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CARsgen Therapeutics Holdings Limited

科濟藥業控股有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2171)

ANNOUNCEMENT OF ANNUAL RESULTS FOR THE YEAR ENDED DECEMBER 31, 2024

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, 2024 (the “**Reporting Period**”), together with the audited comparative figures for the year ended December 31, 2023.

FINANCIAL HIGHLIGHTS

1. REVENUE

The Group’s revenue was around RMB39.4 million for the year ended December 31, 2024 mainly from 赛恺泽® (zevorcabtagene autoleucel, autologous BCMA CAR T-cell product), in which was calculated on the basis of ex-works price, rather than end-of-market prices. Our revenue is recognized upon completion of ex-works delivery of products. Besides, the Company received a milestone payment of RMB75 million from Huadong Medicine for 赛恺泽® for the year ended December 31, 2024. Due to the inherent time cycle of CAR-T manufacturing, there is a discrepancy between the number of orders obtained from Huadong Medicine and number of ex-works deliveries.

2. GROSS PROFIT

The Group’s gross profit was around RMB14.7 million for the year ended December 31, 2024. In the commercialization stage, we are demonstrating a strong cost competitive advantage, which is mainly due to self-manufacture for plasmids and vectors with stable output and high yield per batch.

3. NET LOSS

Our net loss was around RMB798 million for the year ended December 31, 2024, representing an increase in loss of around RMB50 million from around RMB748 million for the year ended December 31, 2023. The increase was primarily due to the increase of net other losses of RMB229 million from RMB31 million for the year ended December 31, 2023 to RMB260 million for the year ended December 31, 2024. Such increase in loss was partially offset by (i) the decrease in research and development expenses of RMB196 million from RMB662 million for the year ended December 31, 2023 to RMB466 million for the year ended December 31, 2024; and (ii) the recognition of gross profit of RMB15 million for the year ended December 31, 2024 as compared to nil for the year ended December 31, 2023.

Our adjusted net loss⁽¹⁾ was around RMB789 million for the year ended December 31, 2024, representing an increase in loss of around RMB56 million from around RMB733 million for the year ended December 31, 2023. The increase in loss was primarily due to (i) lower research and development expenses; (ii) higher other losses – net; (iii) higher gross profit; and (iv) lower share-based compensation.

4. CASH AND BANK BALANCES

Cash and bank balances were around RMB1,479 million as of December 31, 2024, representing a decrease of around RMB371 million from around RMB1,850 million as of December 31, 2023. The decrease was mainly due to the payment of research and development expenses, administrative expenses and investment of capital expenditure. Cash and cash equivalents and deposits at the end of 2025 are expected to be not less than RMB1,080 million. We expect to have adequate cash into the 2028 excluding subsequent cash inflows.

⁽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.

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.

赛恺泽® (zevorcabtagene autoleucel, R&D code: CT053)

Zevorcabtagene autoleucel is an autologous fully human CAR T-cell product against B-cell maturation antigen (BCMA). As informed by the National Medical Products Administration (NMPA) on March 1, 2024, 赛恺泽® was approved on February 23, 2024 for the treatment of adult patients with relapsed or refractory multiple myeloma (R/R MM) who have progressed after at least 3 prior lines of therapy (including a proteasome inhibitor and an immunomodulatory agent). CARsgen entered into a collaboration agreement with Huadong Medicine (Hangzhou) Co., Ltd., a wholly owned subsidiary of Huadong Medicine Co., Ltd. (000963.SZ) (“**Huadong Medicine**”) for the commercialization of 赛恺泽® in mainland China. In terms of commercialization, Huadong Medicine has established a dedicated, professional, and comprehensive commercial team to promote the use of 赛恺泽® and has been utilizing China’s multi-layered insurance system to improve patient accessibility. As of December 31, 2024, certification and regulatory filings for 赛恺泽® have been completed in 23 provinces or cities, covering over 200 healthcare institutes and we have received a total of 154 confirmed orders from Huadong Medicine. Updated results of the pivotal Phase II registrational trial of 赛恺泽® in China were reported as an oral presentation at the 29th European Hematology Association (EHA) Annual Congress, and a subgroup analysis was presented a poster at the 66th American Society of Hematology (ASH) annual congress. We anticipate that growth of sales revenue of 赛恺泽® will further accelerate with continuous marketing activities and broader insurance coverage.

Satricabtagene autoleucel (R&D code: CT041)

Satricabtagene autoleucel (satri-cel) is an autologous humanized CAR T-cell product against Claudin18.2 (CLDN18.2). Patient enrollment has been completed in confirmatory Phase II trial in China (NCT04581473) in advanced gastric/gastroesophageal junction cancer (GC/GEJ). The study has met its primary endpoint of a statistically significant improvement in progression-free survival (PFS) as assessed by the Independent Review Committee (IRC). Patients treated with satri-cel infusion achieved statistically significant improvement in PFS compared to those treated with physician’s choice (paclitaxel, docetaxel, irinotecan, apatinib, or nivolumab). Based on the confirmatory Phase II clinical data, satri-cel has been granted Breakthrough Therapy Designation (BTD) by the Center for Drug Evaluation (CDE) of China NMPA. Updated results from the investigator-initiated trial (CT041-CG4006, NCT03874897) were published in *Nature Medicine* in June 2024 and presented orally at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting in June 2024. Summary of safety and efficacy in patients with refractory metastatic pancreatic cancer (PC) (CT041-CG4006 & CT041-ST-01) were reported in *Journal of Clinical Oncology*.

A Phase I clinical trial for the postoperative adjuvant therapy of Claudin18.2 positive pancreatic cancer in China (CT041-ST-05, NCT05911217) is ongoing. An IIT study has been initiated in China for satri-cel to be used as consolidation treatment following adjuvant therapy in patients with resected gastric cancer/gastroesophageal junction cancer (CT041-CG4010, NCT06857786). On October 31, 2024, U.S. time, FDA lifted the clinical hold on clinical trial of satri-cel in the United States.

Allogeneic CAR T-cell Products

In addition to autologous products, CARsgen has also been advancing differentiated allogeneic CAR T-cell products utilizing the proprietary THANK-uCAR® platform. CARsgen has recently developed the THANK-u Plus™ platform as an enhanced version of its proprietary THANK-uCAR® allogeneic CAR-T technology to address the potential impact of NKG2A expression levels on therapeutic efficacy.

The results of the IIT proof-of-concept study of an allogeneic BCMA-targeting CAR T-cell product candidate CT0590, which deploys the THANK-uCAR® technology platform, were presented as a poster at the 66th ASH Annual Meeting in December 2024, titled “A First-in-Human Study of CT0590, a Triple Knock-out, Allogeneic CAR T-Cell Therapy Targeting BCMA and NKG2A, in Subjects with Relapsed/Refractory Multiple Myeloma”.

In addition, multiple allogeneic CAR T-cell products are under development: CT059X against BCMA for R/R MM and relapsed/refractory plasma cell leukemia (R/R PCL) (THANK-u Plus™); KJ-C2219 against CD19/CD20 for B-cell malignancies and autoimmune diseases (THANK-u Plus™); KJ-C2320 against CD38 for acute myeloid leukemia (AML) (THANK-uCAR®); KJ-C2114 for solid tumors (THANK-u Plus™); and KJ-C2526 against NKG2DL for AML, other malignancies and senescence (THANK-u Plus™).

I. MANAGEMENT DISCUSSION AND ANALYSIS

1. OVERVIEW

CARsgen is a biopharmaceutical company focusing on developing innovative CAR T-cell therapies to address the unmet clinical needs including but not limited to hematologic malignancies, solid tumors and autoimmune diseases. CARsgen has established end-to-end capabilities for CAR T-cell research and development covering target discovery, preclinical research, product clinical development, and commercial-scale production. CARsgen has developed novel in-house technologies and a product pipeline with global rights to address challenges faced by existing CAR T-cell therapies. Efforts include improving safety profile, enhancing the efficacy in treating solid tumors, and reducing treatment costs, etc. CARsgen's mission is to be a global biopharmaceutical leader that provides innovative and differentiated cell therapies for patients worldwide and makes cancer and other diseases curable.

2. BUSINESS REVIEW

Our Products and Product Pipeline

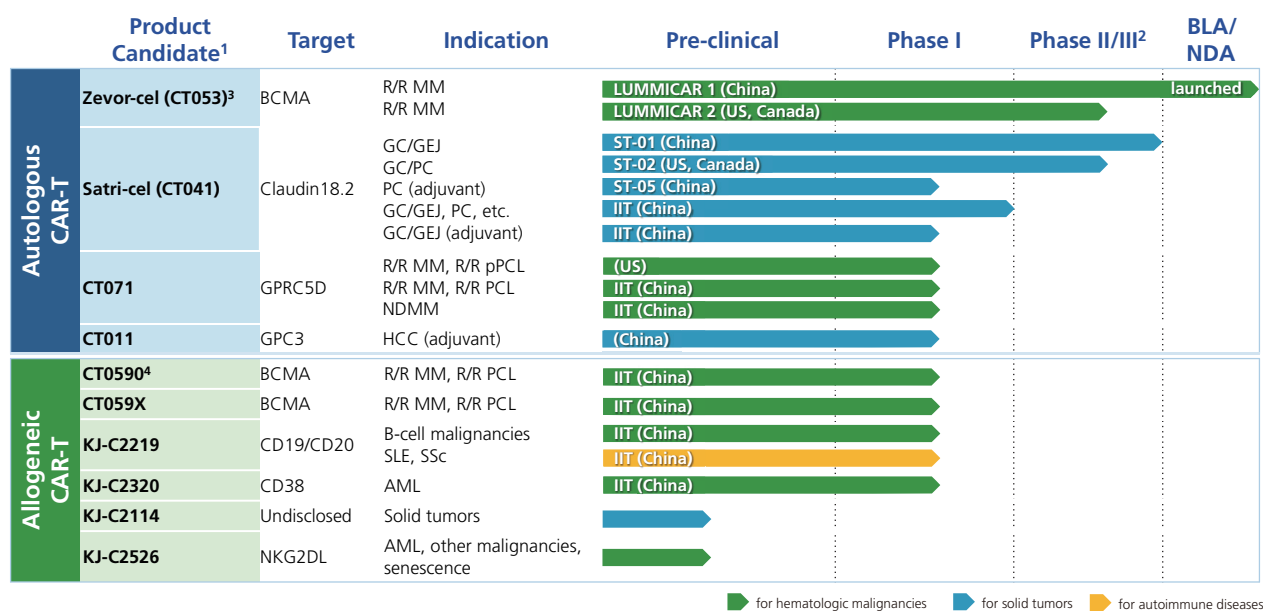
Leveraging comprehensive capabilities and innovative technology platforms, CARsgen remains committed to pioneering in advancements in CAR T-cell therapies. The Company continuously optimizes the strategic priorities and business framework to dynamically adapt to the evolving global industry landscape and market demands. We focus on developing breakthrough CAR T-cell products that address critical unmet medical needs for patients. Through regular pipeline evaluations, we prioritize projects with differentiated clinical and commercial value. For the framework of the strategies in the U.S. market, we are actively driving resource integration and innovation synergy, with an emphasis on technological breakthroughs and localized applications in cutting-edge fields. Looking ahead, we anticipate collaborating with more partners to build an open ecosystem, fostering value co-creation through forward-looking strategic partnerships and jointly exploring broader development opportunities.

In 2024, the Company achieved its first significant milestone in its development journey – the successful approval and launch of its first product 赛恺泽® (zevorcabtagene autoleucel, R&D code: CT053) 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 immunomodulatory agent). The commercialization of 赛恺泽® is of great significance not only to the Company but also brings new hope and treatment option for multiple myeloma patients in China. With the collaboration with Huadong Medicine, the commercialization of 赛恺泽® in mainland China has been progressing smoothly.

The Company's pipeline against hematologic malignancies includes CT071, which targets GPRC5D and is manufactured using CARsgen's proprietary CARcelerate® platform. CT071 has shown promising and differentiating potentials based on IIT study preliminary results. For treatment of solid tumors, the most advanced product is satri-cel (CT041), for which enrollment has been completed for the confirmatory Phase II study (CT041-ST-01, NCT04581473) in China in patients with advanced GC/GEJ cancer. The study has met its primary endpoint of PFS as assessed by IRC with statistical significance. The Company is actively expanding CAR T application in early line treatments of solid tumors: with an ongoing Phase I clinical trial for pancreatic cancer adjuvant treatment; one ongoing IIT for consolidation treatment following adjuvant therapy in patients with resected GC/GEJ; and one Phase I study for hepatocellular carcinomas adjuvant treatment.

CARsgen has been active in advancing several allogeneic CAR T-cell products that offer differentiated clinical value. The Company is committed to advancing several allogeneic CAR T-cell products using the proprietary THANK-uCAR® allogeneic CAR-T technology and the enhanced version THANK-u Plus™ platform. Multiple products are under development: CT0590 against BCMA for R/R MM and R/R PCL (THANK-uCAR®); CT059X against BCMA for R/R MM and R/R PCL (THANK-u Plus™); KJ-C2219 against CD19/CD20 for B-cell malignancies and autoimmune diseases (THANK-u Plus™); KJ-C2320 against CD38 for AML (THANK-uCAR®); KJ-C2114 for solid tumors (THANK-u Plus™); and KJ-C2526 against NKG2DL for AML, other malignancies and senescence (THANK-u Plus™).

The chart below summarizes the development status of our pipeline as of the date of this announcement.



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; NDMM: newly diagnosed multiple myeloma; SLE: systemic lupus erythematosus; SSc: systemic sclerosis; 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. 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).
4. CT0590 enrollment finished.

赛恺泽® (*zevorcabtagene autoleucel*, R&D code: CT053) – Fully Human BCMA CAR T

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

As informed by the NMPA on March 1, 2024, 赛恺泽® was approved on February 23, 2024 for the treatment of adult patients with R/R MM who have progressed after at least 3 prior lines of therapy (including a proteasome inhibitor and an immunomodulatory agent). It is our Company's first product commercialized in mainland China. In January 2023, CARsgen and Huadong Medicine (Hangzhou) Co., Ltd. entered an agreement for the exclusive right to commercialization of 赛恺泽® in mainland China. In addition to the RMB200 million upfront payment, CARsgen received a regulatory milestone payment of RMB75 million. CARsgen is eligible to receive regulatory and commercial milestone payments up to RMB1,025 million under the terms of the agreement. CARsgen continues to be responsible for the development, regulatory approval, and manufacturing of 赛恺泽® in mainland China. In terms of commercialization, Huadong Medicine has established a dedicated, professional, and comprehensive commercial team to promote the use of 赛恺泽® and has been utilizing China's multi-layered insurance system to improve patient accessibility. As of December 31, 2024, certification and regulatory filings for 赛恺泽® have been completed in 23 provinces or cities, covering over 200 healthcare institutes and we have received a total of 154 confirmed orders from Huadong Medicine.

Huadong Medicine has extensive commercialization experience and a large-scale sales network in mainland China. Huadong Medicine's strategic goal of being a leader in the oncology therapeutic area created the opportunity for a strong partnership between the two companies. We believe that the partnership with Huadong Medicine will maximize commercial success of 赛恺泽® in mainland China. Since reaching the agreement, teams from CARsgen and Huadong Medicine have been working together closely to implement commercialization strategy and ensure optimal product access.

The subgroup analyses from the zevorcabtagene autoleucel LUMMICAR STUDY 1 trial were presented as a poster at the 66th ASH Annual Congress in December 2024, which was titled "Subgroup Analyses of Phase 2 Study: Evaluating the Efficacy of Fully Human BCMA-Targeting CAR T Cells (Zevorcabtagene Autoleucel) in Patients with Relapsed/Refractory Multiple Myeloma".

The results of LUMMICAR-1 study were reported as an oral presentation at the 29th EHA Annual Congress on June 15, 2024, titled “Phase 2 study of fully human BCMA-targeting CAR-T cells (zevorcabtagene autoleucel) in patients with relapsed/refractory multiple myeloma”. In 102 patients treated with 赛恺泽®, the overall response rate (ORR) was 92.2% (94/102), and the remission rate at very good partial response (VGPR) or above was 91.2% (93/102), and the complete response (CR)/stringent complete response (sCR) rate was 71.6% (73/102). A trend toward deepening of responses was observed with longer duration of follow-up.

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 the Phase I/II registrational study in China (LUMMICAR-1, NCT03975907).

On October 31, 2024, U.S. time, FDA lifted the clinical hold on clinical trial of zevorcabtagene autoleucel in the United States. Considering the delay in the clinical program due to clinical hold and an evolving competitive landscape, CARsgen decided to deprioritize the LUMMICAR-2 study of zevorcabtagene autoleucel in the U.S. and Canada as a part of our strategic adjustment.

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 mainland 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 (R&D code: CT041) – Humanized Claudin18.2 CAR T

Satricabtagene autoleucel is an autologous CAR T-cell product against protein Claudin18.2 and has 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, to our knowledge, 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. To further address the challenges of CAR T-cell therapies in treating solid tumors, we developed an innovative, patent-protected preconditioning regimen which is to be 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.

Enrollment in accordance with the clinical trial protocol for advanced gastric/gastroesophageal junction adenocarcinoma confirmatory Phase II trial (CT041-ST-01, NCT04581473) in China has been completed. The study met its primary endpoint of a statistically significant improvement in PFS assessed by IRC for patients treated with satricel infusion as compared to treatment of physician’s choice (paclitaxel, docetaxel, irinotecan, apatinib, or nivolumab). CARsgen plans to submit an NDA to the NMPA in China during the first half of 2025.

The Company has started moving the investigation of satricabtagene autoleucel treatment to early line: including an ongoing Phase I clinical trial for PC adjuvant therapy in China (CT041-ST-05, NCT05911217) and an IIT for consolidation treatment following adjuvant therapy in patients with resected GC/GEJ (CT041-CG4010, NCT06857786).

The final results of the investigator-initiated trial CT041-CG4006 have been published in *Nature Medicine* on June 3, 2024, which was titled “Claudin18.2-specific CAR T Cells in gastrointestinal cancers: Phase 1 trial final results”. Data were presented as an oral presentation at the 2024 ASCO Annual Meeting in June 2024. In patients with GC/GEJ who received satri-cel monotherapy (n = 59), 51 had target lesions. The objective response rate and disease control rate (DCR) were 54.9% (28/51) and 96.1% (49/51), respectively.

An article titled “Safety and Efficacy of CT041 in Patients With Refractory Metastatic Pancreatic Cancer: A Pooled Analysis of Two Early-Phase Trials” was published in May 2024 in *Journal of Clinical Oncology*, reporting the results of patients with previously treated pancreatic cancer in two multicenter, open-label Phase I/Ib trials (CT041-CG4006 & CT041-ST-01).

An article titled “Metastatic gastric cancer target lesion complete response with Claudin18.2-CAR T cells” was published in February 2024 in *Journal for ImmunoTherapy of Cancer* reporting a patient with metastatic gastric cancer, 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.

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” in September 2023.

The Phase Ib results from the Phase Ib/II satricabtagene autoleucel study in China (CT041-ST-01, NCT04581473) were presented at the 2022 ASCO Annual Meeting with the poster titled “Safety, Tolerability and Preliminary Efficacy Results in Patients with Advanced Gastric/Gastroesophageal Junction Adenocarcinoma from a Phase Ib/II Study of CLDN18.2 CAR T-cell therapy (CT041)”.

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). FDA lifted the clinical hold on clinical trial of satricabtagene autoleucel in the United States. 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 study results for satricabtagene autoleucel in the Phase 1b trial in the U.S..

Satricabtagene autoleucel received Orphan Drug designation from the FDA in September 2020 for the treatment of GC/GEJ. Satricabtagene autoleucel was granted RMAT Designation by FDA for the treatment of advanced GC/GEJ with Claudin18.2-positive tumors in January 2022. Based on the confirmatory Phase II clinical data, in February 2025, the CDE of NMPA has granted BTM to satri-cel for the treatment of Claudin18.2-positive advanced GC/GEJ in patients who have failed at least two prior lines of therapy.

CARsgen and Moderna, Inc. (Nasdaq: MRNA, “**Moderna**”) have been collaborating to investigate satricabtagene autoleucel in combination with Moderna’s investigational Claudin18.2 mRNA product. Since entering the collaboration in 2023, a series of pre-clinical studies have been conducted to evaluate the combination.

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 with proof-of-concept clinical data for the treatment of hepatocellular carcinoma (HCC). 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.

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. Two advanced HCC patients who received local therapy followed by sequential infusions of CAR-GPC3 T-cells achieved more than 7-year disease-free survival.

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

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 product targeting 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). It incorporates a fully-human single-chain variable fragment (scFv) developed by CARsgen.

CARsgen’s proprietary CARcelerate® platform can shorten CT071’s manufacturing time to approximately 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 availability of the product to patients, enhances the supply capacity, and reduces manufacturing costs.

The updated results of the CT071 IIT study (NCT05838131) were presented as a poster at the 66th ASH Annual Congress in December 2024, which was titled “GPRC5D-Targeted CAR T-Cell Therapy CT071 for the Treatment of Refractory/Relapsed Multiple Myeloma”.

Results from the investigator-initiated trial (NCT05838131) for R/R MM and R/R PCL were presented as a poster at the 29th EHA Annual Congress in June 2024, titled “First-in-human study of GPRC5D-targeted CAR T cells (CT071) with an accelerated manufacturing process in patients with relapsed/refractory multiple myeloma (RRMM)”.

Another investigator-initiated trial (NCT06407947) is ongoing in China for the treatment of NDMM. CT071 IND was cleared by the FDA in November 2023 for the treatment of patients with R/R MM and R/R pPCL. FDA lifted the clinical hold on clinical trial of CT071 in the United States.

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.

Allogeneic CAR T-cell Product

In addition to autologous products, CARsgen has also been advancing differentiated allogeneic CAR T-cell products utilizing the proprietary THANK-uCAR[®] platform. CARsgen has recently developed the THANK-u Plus[™] platform as an enhanced version of THANK-uCAR[®] allogeneic CAR-T technology to address the potential impact of NKG2A expression levels on therapeutic efficacy.

CT0590 is a BCMA-targeting allogeneic CAR T-cell product candidate deploying our THANK-uCAR[®] technology. An IIT has been initiated in China to evaluate the safety and efficacy of CT0590 for the treatment of R/R MM. The results of the IIT proof-of-concept study results of CT0590 were presented as a poster at the 66th ASH Annual Congress in December 2024, which was titled “A First-in-Human Study of CT0590, a Triple Knock-out, Allogeneic CAR T-Cell Therapy Targeting BCMA and NKG2A, in Subjects with Relapsed/Refractory Multiple Myeloma”.

CT059X is a BCMA-targeting allogeneic CAR T-cell product candidate deploying our THANK-u Plus[™] technology. An IIT has been initiated in China to evaluate the safety and efficacy of CT059X for the treatment of R/R MM and R/R PCL. CT059X has administered the first dose to a patient in an investigator-initiated trial. The first subject treated with an allogeneic BCMA CAR-T therapy developed on the THANK-u Plus[™] platform, has achieved stringent complete response (sCR) and minimal residual disease (MRD) negativity at the Day-28 assessment.

KJ-C2219 is an allogeneic CAR T-cell product candidate targeting CD19/20 deploying our THANK-u Plus[™] technology, for hematologic malignancies and autoimmune diseases. An IIT for relapsed/refractory B-cell non-Hodgkin lymphoma (R/R B-NHL) has been initiated at the end of 2024. A separate IIT for systemic lupus erythematosus (SLE) and systemic sclerosis (SSc) has been initiated in the first half of 2025. KJ-C2219 has administered the first dose to a patient in an investigator-initiated trial for R/R B-NHL and to another patient in an IIT for SLE and SSc.

KJ-C2320 is an allogeneic CAR T-cell product candidate targeting CD38, deploying our THANK-uCAR[®] technology for the treatment of AML. An IIT for AML has been initiated at the end of 2024. KJ-C2320 has administered the first dose to a patient in an investigator-initiated trial.

KJ-C2114 is an allogeneic CAR T-cell product candidate deploying our THANK-u Plus[™] technology with an undisclosed target for the treatment of certain solid tumors.

KJ-C2526 is an allogeneic CAR T-cell product candidate against NKG2DL deploying our THANK-u Plus™ technology, for AML, other malignancies and senescence.

On February 25, 2025, certain subsidiaries of the Company have entered into the agreements with an investment fund (the “**Investor**”) managed by Zhuhai Hengqin SB Xinchuang Equity Investment Management Enterprise (Limited Partnership), pursuant to which, among others, the Investor has agreed to subscribe to additional registered capital of UCARsgen Biotech Limited (“**UCARsgen**”) at a cash consideration of RMB80,000,000, representing 8% stake of the enlarged registered capital of UCARsgen (the “**Capital Increase**”). Upon the completion of the Capital Increase, the Company’s share in UCARsgen will be diluted from 100% to 92%.

UCARsgen is a China-based new drug discovery biotechnology company focused on allogeneic CAR T-cell therapies for the treatment of hematologic malignancies. Under the Agreements, UCARsgen has secured the exclusive rights in mainland China for the research, development, manufacture, and commercialization of the following allogeneic CAR T-cell products from the Company: the BCMA-targeted allogeneic CAR T-cell therapy for the treatment of multiple myeloma and plasma cell leukemia and the CD19/CD20 dual-targeted allogeneic CAR T-cell therapy for the treatment of B-cell malignancies (excluding indications for the treatment of autoimmune diseases).

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 cancer patients globally.

We have established an integrated research and development platform covering the full CAR T development cycle including target discovery, vector design, manufacturing, quality assurance, and quality control. Our integrated cell therapy platform is composed of target discovery, 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.

We continue to dedicate ourselves to advancing innovative technologies to address remaining challenges in the CAR-T industry:

- (1) **Better patient access with allogeneic CAR-T:** To reduce the cost and increase 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 beta-2 microglobulin (B2M) to eliminate surface expression of the TCR or the human leukocyte antigen class I (HLA-I), an approach that has been validated by previous research. However, natural killer (NK) cells attack T cells without HLA-I 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' attacks, we arm these TCR/B2M 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 armoring the TCR/B2M T cells with the anti-NKG2A CAR resulted in improved expansion in the presence of NK cells. Based on the clinical data, it is found that baseline NKG2A expression levels on NK cells may be related to treatment outcomes. To leverage this finding, we developed THANK-u Plus™ platform.

CARsgen has developed the THANK-u Plus™ platform as an enhanced version of its proprietary THANK-uCAR® allogeneic CAR-T technology to address the potential impact of NKG2A expression levels on therapeutic efficacy. THANK-u Plus™ demonstrates sustained expansion regardless of varying NKG2A expression levels on NK cells and exhibits significantly improved expansion compared to THANK-uCAR®. Preclinical studies show that THANK-u Plus™ delivers superior antitumor efficacy in the presence of NK cells compared to THANK-uCAR®. Allogeneic BCMA or dual-targeting CD19/CD20 CAR T cells developed using this platform exhibit robust antitumor activity in the presence of NK cells, indicating that THANK-u Plus™ has broad potential for developing diverse allogeneic CAR-T therapies. We are developing allogeneic CAR T-cell products using THANK-u Plus™ platform, which we believe could increase CAR T cell expansion, persistence and efficacy.

- (2) **Improve manufacturing efficiency:** We have developed a proprietary platform that can shorten the manufacturing time for the CAR T cells to approximately 30 hours. The CARcelerate® platform produces CAR T cells that are younger, more likely to remain in a 'naïve' state and less likely to be exhausted. CAR T cells from the CARcelerate® platform are expected to exhibit more potent anti-tumor 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 CT071 for the treatment of patients with MM and pPCL.

(3) Enhance efficacy in solid tumors:

- To enhance efficacy against solid tumors, we developed CycloCAR[®] which 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. Preclinical results 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 which were facilitated by infiltration of T cells and dendritic cells into tumor tissues, CycloCAR T cells exhibited increased survival, and 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.
- The Company continues investigating combinatorial approaches to enhance clinical outcomes of CAR-T therapies. For example, our collaboration with Moderna to explore satricabtagene autoleucel in combination with Claudin18.2 encoding mRNA vaccines to help boost T cell activation, proliferation and persistence.

(4) Target availability:

- In 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 (e.g., 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 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 products or generate future products.

Empowered by these technologies, we strive to further enrich our pipeline and advance these pipeline products to clinical and commercial stage.

As of December 31, 2024, we had more than 300 patents of which 129 patents had been issued globally including China, the United States, Europe, and Japan, with an increase of 26 issued patents and 27 patent applications compared with that of January 1, 2024. Our R&D activities are expected to 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 aiming for faster turnaround times for patients. The integrated manufacturing is also expected to help 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 thought to exhibit more potent tumor killing activity.

With the commercial manufacturing facility in Jinshan, Shanghai (“**Jinshan Manufacturing Facility**”), 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 produce the lentiviral vectors for clinical trials outside of China. The Jinshan Manufacturing Facility is dedicated to providing stable support for the commercial manufacturing of 赛恺泽® and upcoming commercial manufacturing for satri-cel upon NDA approval from NMPA, which ensures that the market demand for both products is fully secured in the coming years.

In December 2023, FDA did an inspection on our Research Triangle Park GMP manufacturing facility in Durham, North Carolina (“**RTP Manufacturing Facility**”), with a total gross floor area of approximately 3,300 sq.m, completed technology transfer and provided CARsgen with additional manufacturing capacity of autologous CAR T-cell products of 700 patients annually. 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 Form 483 was issued and clinical holds were subsequently initiated for the three INDs active in the U.S.. In September 2024, the FDA did a follow-up inspection of the RTP Manufacturing Facility. The inspection was positive, and no observation (Form 483) was issued. On October 31, 2024, U.S. time, FDA lifted the clinical holds on clinical trials of zevorcabtagene autoleucel, satricabtagene autoleucel, and CT071 in the United States.

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. With large scale lentiviral vectors production, we expect to reduce the CAR T manufacturing costs noticeably.

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 approval of the first CAR T-cell therapy product in 2017. The global CAR T-cell therapy market is expected to further grow driven by increasing global cancer incidence, approval of CAR T-cell therapies in more indications, improvements in manufacturing technology and capacities, availability of CAR T-cell products in more markets. As of the date of this announcement, there are seven CAR T-cell products approved by U.S. FDA and six CAR T-cell products approved by NMPA in China. However, there are still significant unmet medical needs for the cancer patients worldwide, calling for better and more innovative CAR T-cell products, particularly for the treatment of solid tumors. With our pipeline products, e.g. zevorcabtagene autoleucel and satricabtagene autoleucel, and innovative technology platforms, e.g. CycloCAR[®], THANK-uCAR[®], THANK-u Plus[™], LADAR[™] and CARcelerate[®], we are committed to developing the innovative therapies to fulfil these unmet medical needs.

Future and Outlook

With CARsgen's mission of "making cancer curable", we devote ourselves to develop innovative products for the treatment of cancer patients worldwide. Building on the milestones achieved, we will continue to focus on rapid clinical development of zevorcabtagene autoleucel and satricabtagene autoleucel both in China and overseas. We plan to expand these products in earlier line treatment as well as advance development of other products in clinical and preclinical stages. With continuous development of innovative CAR T technologies, we strive to further optimize efficacy, safety and affordability of CAR T-cell therapies to patients. We will continue to expand our manufacturing capacity in China and in the United States to support our clinical trials and future commercialization. We will continue to establish additional external partnerships with leading research institutes and pharmaceutical companies on technology and product licensing as a means to maximize the application of our technology platform and the value of our product, 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 had one product, 赛恺泽®, approved on February 23, 2024 for commercial sale and have generated revenue from product sales. We have not been profitable and have incurred operating losses in every year since inception, with operating losses of RMB808 million and RMB768 million for the years ended December 31, 2024 and 2023, respectively. Substantially all of our operating losses resulted from research and development expenses, administrative expenses and net foreign exchange losses for the year ended December 31, 2024.

Loss for the years

Our net loss was RMB798 million for the year ended December 31, 2024, representing an increase of RMB50 million from RMB748 million for the year ended December 31, 2023. The increase was primarily due to the increase of net other losses of RMB229 million from RMB31 million for the year ended December 31, 2023 to RMB260 million for the year ended December 31, 2024. Such increase was partially offset by (i) the decrease in research and development expenses of RMB196 million from RMB662 million for the year ended December 31, 2023 to RMB466 million for the year ended December 31, 2024; and (ii) the recognition of gross profit of RMB15 million for the year ended December 31, 2024 as compared to nil for the year ended December 31, 2023.

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 periods and adjusted net loss per share for the periods represent the net loss and net loss per share respectively excluding the effect of a non-cash item, namely the share-based compensation. The terms adjusted net loss and adjusted net loss per share are not defined under the IFRSs.

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

	Year ended December 31,	
	2024	2023
	RMB'000	RMB'000
	(Audited)	(Audited)
Loss for the years	(798,132)	(747,794)
Add:		
Share-based compensation	<u>9,089</u>	<u>14,458</u>
Adjusted net loss	<u>(789,043)</u>	<u>(733,336)</u>
	Year ended December 31,	
	2024	2023
	RMB	RMB
	(Audited)	(Audited)
Loss per share for the years	(1.44)	(1.34)
Add:		
Share-based compensation per share	<u>0.02</u>	<u>0.03</u>
Adjusted net loss per share	<u>(1.42)</u>	<u>(1.31)</u>

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,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
	(Audited)	(Audited)
Employee benefit expenses	208,780	253,480
Testing and clinical expenses	158,281	249,638
Depreciation of property, plant and equipment	33,449	55,817
Research and development consumables	29,264	54,632
Utilities	18,485	19,178
Depreciation of right-of-use assets	2,667	12,266
Amortization of intangible assets	6,001	6,144
Travelling and transportation expenses	2,839	5,793
Office expenses	1,729	1,861
Short term lease and low value lease expenses	2,444	1,623
Professional service fees	2,064	270
Other expenses	183	957
	<hr/>	<hr/>
Total	<u>466,186</u>	<u>661,659</u>

Research and development expenses decreased to RMB466 million for the year ended December 31, 2024, representing a decrease of RMB196 million from RMB662 million for the year ended December 31, 2023, primarily due to lower testing and clinical expenses, lower employee benefit expenses and lower depreciation expenses.

Administrative Expenses

	Year ended December 31,	
	2024	2023
	RMB'000	RMB'000
	(Audited)	(Audited)
Employee benefit expenses	70,378	71,857
Professional service fees	27,304	20,356
Office expenses	6,874	7,841
Depreciation of property, plant and equipment	26,587	6,411
Depreciation of right-of-use assets	5,998	5,499
Auditors' remuneration	4,084	4,191
– audit service	3,780	4,191
– non-audit service	304	–
Short term lease and low value lease expenses	4,303	3,847
Travelling and transportation expenses	4,174	3,112
Utilities	1,061	1,399
Amortization of intangible assets	1,109	1,258
Other expenses	7,652	5,918
Total	159,524	131,689

Administrative expenses increased to RMB160 million for the year ended December 31, 2024, representing an increase of RMB28 million from RMB132 million for year ended December 31, 2023, primarily due to (i) for the period of clinical on hold, the depreciation of property, plant and equipment of RMB20 million were re-classified from R&D to G&A; and (ii) more professional service fees were incurred as a result of the clinical hold lifted by the FDA.

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,	
	2024	2023
	RMB'000	RMB'000
	(Audited)	(Audited)
Wages and salaries	230,937	276,243
Pension costs	16,200	20,582
Share-based compensation	9,012	14,458
Other employee benefits	23,009	14,054
Total	279,158	325,337
Amount included in Research and Development Expenses	208,780	253,480
Amount included in Administrative Expenses	70,378	71,857

The decrease of employee benefit expenses is mainly due to the decrease in the number of employees.

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,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
	(Audited)	(Audited)
Research and development expenses	4,680	13,910
Administrative expenses	4,332	548
Cost of sales	77	0
Total	<u>9,089</u>	<u>14,458</u>

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 periods indicated:

	Year ended December 31,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
	(Audited)	(Audited)
Net cash used in operating activities	(409,690)	(454,935)
Net cash generated from investing activities	12,522	39,251
Net cash generated from/(used in) financing activities	18,457	(22,142)
Net decrease in cash and cash equivalents	(378,711)	(437,826)
Cash and cash equivalents at beginning of the year	1,849,752	2,268,036
Exchange gain on cash and cash equivalents	8,017	19,542
Cash and cash equivalents at end of the year	<u>1,479,058</u>	<u>1,849,752</u>

Net Cash Used in Operating Activities

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

Our operating activities used RMB410 million and RMB455 million for the year ended December 31, 2024 and 2023, respectively.

We had one product, 赛恺泽®, approved on February 23, 2024 for commercial sale and have generated income in 2024. 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 used in investing activities mainly reflects our cash used for our purchase of term deposits with original maturity between three and twelve months, property, plant and equipment and our cash generated from investing activities mainly reflects our net cash receipts from term deposits with original maturity between three and twelve months.

For the year ended December 31, 2024, our net cash generated from investing activities was RMB12.5 million, which was primarily attributable to 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.

Net Cash Generated from/(used in) Financing Activities

During the Reporting Period, our cash generated from financing activities was RMB18.5 million, primarily due to payments for ordinary share repurchase, net proceeds from bank borrowings and repayment of lease liabilities.

For the year ended December 31, 2024, our net cash generated from financing activities was RMB18.5 million, primarily attributable to net proceeds from bank borrowings of RMB84 million, payments for ordinary share repurchase of RMB50 million, and payment of lease expenses of RMB17 million. 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.

Cash and Bank Balances

	As at December 31, 2024 <i>RMB'000</i> (Audited)	As at December 31, 2023 <i>RMB'000</i> (Audited)
Cash at banks		
– USD	120,778	1,058,394
– RMB	1,358,145	779,122
– HKD	135	12,236
Subtotal	1,479,058	1,849,752
Total	1,479,058	1,849,752

The Group's total cash and bank balances as at December 31, 2024 were RMB1,479 million, representing a decrease of RMB371 million compared to RMB1,850 million as at December 31, 2023. 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, 2024 were RMB89 million, representing an increase of RMB86 million compared to RMB3 million as at December 31, 2023.

As at December 31, 2024 and December 31, 2023, the Group's bank borrowings of approximately RMB89 million and RMB3 million respectively.

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

As at December 31, 2024, the Group's secured borrowings is mature within one to three years with the interest rate of 3.2000% (2023: 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, 2024 and 2023 were 15.75% and 4.73%, 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 RMB77 million as at December 31, 2024 from RMB83 million as at December 31, 2023.

5. OTHER FINANCIAL INFORMATION

Significant Investments, Material Acquisitions and Disposals

As at December 31, 2024, we did not hold any significant investments (including any investment in an investee company) with a value of 5% or more of the Group's total assets. During the year ended December 31, 2024, 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, 2024, the Group had no foreign exchange hedging instruments. However, our management constantly monitors the economic situation and our Group's foreign exchange exposure and will consider appropriate hedging measures in the future should the need arise.

As at December 31, 2024 and 2023, if the USD strengthened/weakened by 5% against the RMB with all other variables held constant, our net loss for the years ended December 31, 2024 and 2023 would have increased/decreased by approximately RMB124 million and RMB89 million respectively.

Capital Expenditure

For the year ended December 31, 2024, the Group's total capital expenditure amounted to approximately RMB20 million, which was mostly used in purchase of property, plant and equipment, and software.

Charge on Assets

As at December 31, 2024, the group did not have any charge on assets, compared with the building pledged with the carrying value of RMB29 million and the land use right pledged with the carrying value of RMB6.5 million for the Group's borrowing as at December 31, 2023.

Asset Impairment

Due to the strategic adjustment in pipeline in late 2024, we are placing greater emphasis on the future layout of allogeneic CAR T-cell products, with high uncertainty over the recoverability of certain non-current assets. Accordingly, an impairment test was conducted on the relevant non-current assets at the year end of 2024. Consequently, a total impairment loss of RMB189,079,000 (2023: nil), determined by the value in use approach, was recognized against the carrying amount of these assets and recorded in 'Other losses – net' in the consolidated statement of profit or loss.

Contingent Liability

As at December 31, 2024, 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 516 employees as at December 31, 2023 to 468 employees as at December 31, 2024. As at December 31, 2024, 63% of our employees 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, 2024

	Notes	2024 RMB'000	2023 RMB'000
Revenue	3	39,425	–
Cost of sales		<u>(24,678)</u>	<u>–</u>
Gross profit		14,747	–
Selling and distribution expenses		(875)	–
Administrative expenses		(159,524)	(131,689)
Research and development expenses		(466,186)	(661,659)
Other income	3	63,934	56,536
Other losses – net	4	<u>(260,287)</u>	<u>(30,837)</u>
Operating loss		(808,191)	(767,649)
Finance income		16,118	24,926
Finance costs		<u>(5,713)</u>	<u>(4,664)</u>
Finance income – net	5	<u>10,405</u>	<u>20,262</u>
Loss before income tax		(797,786)	(747,387)
Income tax expense	7	<u>(346)</u>	<u>(407)</u>
Loss for the year and attributable to ordinary equity holders of the parent		<u>(798,132)</u>	<u>(747,794)</u>
Other comprehensive income for the year:			
<i>Items that may be reclassified to profit or loss</i>			
Exchange differences on translation of subsidiaries		(95,906)	(33,065)
<i>Items that will not be reclassified to profit or loss</i>			
Exchange differences on translation of the Company		<u>188,722</u>	<u>88,317</u>
Other comprehensive income for the year, net of tax		<u>92,816</u>	<u>55,252</u>
Total comprehensive loss for the year and attributable to ordinary equity holders of the parent		<u>(705,316)</u>	<u>(692,542)</u>
Loss per share attributable to ordinary equity holders of the parent			
Basic and diluted loss per share (in RMB)	9	<u>(1.44)</u>	<u>(1.34)</u>

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

December 31, 2024

	<i>Notes</i>	2024	2023
		<i>RMB'000</i>	<i>RMB'000</i>
NON-CURRENT ASSETS			
Property, plant and equipment		106,749	311,952
Right-of-use assets		17,200	49,438
Intangible assets		2,943	8,660
Other non-current assets and prepayments		15,867	14,076
		<hr/>	<hr/>
Total non-current assets		142,759	384,126
CURRENT ASSETS			
Trade receivables	<i>10</i>	8,768	–
Inventories		6,926	683
Other receivables		19,344	9,792
Other current assets and prepayments		16,179	12,861
Cash and bank balances		1,479,058	1,849,752
		<hr/>	<hr/>
Total current assets		1,530,275	1,873,088
CURRENT LIABILITIES			
Accruals and other payables	<i>11</i>	181,623	158,008
Interest-bearing bank borrowings		20,287	2,522
Lease liabilities		13,441	12,230
Deferred income		11,033	13,220
Contract liabilities		27,623	10,237
		<hr/>	<hr/>
Total current liabilities		254,007	196,217
NET CURRENT ASSETS		1,276,268	1,676,871
TOTAL ASSETS LESS CURRENT LIABILITIES		1,419,027	2,060,997
NON-CURRENT LIABILITIES			
Interest-bearing bank borrowings		68,850	–
Lease liabilities		63,844	70,468
Deferred income		7,342	10,387
Contract liabilities		222,284	178,442
		<hr/>	<hr/>
Total non-current liabilities		362,320	259,297
Net assets		1,056,707	1,801,700
		<hr/> <hr/>	<hr/> <hr/>
EQUITY			
Equity attributable to owners of the parent			
Share capital		1	1
Reserves		1,056,706	1,801,699
		<hr/>	<hr/>
Total equity		1,056,707	1,801,700
		<hr/> <hr/>	<hr/> <hr/>

NOTES TO THE FINANCIAL STATEMENTS

1. CORPORATE AND GROUP INFORMATION

CARsgen Therapeutics Holdings Limited (hereinafter the “Company”) was incorporated under the law of the 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 18, 2025.

2. BASIS OF PREPARATION AND ACCOUNTING POLICIES

These financial statements have been prepared in accordance with International Financial Reporting Standards (“IFRSs”) as issued by the International Accounting Standards Board (the “IASB”) and the disclosure requirements of the Hong Kong Companies Ordinance. They have been prepared under the historical cost convention. 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 revised IFRSs for the first time for the current year’s financial statements.

Amendments to IFRS 16	<i>Lease Liability in a Sale and Leaseback</i>
Amendments to IAS 1	<i>Classification of Liabilities as Current or Non-current (the “2020 Amendments”)</i>
Amendments to IAS 1	<i>Non-current Liabilities with Covenants (the “2022 Amendments”)</i>
Amendments to IAS 7 and IFRS 7	<i>Supplier Finance Arrangements</i>

The nature and the impact of the revised IFRSs are described below:

- (a) Amendments to IFRS 16 specify the requirements that a seller-lessee uses in measuring the lease liability arising in a sale and leaseback transaction to ensure the seller-lessee does not recognise any amount of the gain or loss that relates to the right of use it retains. Since the Group has no sale and leaseback transactions with variable lease payments that do not depend on an index or a rate occurring from the date of initial application of IFRS 16, the amendments did not have any impact on the financial position or performance of the Group.
- (b) The 2020 Amendments clarify the requirements for classifying liabilities as current or non-current, including what is meant by a right to defer settlement and that a right to defer must exist at the end of the reporting period. Classification of a liability is unaffected by the likelihood that the entity will exercise its right to defer settlement. The amendments also clarify that a liability can be settled in its own equity instruments, and that only if a conversion option in a convertible liability is itself accounted for as an equity instrument would the terms of a liability not impact its classification. The 2022 Amendments further clarify that, among covenants of a liability arising from a loan arrangement, only those with which an entity must comply on or before the reporting date affect the classification of that liability as current or non-current. Additional disclosures are required for non-current liabilities that are subject to the entity complying with future covenants within 12 months after the reporting period.

The Group has reassessed the terms and conditions of its liabilities as at January 1, 2023 and 2024 and concluded that the classification of its liabilities as current or non-current remained unchanged upon initial application of the amendments. Accordingly, the amendments did not have any impact on the financial position or performance of the Group.

- (c) Amendments to IAS 7 and IFRS 7 clarify the characteristics of supplier finance arrangements and require additional disclosure of such arrangements. The disclosure requirements in the amendments are intended to assist users of financial statements in understanding the effects of supplier finance arrangements on an entity's liabilities, cash flows and exposure to liquidity risk. As the Group does not have supplier finance arrangements, the amendments did not have any impact on the Group's financial statements.

3. REVENUE AND OTHER INCOME

An analysis of revenue is as follows:

	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
Revenue from contracts with customers		
Sales of pharmaceutical products	37,123	–
Provision of cryopreservation services	2,302	–
Total	39,425	–

An analysis of other income is as follows:

	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
Government grants (i)	38,134	8,671
Interest income on term deposits with original maturity between three and twelve months	25,800	47,865
Total	63,934	56,536

- (i) The government grants mainly represent subsidies received from the government to support on certain research and development projects that are related 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, or over the expected useful life of the relevant asset, when all attaching conditions and requirements are compliant with.

4. OTHER LOSSES – NET

	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
Foreign exchange losses – net	(82,244)	(30,467)
Impairment losses	(189,079)	–
Tenant remedies	9,518	–
Others	1,518	(370)
Total	(260,287)	(30,837)

5. FINANCE INCOME – NET

	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
Finance income		
Interest income	<u>16,118</u>	<u>24,926</u>
Finance costs		
Interest expense on lease liabilities	(3,124)	(4,388)
Interest expense on bank borrowings	<u>(2,589)</u>	<u>(276)</u>
Total finance costs	<u>(5,713)</u>	<u>(4,664)</u>
Total finance income – net	<u><u>10,405</u></u>	<u><u>20,262</u></u>

6. LOSS BEFORE TAX

The Group's loss before tax from continuing operations is arrived at after charging:

	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
Employee benefit expenses	279,158	325,337
Testing and clinical expenses	158,281	249,638
Depreciation of property, plant and equipment	60,551	62,228
Research and development consumables	29,264	54,632
Professional service expenses	29,368	20,626
Depreciation of right-of-use assets	11,894	17,765
Impairment of property, plant and equipment (i)	162,263	–
Impairment of right-of-use assets (i)	26,491	–
Impairment of intangible assets (i)	325	–
Utilities	19,546	20,577
Office expenses	8,603	9,702
Travelling and transportation expenses	7,013	8,905
Amortisation of intangible assets	7,110	7,402
Short-term lease and low-value lease expenses	6,747	5,470
Auditors' remuneration	4,084	4,191
– Audit service	3,780	4,191
– Non-audit service	304	–
Cost of inventories sold	24,678	–
Marketing service fees	875	–
Other expenses	<u>4,091</u>	<u>6,875</u>
Total	<u><u>840,342</u></u>	<u><u>793,348</u></u>
Cost of sales	24,678	–
Selling and distribution expenses	875	–
Administrative expenses	159,524	131,689
Research and development expenses	466,186	661,659
Losses of impairment	<u>189,079</u>	<u>–</u>
Total	<u><u>840,342</u></u>	<u><u>793,348</u></u>

- (i) As at December 31, 2024, due to the strategic adjustment in pipeline, the Group is placing greater emphasis on the future layout of allogeneic CAR T-cell products, and the future availability of certain non-current assets is highly uncertain. Based on the requirement of IAS36, the Group performed an impairment test on the geographical non-current assets determined by the value in use approach, and concluded that the recoverable amount was RMB8,300,000. Based on the impairment test, the carrying amount of the non-current assets was impaired by RMB189,079,000 (2023: nil) in total.

7. INCOME TAX EXPENSE

	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
Current income tax		
– Mainland China Tax	–	–
– Ireland Capital Gains Tax	346	407
Deferred income tax	–	–
	<hr/>	<hr/>
Total	346	407
	<hr/> <hr/>	<hr/> <hr/>

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 profits tax

No provision for Hong Kong profits tax has been provided for at the rate of 16.5% (2023: 16.5%) as the Company has no estimated assessable profits in Hong Kong.

(c) Mainland China corporate income tax

Subsidiaries in Mainland China are subject to income tax at a rate of 25%(2023: 25%) pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the “CIT Law”), except for CARsgen Therapeutics Co., Ltd. which obtained its High and New Technology Enterprise qualification in year 2023 and hence is entitled to a preferential tax rate of 15% (2023: 15%) for a three-year period commencing from 2023.

No provision for Mainland China corporate income tax was made for, as there were no assessable profits arising in Mainland China.

(d) US corporate income tax

CARsgen USA, which was incorporated in Delaware, the United States on May 4, 2016, was subject to statutory U.S. Federal corporate income tax at a rate of 21% (2023: 21%) for the year ended December 31, 2024. CARsgen USA was also subject to the state income tax during for the years ended December 31, 2024 and 2023.

No provision for US corporate income tax was provided for as there were no assessable profits arising in the US.

(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 the Group’s BVI subsidiaries, no BVI withholding tax is imposed.

(f) Ireland corporation income tax and Ireland capital gains tax

The subsidiary in Ireland is subject to income tax at rates of 12.5% (2023: 12.5%) on the estimated assessable profit and 33% (2023: 33%) on the capital gains. Provision for Ireland capital gains tax has been provided as the subsidiary has realised capital gains for the years ended December 31, 2024 and 2023.

8. DIVIDEND

No dividend was declared or paid by the Company during the year ended December 31, 2024 (2023: 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 outstanding (excluding shares reserved for share incentive scheme) during the reporting period.

No adjustment has been made to the basic loss per share amount presented for the reporting period in respect of a dilution as the impact of outstanding potential ordinary shares in relation to share-based payments had an anti-dilutive effect on the basic loss per share amount presented.

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

	2024	2023
Loss attributable to ordinary equity holders of the parent (RMB'000)	(798,132)	(747,794)
Weighted average number of ordinary shares in issue during the year, used in the basic and diluted loss per share calculation ('000)	<u>552,875</u>	<u>556,125</u>
<i>Basic and diluted loss per share (RMB)</i>	<u><u>(1.44)</u></u>	<u><u>(1.34)</u></u>

10. TRADE RECEIVABLES

An ageing analysis of the trade receivables as at the end of the periods, based on the invoice date and net of loss allowance, is as follows:

	2024 RMB'000	2023 RMB'000
Within 1 year	<u><u>8,768</u></u>	<u><u>–</u></u>

As at December 31, 2024, the Group's trade receivables were concentrated in a single pharmaceutical company, and the trade receivables generated from the sales of pharmaceutical products and the provision of cryopreservation services are expected to be recovered in a timely manner in view of the customer's past repayment record and stable business relationship with the Group. Therefore, management believes that the risk of expected credit loss is minimal.

11. ACCRUALS AND OTHER PAYABLES

	2024 RMB'000	2023 RMB'000
Accrued expenses (i)	121,830	111,103
Staff salaries and welfare payables	44,189	36,800
Other taxes payable	4,812	2,621
Payables for acquisition of property, plant and equipment	1,095	1,029
Payables for research and development consumables	539	512
Others	<u>9,158</u>	<u>5,943</u>
Total	<u><u>181,623</u></u>	<u><u>158,008</u></u>

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

12. EVENTS AFTER THE REPORTING PERIOD

On February 26, 2025, the Company announced that certain subsidiaries of the Company had entered into the reaching agreements with an investment fund (the “Investor”) managed by Zhuhai Hengqin SB Xinchuang Equity Investment Management Enterprise (Limited Partnership), pursuant to which, among others, the Investor had agreed to subscribe for the additional registered capital of UCARsgen Biotech Limited (“UCARsgen”) at a cash consideration of RMB80,000,000, representing 8% of the enlarged registered capital of UCARsgen (the “Capital Increase”). Upon the completion of the Capital Increase, the Company’s interest in UCARsgen will be diluted from 100% to 92%.

III. CORPORATE GOVERNANCE RELATED INFORMATION

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

During the Reporting Period, the Company repurchased a total of 4,135,500 Shares (the “Shares Repurchased”) on the Stock Exchange at the aggregate consideration of approximately HK\$24,116,134.85 before expenses. The repurchase was effected to benefit the Company and create value to its Shareholders. Particulars of the Shares Repurchased are as follows:

Month of Repurchase	No. of Shares Repurchased	Price Paid per Share		Aggregate Consideration (HK\$)
		Highest (HK\$)	Lowest (HK\$)	
May	400,000	6.87	6.87	2,748,000.00
June	3,735,500	7.00	4.74	21,368,134.85
Total	4,135,500			24,116,134.85

On July 29, 2024, all of the Shares Repurchased were cancelled by the Company. As of December 31, 2024, there were no treasury Shares (as defined under the Listing Rules) held by the Company.

Save as disclosed above, during the Reporting Period, neither the Company nor any of its subsidiaries had purchased, sold or redeemed the Company’s listed securities (including sale of treasury Shares (as defined under the Listing Rules)).

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 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 Corporate Governance Code as its own code of corporate governance practices.

The Board is of the view that during the Reporting Period, the Company has complied with all the applicable code provisions as set out in the Corporate Governance 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 Chief Executive Officer (“CEO”) and Dr. Zonghai 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. Zonghai 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

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

Legal Proceedings

As of December 31, 2024, 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, 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; and
- 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, 2024:

Use of proceeds	Planned allocation of Net Proceeds (HKD million)	Planned allocation of Net Proceeds (RMB million)	Utilized amount (as at December 31, 2023) (RMB million)	Utilized for the year ended December 31, 2024 (RMB million)	Utilized amount (as at December 31, 2024) (RMB million)	Remaining amount (as at December 31, 2024) (RMB million)
Further development of our Core Product, BCMA CAR-T (CT053)	902.4	851.7	581.7	270.0	851.7	0
Ongoing and planned research and development of our other pipeline product candidates	932.5	880.1	556.2	140.0	696.2	183.9
Developing full-scale manufacturing and commercialization capabilities	601.6	567.8	296.6	74.0	370.6	197.2
Upgrading of CAR-T technologies and early-stage research and development activities	300.8	283.9	138.2	36.4	174.6	109.3
Working capital and other general corporate purposes	270.7	255.5	230.0	25.5	255.5	0
Total	3,008.0	2,839.0	1,802.7	545.9	2,348.6	490.4

The unutilized amount of net proceeds is expected to be fully utilized for the intended use by 2026, which is later than originally planned, due to cost savings achieved via improved operational efficiency and moving outsourced services internally.

The above RMB amounts were converted using the December 31, 2024 exchange rate of HK\$1 to RMB0.9438.

Audit Committee

As at the date of this announcement, the Audit Committee has three members comprising Ms. Xiangke ZHAO (chairperson), Mr. Huaqing GUO and Dr. Wen ZHOU, with terms of reference in compliance with the Listing Rules.

The Audit Committee has reviewed and agreed with 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, 2024. The Audit Committee considers that the financial results for the year ended December 31, 2024 are in compliance with the relevant accounting standards, rules and regulations and appropriate disclosures have been duly made.

Scope of Work of Ernst & Young

The figures in respect of the Group's consolidated statement of financial position, consolidated statement of profit or loss and consolidated statement of comprehensive income and the related notes thereto for the year ended December 31, 2024 as set out on this announcement have been agreed by the Group's auditor, Ernst & Young, to the amounts set out in the Group's audited consolidated financial statements for the year. The work performed by Ernst & Young in this respect did not constitute an assurance engagement in accordance with Hong Kong Standards on Auditing, Hong Kong Standards on Review Engagements or Hong Kong Standards on Assurance Engagements issued by the Hong Kong Institute of Certified Public Accountants and consequently no assurance has been expressed by Ernst & Young on this announcement.

Final Dividend

The Board has resolved not to recommend the payment of a final dividend for the year ended December 31, 2024 (2023: Nil).

Annual General Meeting

The annual general meeting is scheduled to be held on Thursday, May 22, 2025 (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 Monday, May 19, 2025 to Thursday, May 22, 2025, 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 Thursday, May 22, 2025. Shareholders whose name appear on the register of members of the Company on Thursday, May 22, 2025 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 Friday, May 16, 2025.

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, 2024 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.

DEFINITIONS

“affiliate”	any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
“Audit Committee”	the audit committee of the Company
“Board of Directors”, “Board” or “our Board”	our board of Directors
“BVI”	the British Virgin Islands
“China” or “PRC”	the People’s Republic of China, which for the purpose of the Prospectus and for geographical reference only, excludes Hong Kong, Macao and Taiwan
“Company”, “our Company”, “the Company”, “CARsgen Therapeutics” or “CARsgen”	CARsgen Therapeutics Holdings Limited (科濟藥業控股有限公司), an exempted company incorporated in the Cayman Islands with limited liability on February 9, 2018
“Core Product”	has the meaning ascribed to it in Chapter 18A of the Listing Rules and in this context, refers to CT053
“Corporate Governance Code”	the Corporate Governance Code and Corporate Governance Report set out in Appendix C1 to the Listing Rules
“Director(s)”	the director(s) of the Company
“Global Offering”	the initial public offering of the Shares on the terms and subject to the conditions as described in the Prospectus

“Group”, “our Group”, “we”, “us” or “our”	our Company, its subsidiaries and consolidated affiliated entities from time to time or, where the context so requires, in respect of the period prior to our Company becoming the holding company of its present subsidiaries and consolidated affiliated entities, such subsidiaries and consolidated affiliated entities as if they were subsidiaries and consolidated affiliated entities of our Company at the relevant time
“HK\$”	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
“Huadong Medicine”	Huadong Medicine Co., Ltd. (Stock Code: 000963.SZ), a leading largescale comprehensive pharmaceutical listed company based in Hangzhou, China
“IFRSs”	International Financial Reporting Standards
“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 set out in Appendix C3 to the Listing Rules
“NMPA”	National Medical Products Administration (國家藥品監督管理局), the successor of the China Food and Drug Administration (國家食品藥品監督管理總局), or the CFDA, the State Food and Drug Administration (國家食品藥品監督管理局), or the SFDA and the State Drug Administration (國家藥品監督管理局), or the SDA
“Prospectus”	the prospectus issued by the Company on June 7, 2021 in connection with the Global Offering
“RMB” or “Renminbi”	Renminbi, the lawful currency of China
“Shareholder(s)”	holder(s) of shares of the Company
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“United States”, “U.S.” or “US”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“US\$”, “U.S. dollars” or “USD”	United States dollars, the lawful currency of the United States

GLOSSARY

“antigen”	the substance that is capable of stimulating an immune response, specifically activating lymphocytes, which are the body’s infection-fighting white blood cells
“ASCO”	American Society of Clinical Oncology
“ASCO GI”	American Society of Clinical Oncology Gastrointestinal Cancers Symposium
“ASH”	American Society of Hematology
“BCMA”	B-cell maturation antigen, a protein that is highly expressed in multiple myeloma with limited expression on normal tissues other than plasma cells
“BLA”	biologics license application
“B2M”	Beta-2 microglobulin
“CAR(s)”	chimeric antigen receptor(s)
“CAR-T” or “CAR T”	chimeric antigen receptor T cell
“CD19”	a cell surface protein expressed on the surface of almost all normal B lineage cells and B cell leukemia and lymphoma
“CD20”	cell-surface molecule expressed on the surface of normal B lymphocyte and B-cell malignancies
“CD38”	also named cyclic ADP ribose hydrolase, a glycoprotein expressed on the surface of many immune cells (white blood cells), including T/B lymphocytes and natural killer cells. And it also functions in cell adhesion, signal transduction and calcium signaling
“CGMP”	current good manufacturing practices
“chemotherapy”	a category of cancer treatment that uses one or more anti-cancer chemotherapeutic agents as part of its standardized regimen
“CMC”	chemistry, manufacturing, and controls processes in the development, licensure, manufacturing, and ongoing marketing of pharmaceutical products

“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
“EHA”	European Hematology Association
“FDA” or “U.S. FDA” or “US FDA”	United States Food and Drug Administration
“GMP”	Good Manufacturing Practice
“GPC3”	Glypican-3, an oncofetal antigen expressed in a variety of tumors including certain liver and lung cancers
“GC/GEJ”	gastric/gastroesophageal junction cancer, a type of cancer
“GvHD”	graft versus host disease
“HCC”	hepatocellular carcinoma, a type of cancer arising from hepatocytes in predominantly cirrhotic liver patients
“HLA”	human leukocyte antigen
“HvGR”	host versus graft response
“IIT” or “investigator-initiated trial”	clinical trial sponsored and conducted by independent investigators
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China
“LADAR™”	Local Action Driven by Artificial Receptor technology, with similar mechanism of synNotch system, in which the intracellular transcription of the gene of interest is controlled by a chimeric regulatory antigen receptor

“mAb” or “monoclonal antibody”	antibodies that are made by identical immune cells which are all clones belonging to a unique parent cell
“mesothelin”	cell-surface protein whose expression is mostly restricted to mesothelial cell layers lining the pleura, pericardium and peritoneum
“MM” or “R/R MM”	multiple myeloma, a type of cancer that forms in the plasma 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
“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
“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 18, 2025

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, Ms. Xiangke ZHAO and Dr. Wen ZHOU as the independent non-executive Directors.

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