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CARsgen Therapeutics Holdings Limited

科濟藥業控股有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2171)

ANNOUNCEMENT OF INTERIM RESULTS FOR THE SIX MONTHS ENDED JUNE 30, 2024

The board (the “**Board**”) of directors (the “**Director(s)**”) of CARsgen Therapeutics Holdings Limited (the “**Company**”, “**CARsgen Therapeutics**” or “**CARsgen**”) is pleased to announce the unaudited consolidated interim results of the Company, its subsidiaries and consolidated affiliated entities (the “**Group**” or “**We**”) for the six months ended June 30, 2024 (the “**Reporting Period**”), together with comparative figures for the same period of 2023.

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 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 July 31, 2024, 赛恺泽® has been included in nearly 20 provincial or municipal government subsidized insurance programs or private health insurance products, certification and regulatory filings for 赛恺泽® have been completed in 19 provinces or cities, covering over a 100 healthcare institutes, and we have received a total of 52 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. We anticipate that growth of sales revenue of 赛恺泽® will further accelerate with continuous marketing activities and broader insurance coverage.

Satricabtagene autoleucel (CT041)

Satricabtagene autoleucel (satri-cel) is an autologous humanized CAR T-cell product against Claudin18.2 (CLDN18.2). Patient enrollment in accordance with the clinical trial protocol for the gastric cancer/gastroesophageal junction cancer (GC/GEJ) confirmatory Phase II (NCT04581473) trial in China has been completed. Data updates 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. 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*.

An IIT is being initiated in China for satri-cel to be used as consolidation treatment following adjuvant therapy in patients with resected gastric cancer/gastroesophageal junction cancer. The study (CT041-ST-02, NCT04404595) in the US and Canada is currently under clinical hold by the FDA due to CMC observations related to our RTP Manufacturing Facility.

The collaboration with Moderna, Inc. (Nasdaq: MRNA, “**Moderna**”) is ongoing to investigate Moderna’s investigational Claudin18.2 mRNA product in combination with satri-cel in preclinical studies.

CT011

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

CT071

CT071 is an autologous fully human CAR T-cell product against G-protein coupled receptor class C group 5 member D (GPRC5D). CT071 was developed utilizing CARsgen’s CARcelerate® platform, for the treatment of MM and primary plasma cell leukemia (pPCL). CARcelerate® is a proprietary platform CARsgen developed that shortens the manufacturing time to approximately 30 hours and therefore yields younger and possibly more potent CAR T cells when compared to conventional manufacturing processes. Results from the investigator-initiated trial (NCT05838131) for R/R MM and relapsed/refractory plasma cell leukemia (R/R PCL) were presented as a poster at the 29th EHA Annual Congress in June 2024. Another investigator-initiated trial (NCT06407947) is currently underway in China for the treatment of high-risk newly diagnosed multiple myeloma (NDMM). The US study (CT071-HM-001, NCT06333509) is currently under clinical hold by the FDA due to CMC observations related to our RTP Manufacturing Facility.

Allogenic CAR T-cell Products

In addition to autologous products, CARsgen has also been advancing differentiated allogenic CAR T-cell products based on the THANK-uCAR[®] platform. Some examples include: an IIT is ongoing for CT0590 for treatment of R/R MM and PCL; KJ-C2320 is developed for the treatment of acute myeloid leukemia (AML), a disease with high unmet medical needs and lack of efficacious treatment options; KJ-C2219 is a CD19 and CD20 dual-targeting allogeneic CAR T-cell product for the treatment of B-cell related hematologic malignancies and autoimmune diseases; and KJ-C2114 is for the treatment of solid tumor(s).

Manufacturing Capacity

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

We have expanded our global manufacturing capacity in China and the U.S. to support both clinical trials and subsequent commercialization of our pipeline. With the clinical manufacturing facility in Xuhui, Shanghai and commercial GMP manufacturing facility in Jinshan, Shanghai (“**Jinshan Manufacturing Facility**”), we manufacture CAR T-cell products in-house to support clinical trials in China and manufacture the lentiviral vectors in-house to support clinical trials globally. Our Research Triangle Park (RTP) GMP manufacturing facility in Durham, North Carolina (“**RTP Manufacturing Facility**”) has commenced operations of production of autologous CAR T-cell products, which will provide CARsgen additional manufacturing capacity of autologous CAR T-cell products for 700 patients annually to support clinical studies and early commercial launch in the United States, Canada and Europe.

In December 2023, during its inspection of RTP Manufacturing Facility, FDA found that certain procedures related to the manufacturing of the CAR T-cell 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 a clinical hold was subsequently initiated for zevorcabtagene autoleucel, satricabtagene autoleucel, and CT071. A response regarding the Corrective and Preventive Actions (CAPAs) plan was submitted to the FDA in December 2023 in relation to the findings in the Form 483. Updates related to the implementation of corrective action were made in March, April and May, 2024. A complete response to the clinical hold was submitted to the FDA in May 2024. The FDA responded on June 7, 2024 with four items while the response review was still ongoing. The Company has been implementing the CAPAs as planned and has provided the FDA with updates on the progress and results. The remaining CAPAs progress will be updated to the FDA on a regular basis. We are committed to work diligently to address any additional FDA comments. We have already been conducting a comprehensive review and improvement of our processes based on CGMP and are working closely with the FDA to ensure the smooth progress and resume the development activities.

FINANCIAL HIGHLIGHTS

1. REVENUE

The Group's revenue was around RMB6 million for the six months ended June 30, 2024 mainly from 赛恺泽® (zevorcabtagene autoleucel, autologous BCMA CAR T-cell product) in which the primary revenue of 赛恺泽® was calculated on the basis of ex-works price, rather than on the basis of 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 six months ended June 30, 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 RMB2 million for the six months ended June 30, 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 RMB352 million for the six months ended June 30, 2024, representing a decrease of around RMB52 million from around RMB404 million for the six months ended June 30, 2023. The decrease was primarily due to (i) the decrease in share-based compensation, which totaled around RMB9 million for the six months ended June 30, 2024, representing a decrease of around RMB10 million from around RMB19 million for the six months ended June 30, 2023; (ii) lower research and development expenses; and (iii) our recognition of revenue of around RMB6 million for the six months ended June 30, 2024, while we had not recorded any revenue before.

Our adjusted net loss⁽¹⁾ was around RMB342 million for the six months ended June 30, 2024, representing a decrease of around RMB44 million from around RMB386 million for the six months ended June 30, 2023. The decrease was primarily due to (i) lower research and development expenses; and (ii) our recognition of revenue of around RMB6 million for the six months ended June 30, 2024, while we had not recorded any revenue before.

4. CASH AND BANK BALANCES

Cash and bank balances were around RMB1,653 million as of June 30, 2024, representing a decrease of around RMB197 million from around RMB1,850 million as of December 31, 2023. The decrease was mainly due to research and development expenses, administrative expenses and investment of capital expenditure. Cash and cash equivalents and deposits at the end of 2024 are expected to be not less than RMB1,350 million. We expect to have adequate cash into 2027, excluding subsequent cash inflows.

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

MANAGEMENT DISCUSSION AND ANALYSIS

I. OVERVIEW

CARsgen is a biopharmaceutical company with operations in China and the U.S., focusing on innovative CAR T-cell therapies for the treatment of hematologic malignancies and solid tumors. 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 cancer patients worldwide and makes cancer curable.

II. BUSINESS REVIEW

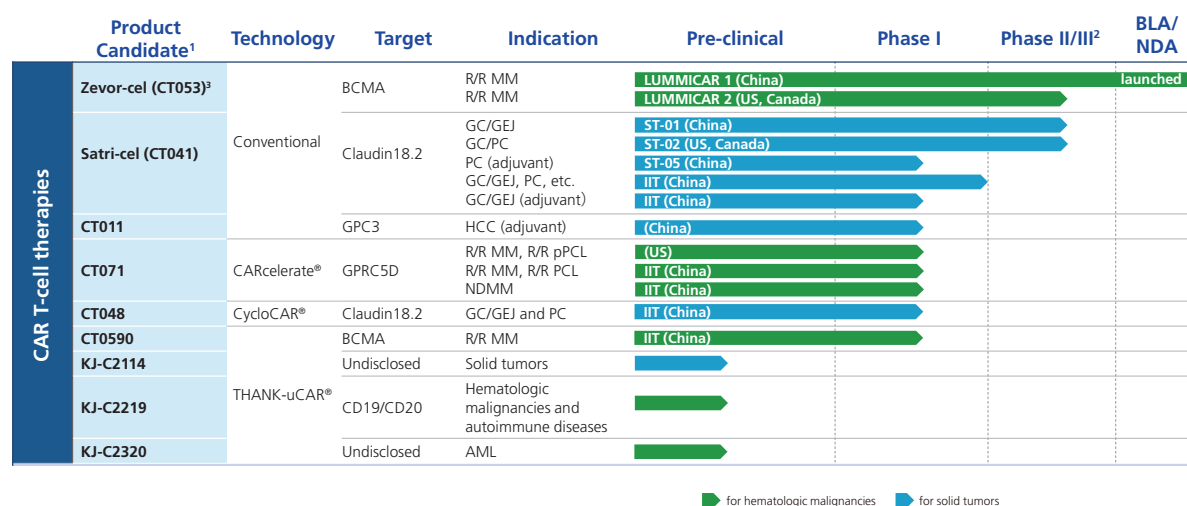
Our Products and Product Pipeline

CARsgen remains committed to be a pioneer in advancements of CAR T-cell therapies by leveraging our comprehensive capabilities and innovative technology platforms. We focus on developing CAR T-cell products that deliver breakthrough innovations for patients with significant unmet medical needs. Our pipeline is regularly assessed to prioritize programs that demonstrate differentiated clinical and commercial value.

Considering the delay in US clinical program due to clinical hold and the 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. Resources will be re-allocated to support clinical programs and products that promise greater clinical impact and are in better alignment with Company's strategic goals.

The Company's pipeline focus in hematologic malignancies will be spearheaded by CT071, which is designed towards GPRC5D and 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 CT041, for which enrollment in accordance with the clinical trial protocol has been completed for the confirmatory advanced GC/GEJ Phase II study (CT041-ST-01, NCT04581473) in China. The Company is actively expanding CAR T application in early line treatments of solid tumors: with one ongoing Phase I clinical trial for pancreatic cancer; one IIT under start-up activities for gastric cancer/gastroesophageal junction cancer; and one Phase I study for hepatocellular carcinomas. CARsgen has been active in advancing several allogeneic CAR T-cell products that offer differentiated clinical value.

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

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 July 31, 2024, 赛恺泽® has been included in nearly 20 provincial or municipal government subsidized insurance programs or private health insurance products, certification and regulatory filings for 赛恺泽® have been completed in 19 provinces or cities, covering over a 100 healthcare institutes, and we have received a total of 52 orders from Huadong Medicine.

Huadong Medicine has extensive commercialization experience and a large-scale sales network in mainland China. Huadong'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 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 ORR was 92.2% (94/102), and the remission rate at VGPR or above was 91.2% (93/102), and the CR/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).

The LUMMICAR-2 study in the U.S. is currently on clinical hold by the FDA due to CMC observations at our RTP Manufacturing Facility. 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 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 – 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 (FNC) 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 the GC/GEJ confirmatory Phase II trial (CT041-ST-01, NCT04581473) in China has been completed. 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 a planned IIT for consolidation treatment following adjuvant therapy in patients with resected GC/GEJ.

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 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 cancer who received satri-cel monotherapy (n = 59), 51 had target lesions. The ORR and DCR were 54.9% (28/51) and 96.1% (49/51), respectively.

The Phase 2 part of the satricabtagene autoleucel Phase 1b/2 clinical trial was initiated in the U.S. and Canada for advanced GC/GEJ trial (CT041-ST-02, NCT04404595). The study is currently under clinical hold by the FDA due to CMC observations related to our RTP Manufacturing Facility. At the 2024 ASCO GI meeting, CARsgen presented a poster entitled “CLDN18.2 chimeric Antigen Receptor T cell Therapy for Patients with Advanced Gastric and Pancreatic Adenocarcinoma: Results of ELIMYN18.2 Phase 1b Clinical Trial” with study results for satricabtagene autoleucel in the Phase 1b trial in the U.S..

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 *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) in May 2024.

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.

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 GC, who had progressed on four lines of combined systemic chemotherapy and immunotherapy after receiving two satricabtagene autoleucel infusions achieved target lesion complete response and sustained an 8-month overall partial response with only minimal ascites.

Satricabtagene autoleucel received Orphan Drug designation from the FDA in September 2020 for the treatment of GC/GEJ and Orphan Medicinal Product designation from the EMA in February 2021 for the treatment of advanced gastric cancer. Satricabtagene autoleucel was granted PRIME eligibility by the EMA for the treatment of advanced gastric cancer in November 2021 and was granted RMAT Designation by FDA for the treatment of advanced GC/GEJ with Claudin18.2-positive tumors in January 2022.

CARsgen and 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.

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

In July 2023, an article titled “Combined local therapy and CAR-GPC3 T-cell therapy in advanced hepatocellular carcinoma: a proof-of-concept treatment strategy” was published in Cancer Communication. 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.

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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 R/R pPCL. It incorporates a fully-human single-chain variable fragment (scFv) developed by CARsgen.

CARsgen's proprietary CARcelerate® platform may shorten CT071's manufacturing time to 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.

Results from the investigator-initiated trials (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)”. Further data updates are planned to be published during the second half of 2024.

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. The Phase 1 clinical trial of CT071 in the U.S. is currently on clinical hold by the FDA due to CMC observations at our RTP Manufacturing Facility.

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

IND-Enabling or Preclinical Stage Product

In addition to the above clinical-stage products, CARsgen has multiple programs in the IND-enabling or preclinical stage.

CT048 is a next-generation autologous CAR T-cell product developed with our CycloCAR[®] technology to treat patients with Claudin18.2-positive GC/GEJ or PC. We expect that by co-expressing cytokine IL-7 and chemokine CCL21, CT048 may provide greater clinical efficacy potentially with reduced requirement for lymphodepletion conditioning. An IIT is ongoing in China to evaluate the safety and efficacy of CT048 for the treatment of GC/GEJ and PC.

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 Company plans to disclose the proof-of-concept study results during the second half of 2024.

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

KJ-C2219 is an allogeneic CAR T-cell product targeting CD19/20, for the treatment of hematologic malignancies and autoimmune diseases.

KJ-C2320 is an allogeneic CAR T-cell product for the treatment of AML. Start-up activities for an IIT in China will be initiated in the second half of 2024.

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, antibody development, vector design, manufacturing, quality assurance, and quality control. Our integrated cell therapy platform is composed of target discovery, hybridoma and antibody humanization platform, fully human phage display antibody library platform, antibody identification platform, immune cell function evaluation platform, plasmid and lentiviral vector preparation platforms, cell therapy process development platform, analytical platforms with molecular, flow cytometry, biochemical, physical-chemical, and cell-based analytical capabilities, biological samples tests platform, clinical-scale and commercial-scale CAR T manufacturing platform, and platform for clinical studies.

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/HLA-I-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/HLA-I-T cells with the anti-NKG2A CAR resulted in improved expansion in the presence of NK cells. We are developing allogeneic CAR T-cell products using THANK-uCAR® technology, 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 or 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 on exploration of combinatorial approaches to enhance clinical outcomes of CAR-T therapies. For example, our recent 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 June 30, 2024, we had more than 300 patents of which 114 patents had been issued globally including China, the United States, Europe, and Japan, with an increase of 10 issued patents and 10 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.

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

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

The RTP Manufacturing Facility, with a total GFA of approximately 3,300 sq.m, started operating in September 2022 with technology transfer completed and provides CARsgen with additional manufacturing capacity of autologous CAR T-cell products for 700 patients annually.

In December 2023, during its inspection, FDA found that certain procedures related to the manufacturing of the CAR T products were not conducted in accordance with Current Good Manufacturing Practices (CGMP) or other procedural controls and requirements associated with the manufacturing facility, and a Form 483 was issued and a clinical hold was subsequently initiated for the three INDs active in the U.S.. Recently, a warning letter from FDA was received and our full response was submitted on August 16, 2024, U.S. time. During this period, a response regarding the Corrective and Preventive Actions (CAPAs) plan has been submitted to the FDA in December 2023 in relation to the findings in the Form 483. Updates related to the implementation of corrective action were made in March, April and May, 2024. A complete response to the clinical hold for zevorcabtagene autoleucel, satricabtagene autoleucel, and CT071 was submitted in May 2024, and feedback was received from the FDA on June 7, 2024, U.S. time with four items. The Company has been implementing the CAPAs as planned and has provided the FDA with updates on the progress and results. The remaining CAPAs progress will be updated to the FDA on a regular basis. We are committed to work diligently to address any additional FDA comments. We have already been conducting a comprehensive review and improvement on the CGMP and are working closely with the FDA to ensure the smooth progress and production quality for clinical trials and launching applications and resume the development activities.

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

Expansion and Retention of Talent

As of June 30, 2024, we had a total of 477 employees.

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

Industry Overview

As a novel treatment modality, CAR T-cell therapy offers breakthrough efficacy and curative potential for cancer patients. The global CAR T-cell therapy market has been experiencing strong growth since 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 six CAR T-cell products approved by U.S. FDA and five CAR T-cell products approved by NMPA in China. However, there are still significant unmet medical needs for the cancer patients worldwide, calling for more and better innovative CAR T-cell products, particularly for the treatment of solid tumors. With our pipeline products, e.g. zevorcabtagene autoleucel and satricabtagene autoleucel, and innovative technology platforms, e.g. CycloCAR®, THANK-uCAR®, LADAR™ and CARcelerate®, we are committed to developing the innovative therapies to fulfill 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 the CAR T-cell therapies to patients. We will continue to expand our manufacturing capacity in China and in the United States to support the 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 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.

III. 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 never been profitable and have incurred operating losses in every year since inception, with operating losses of RMB362 million and RMB409 million for the six months ended June 30, 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 six months ended June 30, 2024.

Loss for the Period

Net loss was RMB352 million for the six months ended June 30, 2024, representing a decrease of RMB52 million from RMB404 million for the six months ended June 30, 2023. The decrease was primarily due to (i) the decrease in share-based compensation, which totaled RMB9 million for the six months ended June 30, 2024, representing a decrease of RMB10 million from RMB19 million for the six months ended June 30, 2023; (ii) lower research and development expenses; and (iii) our recognition of revenue of approximately RMB6 million for the six months ended June 30, 2024, while we had not recorded any revenue before.

Non-IFRS Measures

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

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

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

	Six months ended June 30,	
	2024	2023
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Loss for the periods	(351,558)	(404,472)
Add:		
Share-based compensation	<u>9,190</u>	<u>18,746</u>
Adjusted net loss	<u>(342,368)</u>	<u>(385,726)</u>

	Six months ended June 30,	
	2024	2023
	<i>RMB</i>	<i>RMB</i>
	(Unaudited)	(Unaudited)
Loss per share for the periods	(0.63)	(0.73)
Add:		
Share-based compensation per share	<u>0.02</u>	<u>0.03</u>
Adjusted net loss per share	<u><u>(0.61)</u></u>	<u><u>(0.70)</u></u>

The Company believes that the adjusted non-IFRS measures are useful for understanding and assessing the underlying business performance and operating trends, and that the Company's management and investors may benefit from referring to these adjusted financial measures in assessing the Group's financial performance by eliminating the impact of certain unusual, non-recurring, non-cash and/or non-operating items that the Group does not consider indicative of the performance of the Group's core business. These non-IFRS measures, as the management of the Group believes, are widely accepted and adopted in the industry in which the Group is operating. However, the presentation of these non-IFRS measures is not intended to be considered in isolation or as a substitute for the financial information prepared and presented in accordance with the IFRS. Shareholders of the Company and potential investors should not view the adjusted results on a stand-alone basis or as a substitute for results under IFRS, and these non-IFRS measures may not be comparable to similarly-titled measures represented by other companies.

Revenue

	Six months ended June 30,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Revenue	<u>6,340</u>	<u>—</u>
Total	<u><u>6,340</u></u>	<u><u>—</u></u>

Research and Development Expenses

	Six months ended June 30,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Employee benefit expenses	121,842	137,294
Testing and clinical expenses	79,035	101,474
Depreciation of property, plant and equipment	15,503	28,386
Research and development consumables	10,287	28,691
Utilities	8,359	9,238
Amortization of intangible assets	3,343	2,999
Short-term lease and low-value lease expenses	1,945	516
Travelling and transportation expenses	1,871	2,994
Depreciation of right-of-use assets	1,777	8,318
Office and other expenses	1,593	3,403
Total	245,555	323,313

Research and development expenses decreased to RMB246 million for the six months ended June 30, 2024, representing a decrease of RMB77 million from RMB323 million for the six months ended June 30, 2023, primarily due to the decrease in depreciation of property, plant and equipment for testing and productions in support of our clinical trials.

Administrative Expenses

	Six months ended June 30,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Employee benefit expenses	32,447	35,819
Professional service fees	22,863	9,047
Depreciation of property, plant and equipment	15,346	2,414
Depreciation of right-of-use assets	4,074	1,278
Office expenses	3,340	5,212
Travelling and transportation expenses	1,994	1,944
Auditors' remuneration	1,944	1,815
– audit service	1,944	1,630
– non-audit service	–	185
Utilities	634	542
Amortization of intangible assets	588	660
Short-term lease and low-value lease expenses	248	292
Other expenses	2,835	3,291
Total	86,313	62,314

Administrative expenses are RMB86 million for the six months ended June 30, 2024, representing an increase of RMB24 million from RMB62 million for the six months ended June 30, 2023, primarily due to the increase in depreciation of property, plant and equipment and professional service fees.

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

Employee benefit expenses

	Six months ended June 30,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Wages and salaries	121,937	126,320
Pension costs	10,367	10,637
Share-based compensation	9,106	18,746
Other employee benefits	12,879	17,410
Total	154,289	173,113
Amount included in research and development expenses	121,842	137,294
Amount included in administrative expenses	32,447	35,819

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

Share-based payments

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

	Six months ended June 30,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Administrative expenses	2,398	3,144
Research and development expenses	6,708	15,602
Cost of sales	84	—
Total	9,190	18,746

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:

	For the six months ended	
	June 30,	
	2024	2023
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Net cash used in operating activities	(255,947)	(141,815)
Net cash generated from/(used in) investing activities	6,584	(404,526)
Net cash generated from/(used in) financing activities	24,688	(7,504)
Net decrease in cash and cash equivalents	(224,675)	(553,845)
Cash and cash equivalents at beginning of the period	1,849,752	2,268,036
Exchange gain/(loss) on cash and cash equivalents	27,492	(30,240)
Cash and cash equivalents at end of the period	1,652,569	1,683,951

Net Cash Used in Operating Activities

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

Our net cash used in operating activities were RMB256 million and RMB142 million for the six months ended June 30, 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/(Used in) Investing Activities

Our cash used in investing activities mainly reflects our cash used for our purchase of term deposits with original maturity between three and twelve months, property, plant and equipment and our cash generated from investing activities mainly reflects our net cash receipts from term deposits with original maturity between three and twelve months. For the six months ended June 30, 2024, our net cash generated from investing activities was RMB7 million, which was primarily attributable to interest receipts from term deposit with original maturity between three and twelve months. For the six months ended June 30, 2023, our net cash used in investing activities was RMB405 million, which was primarily attributable to cash payment for investment of term deposit and purchase of equipment.

Net Cash Generated from/(Used in) Financing Activities

For the six months ended June 30 2024, our net cash generated from financing activities was RMB25 million primarily attributable to payment of lease expenses of RMB9 million, repurchase of shares of RMB92 million and proceed of new bank loan of RMB130 million. For the six months ended June 30, 2023, our net cash used in financing activities was RMB8 million, primarily attributable to payment of principals and interest of lease liabilities and payment of principals of bank borrowings.

Cash and Bank Balances

	As at June 30, 2024 <i>RMB'000</i> (Unaudited)	As at December 31, 2023 <i>RMB'000</i> (Audited)
Cash at banks		
– RMB	744,682	779,122
– USD	907,858	1,058,394
– HKD	29	12,236
Subtotal	<u>1,652,569</u>	<u>1,849,752</u>

The Group's cash and bank balances as at June 30, 2024 were RMB1,653 million, representing a decrease of RMB197 million compared to RMB1,850 million as at December 31, 2023. The decrease was mainly due to our research and development expenses, administrative expenses and investment of capital expenditure.

Borrowing and Gearing Ratio

The Group's total borrowings, including interest-bearing borrowings, as at June 30, 2024 were RMB129 million, representing an increase of RMB126 million compared to RMB3 million as at December 31, 2023.

As at June 30, 2024 and December 31, 2023, the Group's bank borrowings of approximately nil and RMB3 million respectively are pledged by property, plant and equipment and right-of-use assets of the Group.

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

As at June 30, 2024, the Group's secured borrowings will mature within one year with the interest rate of 3.1690% (2023: 5.2250%).

The gearing ratio (calculated by dividing the sum of borrowings and lease liabilities by total equity) of the Group as at June 30, 2024 was 14.23%, representing an increase of 9.50 percentage points compared to 4.73% as at December 31, 2023.

Lease Liabilities

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

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

Our lease liabilities increased to RMB84 million as at June 30, 2024 from RMB83 million as at December 31, 2023, mainly due to increase of factory lease.

Significant Investments

As at June 30, 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.

Material Acquisitions and Disposals

During the six months ended June 30, 2024, we did not have material acquisitions or disposals of subsidiaries, associates and joint ventures.

Foreign Exchange Risk

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

Capital Expenditure

For the six months ended June 30, 2024, the Group's total capital expenditure amounted to approximately RMB6 million, which was used in purchase of property, plant and equipment, and software.

Charge on Assets

As at June 30, 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.

Contingent Liability

As at June 30, 2024, the Group did not have any material contingent liabilities.

Employees and Remuneration Policies

As of June 30, 2024, we had a total of 477 employees.

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

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

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

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

Future Investment Plans and Expected Funding

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

**INTERIM CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND
OTHER COMPREHENSIVE INCOME**
FOR THE SIX MONTHS ENDED JUNE 30, 2024

	<i>Notes</i>	2024 (Unaudited) RMB'000	2023 (Unaudited) RMB'000
Revenue	4	6,340	—
Cost of sales	6	(4,723)	—
Gross profit		1,617	—
Other income	4	23,062	41,605
Selling and distribution expenses	6	(721)	—
Administrative expenses	6	(86,313)	(62,314)
Research and development expenses	6	(245,555)	(323,313)
Other losses – net	5	(53,630)	(65,208)
Operating loss		(361,540)	(409,230)
Finance income	6	12,596	7,299
Finance costs	6	(2,614)	(2,541)
Finance income – net		9,982	4,758
Loss before income tax		(351,558)	(404,472)
Income tax expense	7	—	—
Loss for the period and attributable to owners of the parent		(351,558)	(404,472)
Other comprehensive (loss)/income for the period:			
<i>Items that may be reclassified to profit or loss</i>			
Exchange differences on translation of subsidiaries		(72,183)	7,710
<i>Items that will not be reclassified to profit or loss</i>			
Exchange differences on translation of the Company		158,609	106,005
Other comprehensive income for the period, net of tax		86,426	113,715
Total comprehensive loss for the period and attributable to the owners of the parent		(265,132)	(290,757)
Loss per share attributable to ordinary equity holders of the parent			
Basic and diluted loss per share (in RMB)	9	(0.63)	(0.73)

INTERIM CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION
AS AT JUNE 30, 2024

	<i>Notes</i>	June 30, 2024 (Unaudited) RMB'000	December 31, 2023 (Audited) RMB'000
NON-CURRENT ASSETS			
Property, plant and equipment		288,785	311,952
Right-of-use assets		51,131	49,438
Intangible assets		6,542	8,660
Other non-current assets and prepayments		16,342	14,076
		<u>362,800</u>	<u>384,126</u>
Total non-current assets			
CURRENT ASSETS			
Trade receivables	10	3,471	—
Inventories		5,067	683
Other receivables		16,176	9,792
Other current assets and prepayments		62,414	12,861
Cash and bank balances		1,652,569	1,849,752
		<u>1,739,697</u>	<u>1,873,088</u>
Total current assets			
CURRENT LIABILITIES			
Accruals and other payables	11	112,683	158,008
Interest-bearing bank borrowings	12	19,967	2,522
Lease liabilities		13,165	12,230
Deferred income		11,185	13,220
Contract liabilities	13	26,680	10,237
		<u>183,680</u>	<u>196,217</u>
Total current liabilities			
NET CURRENT ASSETS		<u>1,556,017</u>	<u>1,676,871</u>
TOTAL ASSETS LESS CURRENT LIABILITIES		<u>1,918,817</u>	<u>2,060,997</u>
NON-CURRENT LIABILITIES			
Interest-bearing bank borrowings	12	109,150	—
Lease liabilities		70,792	70,468
Deferred income		9,957	10,387
Contract liabilities	13	231,603	178,442
		<u>421,502</u>	<u>259,297</u>
Total non-current liabilities			
Net assets		<u>1,497,315</u>	<u>1,801,700</u>
EQUITY			
Equity attributable to owners of the parent			
Share capital	14	1	1
Reserves		1,497,314	1,801,699
		<u>1,497,315</u>	<u>1,801,700</u>
Total equity			

1. GENERAL INFORMATION

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

The Company is an investment holding company. The Company and its subsidiaries (hereinafter collectively referred to as the “Group”) are biopharmaceutical companies with operations in Chinese Mainland (the “PRC”) and the United States of America (the “US”). The group has established capabilities for CAR T-cell research and development covering target discovery, preclinical research, product clinical development and commercial-scale production.

2. BASIS OF PREPARATION

The interim condensed consolidated financial information for the six months ended June 30, 2024 has been prepared in accordance with IAS 34 *Interim Financial Reporting*. The interim condensed consolidated financial information does not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Group’s annual consolidated financial statements for the year ended 31 December 2023.

3. CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The accounting policies adopted in the preparation of the interim condensed consolidated financial information are consistent with those applied in the preparation of the Group’s annual consolidated financial statements for the year ended 31 December 2023, except for the adoption of the following revised International Financial Reporting Standards (“IFRSs”) for the first time for the current period’s financial information.

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</i> <i>(the “2020 Amendments”)</i>
Amendments to IAS 1	<i>Non-current Liabilities with Covenants</i> <i>(the “2022 Amendments”)</i>
Amendments to IAS 7 and IFRS 7	<i>Supplier Finance Arrangements</i>

The Group has assessed the impact of these amendments and concluded that they did not have any impact on the financial position or performance of the Group.

4. REVENUE AND OTHER INCOME

An analysis of revenue is as follows:

	For the six months ended June 30,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Revenue from contracts with customers	6,340	—

An analysis of other income is as follows:

	For the six months ended June 30,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Government grants (i)	2,907	10,869
Interest income on term deposits with original maturity between three and twelve months	20,155	30,736
Total	23,062	41,605

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

5. OTHER LOSSES – NET

	For the six months ended June 30,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Foreign exchange losses – net	(53,476)	(65,259)
Others	(154)	51
Total	(53,630)	(65,208)

6. LOSS BEFORE TAX

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

	For the six months ended June 30,	
	2024	2023
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Employee benefit expenses	154,288	173,113
Testing and clinical expenses	79,035	101,474
Depreciation of property, plant and equipment	31,708	30,800
Research and development consumables	10,287	28,691
Professional service expenses	22,664	10,579
Depreciation of right-of-use assets	6,008	9,596
Utilities	8,993	9,780
Office expenses	3,893	5,263
Travelling and transportation expenses	3,865	4,938
Amortization of intangible assets	3,976	3,659
Short term lease and low value lease expenses	2,456	808
Auditors' remuneration	1,944	1,815
– Audit service	1,944	1,630
– Non-audit service	–	185
Other expenses	2,751	5,111
Cost of inventories sold	4,723	–
Marketing service fees	721	–
Interest income	(12,596)	(7,299)
Interest expense on lease liabilities	1,679	2,344
Interest expense on bank borrowings	935	197
Total	327,330	380,869
Cost of inventories sold	4,723	–
Selling and distribution expenses	721	–
Administrative expenses	86,313	62,314
Research and development expenses	245,555	323,313
Finance income	(12,596)	(7,299)
Finance costs	2,614	2,541
Total	327,330	380,869

7. INCOME TAX EXPENSE

Current income tax

The Group is subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of the Group are domiciled and operated.

(a) *Cayman Islands income tax*

The Company was incorporated in the Cayman Islands as an exempted company with limited liability under the Companies Law of the Cayman Islands and accordingly, is exempted from Cayman Islands income tax.

(b) *Hong Kong income tax*

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

(c) *Chinese Mainland corporate income tax*

Subsidiaries in Chinese Mainland 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”), with the exception that CARsgen Therapeutics obtained its High and New Technology Enterprises status in year 2023 and hence is entitled to a preferential tax rate of 15% (2023: 15%) for a three-year period commencing 2023.

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

(d) *The US corporate income tax*

CARsgen USA, which was incorporated in Delaware, the United States on May 4, 2016, was subject to statutory U.S. Federal corporate income tax at a rate of 21% (2023: 21%) for the six months ended June 30, 2024. CARsgen USA was also subject to the state income tax during for the six months ended June 30, 2024 and 2023.

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

(e) *British Virgin Islands income tax*

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

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

Subsidiary in Ireland is subject to income tax at a rate of 12.5% (2023: 12.5%) on the estimated assessable profit and 33% (2023: 33%) on the capital gains.

No provision for Ireland corporate income tax was provided for as there’s no assessable profit.

8. DIVIDEND

No dividend was declared or paid by the Company during the six months ended June 30, 2024 (six months ended June 30, 2023: Nil).

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

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

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

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

	For the six months ended June 30,	
	2024	2023
	(Unaudited)	(Unaudited)
Loss attributable to the ordinary equity holders of the parent (<i>RMB'000</i>)	(351,558)	(404,472)
Weighted average number of ordinary shares in issue during the period, used in the basic and diluted loss per share calculation (<i>'000</i>)	557,030	555,475
Basic and diluted loss per share (<i>RMB</i>)	(0.63)	(0.73)

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:

	June 30, 2024	December 31, 2023
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Audited)
Within 3 months	3,471	—

11. ACCRUALS AND OTHER PAYABLES

	June 30, 2024	December 31, 2023
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Audited)
Accrued expenses (<i>i</i>)	71,937	111,103
Staff salaries and welfare payables	30,706	36,800
Other taxes payable	2,554	2,621
Payables for research and development consumables	1,045	512
Payables for acquisition of property, plant and equipment	274	1,029
Interest payables	—	33
Others	6,167	5,910
Total	112,683	158,008

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

12. INTEREST-BEARING BANK BORROWINGS

	June 30, 2024 <i>RMB'000</i> (Unaudited)	December 31, 2023 <i>RMB'000</i> (Audited)
<i>Non-current</i>		
Secured bank borrowings	<u>109,150</u>	<u>—</u>
<i>Current</i>		
Secured bank borrowings	<u>19,967</u>	<u>2,522</u>
Total	<u>129,117</u>	<u>2,522</u>

13. CONTRACT LIABILITIES

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

	June 30, 2024 <i>RMB'000</i> (Unaudited)	December 31, 2023 <i>RMB'000</i> (Audited)
<i>Advances received from a customer</i>		
Grant of an exclusive distribution agreement	<u>258,283</u>	<u>188,679</u>
Non-current	<u>231,603</u>	<u>178,442</u>
Current	<u>26,680</u>	<u>10,237</u>
Total	<u>258,283</u>	<u>188,679</u>

Contract liabilities include upfront payments received for the grant of an exclusive distribution right. On January 16, 2023, CARsgen Life Sciences Co., Ltd. (“CARsgen Life Science”), a wholly-owned subsidiary of the Company and Huadong Medicine (Hangzhou) Co., Ltd., a wholly-owned subsidiary of Huadong Medicine Co., Ltd. entered into an exclusive distribution agreement for the commercialisation of zevorcabtagene autoleucel (the “Agreement”) with total upfront and milestone payments up to RMB1,225 million. In March, 2023, CARsgen Life Sciences received an upfront payment of RMB200,000,000 (RMB188,679,000 excluding VAT) under the Agreement. In March 2024, CARsgen Life Sciences received a milestone payment of RMB75,000,000 (RMB70,755,000 excluding VAT) upon the achievement of a regulatory milestone.

The upfront fee and the milestone payment are restricted by the term in the Agreement, and the current portion is expected to be realised within one year.

14. SHARE CAPITAL

Authorized:

	Number of shares <i>In thousands</i>	Nominal value of shares <i>USD</i>
As at January 1, 2023 and June 30, 2023	200,000,000	50,000
As at January 1, 2024 and June 30, 2024	200,000,000	50,000

Issued and fully paid:

	Number of ordinary shares at USD0.00000025 par value <i>In thousands</i>	RMB equivalent value <i>RMB'000</i>
As at December 31, 2022 (audited)	572,625	1
Issue of shares held in trust	2,013	—*
Issue of shares to employees under Employee Incentive Schemes (i)	686	—*
As at June 30, 2023 (unaudited)	575,324	1
As at December 31, 2023 (audited)	575,640	1
Issue of shares to employees under Employee Incentive Schemes (i)	35	—*
As at June 30, 2024 (unaudited)	575,675	1

* The amounts are less than RMB1,000.

(i): During the six months ended June 30, 2024, the Company issued 35,394 ordinary shares at the cost of HK\$97,000 (equivalent to RMB89,000 approximately) in total at the prices ranging from nil to HK\$7.06 per share to employees under Employee Incentive Schemes (six months ended June 30, 2023: 685,834 ordinary shares at HKD4,913,000 (equivalent to RMB4,431,000 approximately)).

IV. CORPORATE GOVERNANCE AND OTHER INFORMATION

Interim dividend

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

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

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. 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	<u>3,735,500</u>	7.00	4.74	<u>21,368,134.85</u>
Total	<u>4,135,500</u>			<u>24,116,134.85</u>

As of June 30, 2024, there were no treasury shares (as defined under the Listing Rules) held by the Company.

On July 29, 2024, all of the Shares Repurchased were cancelled by the Company.

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

Model Code for Securities Transactions

The Company has adopted the Model Code. Specific enquiries have been made to all Directors and the Directors have confirmed that they have complied with the Model Code for the Reporting Period.

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

Compliance with the Corporate Governance Code

The Company recognizes the importance of good corporate governance for enhancing the management of the Company as well as preserving the interests of the Shareholders as a whole. The Company has adopted and applied the principles and code provisions as set out in the Part 2 of Corporate Governance Code.

For 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”). Dr. Zonghai LI (“**Dr. LI**”), the Chairman of our Board and CEO, currently performs these two roles. Our Board believes that, in view of his experience, personal profile and his roles in our Company, Dr. LI is the Director best suited to identify strategic opportunities and focus of the Board due to his extensive understanding of our business as our CEO. Our Board also believes that the combined role of Chairman of the Board and CEO can promote the effective execution of strategic initiatives and facilitate the flow of information between management and the Board. Our Board will continue to review and consider splitting the roles of Chairman of the Board and the CEO at a time when it is appropriate by taking into account the circumstances of our Group as a whole.

Subsequent Event

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

Legal Proceedings

As of June 30, 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
- approximately HK\$270.7 million (US\$34.7 million) (or approximately 9% of the net proceeds) will be used for our working capital and other general corporate purposes

The net proceeds from the Global Offering have been utilized in accordance with the purposes set out in the Prospectus. The table below sets out the applications of the net proceeds and actual usage up to June 30, 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 six months ended June 30, 2024 (RMB million)	Utilized amount (as at June 30, 2024) (RMB million)	Remaining amount (as at June 30, 2024) (RMB million)
Further development of our Core Product, BCMA CAR-T (CT053)	902.4	843.2	581.7	144.9	726.6	116.6
Ongoing and planned research and development of our other pipeline product candidates	932.5	871.3	556.2	112.0	668.2	203.1
Developing full-scale manufacturing and commercialization capabilities	601.6	562.1	296.6	26.4	323.0	239.1
Upgrading of CAR-T technologies and early – stage research and development activities	300.8	281.1	138.2	30.2	168.4	112.7
Working capital and other general corporate purposes	270.7	252.9	230.0	22.9	252.9	–
Total	3,008.0	2,810.6	1,802.7	336.4	2,139.1	671.5

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 exchange rate of HK\$1 to RMB0.9344 as of June 30, 2024.

Audit Committee

As at the date of this announcement, the Audit Committee has three members comprising Ms. Xiangke ZHAO (chairman), Mr. Huaqing GUO and Dr. 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 unaudited condensed consolidated interim financial results of the Group for the six months ended June 30, 2024. The Audit Committee considers that the interim financial results for the six months ended June 30, 2024 are in compliance with the relevant accounting standards, rules and regulations and appropriate disclosures have been duly made.

Publication of Interim Results Announcement and Interim Report

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

The interim report for the Reporting Period containing all the information required by Appendix D2 to the Listing Rules will be published on the websites of the Stock Exchange and the Company in due course.

DEFINITION

“affiliate”	any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
“Audit Committee”	the audit committee of the Company
“Board of Directors”, “Board” or “our Board”	our board of Directors
“BVI”	the British Virgin Islands
“China” or “PRC”	the People’s Republic of China, which for the purpose of 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 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
“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”	Renminbi, the lawful currency of China
“Shareholder(s)”	holder(s) of shares of the Company
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“United States” or “U.S.” or “US”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“US\$” or “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 B cell leukemia and lymphoma
“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
“EMA”	European Medicines Agency
“FDA” or “U.S. FDA” or “US FDA”	United States Food and Drug Administration
“GMP”	Good Manufacturing Practice
“GPC3”	Glypican-3, an oncofetal antigen expressed in a variety of tumors including certain liver and lung cancers
“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
“PRIME”	PRiority MEdicine. A scheme launched by the EMA to offer early and proactive support to medicine developers to optimize the generation of robust data on medicine’s benefits and risks, and accelerate assessment of medicines applications, for medicines that target an unmet medical need with advantages over existing treatments
“regenerative medicine advanced therapy” or “RMAT”	a special status granted by the FDA to regenerative medicine therapies, including cell therapies, intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition
“solid tumor”	an abnormal mass of tissue that usually does not contain cysts or liquid areas
“TCR”	T cell receptor

“THANK-uCAR®”

the Company’s proprietary technology to generate CAR T cells with improved expansion and persistence from T cells that are sourced from third-party donors

CAUTIONARY LANGUAGE REGARDING FORWARD-LOOKING STATEMENTS

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

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

Hong Kong, August 28, 2024

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