to possess inside information in relation to the Group or the Company's securities.

Specific enquiries have been made to all Directors and the Directors have confirmed that they have complied with the Policy throughout the Reporting Period.

No incident of non-compliance of the Policy 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 C1 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.

Significant Event After the Reporting Period

On March 1, 2024, the Company announced that the NMPA of China has approved the NDA of zevorcabtagene autoleucel, for the treatment of adult patients with relapsed or refractory multiple myeloma who have progressed after at least 3 prior lines of therapy. According to the contract with Huadong Medicine Co., Ltd., the Company has received the first commercial milestone payments of RMB75 million as at the date of this announcement.

Legal Proceedings

As of December 31, 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 Listing (adjusted on a pro rata basis based on the actual net proceeds) have been and will be utilized in accordance with the purposes set out in the Prospectus. There was no change in the intended use of net proceeds as previously disclosed in the Prospectus as follows:

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

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

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

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

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

The net proceeds from the Global Offering have been utilized in accordance with the purposes set out in the Prospectus. The table below sets out the applications of the net proceeds and actual usage up to December 31, 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 twelve months ended December 31, 2023 *(RMB million)*	Utilized amount (as at December 31, 2023) *(RMB million)*	Remaining amount (as at December 31, 2023) *(RMB million)*
Further development of our Core Product Candidate, BCMA CAR-T (CT053)	902.4	817.8	302.3	279.4	581.7	236.1
Ongoing and planned research and development of our other pipeline product candidates	932.5	845.1	324.6	231.6	556.2	288.9
Developing full-scale manufacturing and commercialization capabilities	601.6	545.2	278.5	18.1	296.6	248.6
Upgrading of CAR-T technologies and early – stage research and development activities	300.8	272.6	68.0	70.2	138.2	134.4
Working capital and other general corporate purposes	270.7	245.3	93.9	136.1	230.0	15.3
Total	3,008.0	2,725.9	1,067.3	735.4	1,802.7	923.2

The unutilized amount of net proceeds is expected to be fully utilized by 2025, which is later than originally planned, due to cost savings achieved via improved operational efficiency and moving outsourced services internally.

Audit Committee

The Audit Committee has three members comprising Ms. Xiangke ZHAO (chairperson), 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 audited consolidated financial statements of the Group for the year ended December 31, 2023. The Audit Committee considers that the financial results for the year ended December 31, 2023 are in compliance with the relevant accounting standards, rules and regulations and appropriate disclosures have been duly made.

FINAL DIVIDEND

The Board has resolved not to recommend the payment of a final dividend for the year ended December 31, 2023 (2022: Nil).

ANNUAL GENERAL MEETING

The annual general meeting is scheduled to be held on Tuesday, May 21, 2024 (the "**AGM**"). A notice convening the AGM will be published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.carsgen.com) in due course.

CLOSURE OF REGISTER OF MEMBERS AND RECORD DATE

The register of members of the Company will be closed from Thursday, May 16, 2024 to Tuesday, May 21, 2024, both days inclusive, in order to determine the identity of Shareholders who are entitled to attend and vote at the AGM to be held on Tuesday, May 21, 2024. Shareholders whose name appear on the register of members of the Company on Tuesday, May 21, 2024 will be entitled to attend and vote at the AGM. In order to be eligible to attend and vote at the AGM, all transfer documents accompanied by relevant share certificates and transfer forms must be lodged with the Company's branch share registrar in Hong Kong, Computershare Hong Kong Investor Services Limited, at Shops 1712-1716, 17th Floor, Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong before 4:30 p.m. on Tuesday, May 14, 2024.

PUBLICATION OF ANNUAL RESULTS ANNOUNCEMENT AND ANNUAL REPORT

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

The annual report of the Company for the year ended December 31, 2023 containing all the information required by the Listing Rules will be published on the websites of the Stock Exchange and the Company in due course.

APPRECIATION

The Board would like to express its sincere gratitude to the shareholders, management team, employees, business partners and customers of the Group for their support and contribution to the Group.

"2019 Equity Incentive Plan"	the equity incentive plan of our Company as adopted by way of written resolutions of the Board on January 22, 2019, the principal terms of which are set out in the section headed "Statutory and General Information – D. 2019 Equity Incentive Plan" in the Prospectus
"affiliate"	any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
"Audit Committee"	the audit committee of the Company
"Board of Directors", "Board" or "our Board"	our board of Directors
"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 C1 to the Listing Rules
"Director(s)"	the director(s) of the Company
"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 IPO
"Reporting Period"	the period from January 1, 2023 to December 31, 2023
"RMB" or "Renminbi"	Renminbi, the lawful currency of China
"Share(s)"	ordinary share(s) in the share capital of our Company with a par value of US$0.00000025 each
"United States" or "U.S." or "US"	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
"US$" or "U.S. dollars" or "USD"	United States dollars, the lawful currency of the United States

In this announcement, the terms "associate", "connected person", "controlling shareholder" and "subsidiary" shall have the meanings given to such terms in the Listing Rules, unless the context otherwise requires.

GLOSSARY

"ADCC"	antibody-dependent 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
"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
"CDE"	Center for Drug Evaluation, an institution under the NMPA
"CGMP"	Current Good Manufacturing Practices
"chemotherapy"	a category of cancer treatment that uses one or more anti-cancer chemotherapeutic agents as part of its standardized regimen
"CLDN18.2"	Claudin18.2, a target in the treatment of certain solid tumors such as gastric cancer, esophageal cancer and pancreatic cancer
"CMC"	chemistry, manufacturing, and controls processes in the development, licensure, manufacturing, and ongoing marketing of pharmaceutical products
"cohort"	a group of patients as part of a clinical study who share a common characteristic or experience within a defined period and who are monitored over time
"combination therapy"	treatment in which a patient is given two or more therapeutic agents for 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
"EGFR"	epidermal growth factor receptor
"EGFRvIII"	variant III of epidermal growth factor receptor
"EMA"	European Medicines Agency
"FDA" or "U.S. FDA"	U.S. 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
"IHC"	immunohistochemistry, which is the identification of antigens in tissues using antibodies that are linked to enzymes, fluorescent dyes, or radioactive labels. IHC is used to diagnose and track specific cellular anomalies, such as cancers
"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
"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
"neurotoxicity"	possible adverse side effect of T cell therapies that leads to a state of confusion, aphasia, encephalopathy, tremor, muscular weakness, and somnolence
"PD-L1"	PD-1 ligand 1, which is a protein on the surface of a normal cell or a cancer cell that attaches to PD-1 on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell
"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 facts or that do not relate to present facts or current conditions are forward-looking statements. Such forward-looking statements express the Company'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 Company'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, March 26, 2024

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.