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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 ON INTERIM RESULTS FOR THE SIX MONTHS ENDED JUNE 30, 2025 AND

SUPPLEMENTAL ANNOUNCEMENT IN RELATION TO THE ANNUAL REPORT FOR THE YEAR ENDED DECEMBER 31, 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, 2025 (the “**Reporting Period**”), together with comparative figures for the same period of 2024.

FINANCIAL HIGHLIGHTS

1. REVENUE

The Group’s revenue was around RMB51 million for the six months ended June 30, 2025 mainly from 赛恺泽® (zevorcabtagene autoleucel, autologous BCMA CAR T-cell product), in which was calculated on the basis of ex-works price, rather than end-of-market prices. Our revenue is recognized upon completion of ex-works delivery of products. 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 RMB29 million for the six months ended June 30, 2025. 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 RMB75 million for the six months ended June 30, 2025, representing a decrease in loss of around RMB277 million from around RMB352 million for the six months ended June 30, 2024. The decrease was primarily due to (i) the change in net other losses and gains of RMB112 million from RMB54 million in losses for the six months ended June 30, 2024 to RMB58 million in gains for the six months ended June 30, 2025; (ii) the decrease in research and development expenses of RMB116 million from RMB246 million for the six months ended June 30, 2024 to RMB130 million for the six months ended June 30, 2025; (iii) the decrease in administrative expenses of RMB47 million from RMB86 million for the six months ended June 30, 2024 to RMB39 million for the six months ended June 30, 2025; (iv) the recognition of gross profit of RMB29 million for the six months ended June 30, 2025 as compared to RMB1.6 million for the six months ended June 30, 2024.

Our adjusted net loss⁽¹⁾ was around RMB72 million for the six months ended June 30, 2025, representing a decrease of around RMB270 million from RMB342 million for the six months ended June 30, 2024. The decrease was primarily due to (i) higher other gains – net; (ii) lower research and development expenses; (iii) lower administrative expenses; (iv) higher gross profit; (v) lower share-based compensation.

4. CASH AND BANK BALANCES

Cash and bank balances were around RMB1,261 million as of June 30, 2025, representing a decrease of around RMB218 million from around RMB1,479 million as of December 31, 2024. The decrease was mainly due to the payment of research and development expenses, administrative expenses and investment of capital expenditure. Cash and cash equivalents and deposits at the end of 2025 are expected to be not less than RMB1,100 million. We expect to have adequate cash into the 2028 excluding subsequent cash inflows.

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

BUSINESS HIGHLIGHTS

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

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) approved by the National Medical Products Administration (NMPA) of China 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. During the first half of 2025, certification and regulatory filings for 赛恺泽® have been completed in more than 20 provinces or cities and we have received a total of 111 confirmed orders from Huadong Medicine. We anticipate that growth of sales revenue of 赛恺泽® will further accelerate with continuous marketing activities and broader insurance coverage.

Satricabtagene autoleucel (R&D code: CT041)

Satricabtagene autoleucel (satri-cel) is an autologous humanized CAR T-cell product against Claudin18.2 (CLDN18.2). In June 2025, the Center for Drug Evaluation (CDE) of NMPA of China has accepted the New Drug Application (NDA) for satri-cel for the treatment of Claudin18.2-positive advanced gastric/gastroesophageal junction adenocarcinoma (G/GEJA) in patients who have failed at least two prior lines of therapy. Satri-cel was granted Priority Review in May 2025 and Breakthrough Therapy Designation (BTD) in March 2025 by the CDE. The results of confirmatory Phase II trial (NCT04581473) in China have been published in *The Lancet* and were orally presented at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting.

Allogeneic CAR T-cell Products

CARsgen has been advancing differentiated allogeneic CAR T-cell products utilizing the CARsgen’s proprietary THANK-uCAR® platform. CARsgen has recently developed the THANK-u Plus™ platform as an enhanced version of THANK-uCAR® to address the potential impact of NKG2A expression levels on therapeutic efficacy of the allogeneic CAR T-cells. Preliminary clinical data for CT0596 (an allogeneic BCMA-targeted CAR T-cell product) utilizing THANK-u Plus™ platform for the treatment of R/R MM or relapsed/refractory plasma cell leukemia (R/R PCL) were released in May 2025 in Newsroom on the Company’s official website.

Multiple allogeneic CAR T-cell products are under development, including CT0596 against BCMA for R/R MM and R/R PCL (THANK-u Plus™); KJ-C2219 against CD19/CD20 for B-cell malignancies and autoimmune diseases (THANK-u Plus™); KJ-C2320 against CD38 for acute myeloid leukemia (AML) (THANK-uCAR®); KJ-C2114 for solid tumors (THANK-u Plus™); and KJ-C2526 against NKG2DL for AML, other malignancies and senescence (THANK-u Plus™).

MANAGEMENT DISCUSSION AND ANALYSIS

I. OVERVIEW

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

II. BUSINESS REVIEW

Our Products and Product Pipeline

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

In the first half of 2025, NMPA has accepted NDA for satri-cel for the treatment of Claudin18.2-positive G/GEJA in patients who have failed at least two prior lines of therapy. To the best of our knowledge, satri-cel is the first and only CAR-T cell therapy for the treatment of solid tumors that has advanced to NDA stage worldwide. Moreover, with the collaboration with Huadong Medicine, the commercialization of 赛恺泽® in mainland China has been progressing smoothly. Meanwhile, the Company has been advancing several allogeneic CAR T-cell products using the proprietary THANK-uCAR® allogeneic CAR-T technology and the enhanced version THANK-u Plus™ platform. Multiple allogeneic CAR T-cell products that offer differentiated clinical value are under development.

	Product Candidate ¹	Target	Indication	Pre-clinical	Phase I	Phase II/III ²	BLA/NDA
Autologous CAR-T	Zevor-cel (CT053) ³	BCMA	R/R MM (4L+) R/R MM	LUMMICAR 1 (China) LUMMICAR 2 (US, Canada)			On Market
	Satri-cel (CT041)	Claudin18.2	G/GEJA (3L+) GC/PC PC (adjuvant) G/GEJA, PC, etc. G/GEJA (adjuvant)	ST-01 (China) ST-02 (US, Canada) ST-05 (China) IIT (China) IIT (China)			
	CT071	GPRC5D	R/R MM, R/R pPCL R/R MM, R/R PCL NDMM	(US) IIT (China) IIT (China)			
	CT011	GPC3	HCC (adjuvant)	(China)			
	CT0590	BCMA	R/R MM, R/R PCL	IIT (China)			
Allogeneic CAR-T	CT0596	BCMA	R/R MM, R/R PCL	IIT (China)			
	KJ-C2219	CD19/CD20	B-cell malignancies SLE, SSc	IIT (China) IIT (China)			
	KJ-C2320	CD38	AML	IIT (China)			
	KJ-C2114	Undisclosed	Solid tumors				
	KJ-C2526	NKG2DL	AML, other malignancies, senescence				

R/R MM: relapsed/refractory multiple myeloma; GC: gastric cancer; G/GEJA: gastric/gastroesophageal junction adenocarcinoma; PC: pancreatic cancer; HCC: hepatocellular carcinoma; R/R pPCL: relapsed/refractory primary plasma cell leukemia; NDMM: newly diagnosed multiple myeloma; SLE: systemic lupus erythematosus; SSc: systemic sclerosis; AML: acute myeloid leukemia

Notes:

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

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

Zevorcabtagene autoleucl 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.

赛恺泽® was approved on February 23, 2024 by NMPA 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. During the first half of 2025, certification and regulatory filings for 赛恺泽® have been completed in more than 20 provinces or cities and we have received a total of 111 confirmed orders from Huadong Medicine. We anticipate that growth of sales revenue of 赛恺泽® will further accelerate with continuous marketing activities and broader insurance coverage.

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

The results of LUMMICAR-1 study were reported as an oral presentation at the 29th European Hematology Association (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 stringent complete response/complete response (sCR/CR) rate was 71.6% (73/102). A trend toward deepening of responses was observed with longer duration of follow-up.

Considering the delay in the clinical program due to clinical hold and an evolving competitive landscape, CARsgen decided to deprioritize the LUMMICAR-2 study of zevorcabtagene autoleucel in the U.S. and Canada as a part of our strategic adjustment. In general, pipeline deprioritization indicates that no major event deadlines are expected in the foreseeable future. Nevertheless, necessary resources will continue to be allocated to certain activities including R&D activities required for regulatory approval, which may also be supported through business collaborations to leverage more robust external resources.

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 (satri-cel) is an autologous CAR T-cell product against protein Claudin18.2 and has potential to be first-in-class globally. Satri-cel targets the treatment of Claudin18.2-positive solid tumors with a primary focus on G/GEJA and PC. Claudin18.2 is expressed in a range of solid tumors, including G/GEJA, 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 satri-cel. This regimen features the addition of low-dose nab-paclitaxel to the conventional lymphodepletion regimen comprising cyclophosphamide and fludarabine.

The CDE of NMPA of China has accepted the NDA for satri-cel for the treatment of Claudin18.2-positive advanced G/GEJA in patients who have failed at least two prior lines of therapy on June 25, 2025. The NDA submission is mainly based on the results of an open-label, multicenter, randomized controlled confirmatory Phase II clinical trial (CT041-ST-01, NCT04581473) conducted in China. In May and March 2025, the CDE has granted Priority Review and BTB to satri-cel respectively.

The data of confirmatory Phase II clinical trial (CT041-ST-01, NCT04581473) have been presented in *The Lancet* and at the 2025 ASCO Annual Meeting. The article in *The Lancet* was titled “Claudin-18 isoform 2-specific CAR T-cell therapy (satri-cel) versus treatment of physician’s choice for previously treated advanced gastric or gastro-oesophageal junction cancer (CT041-ST-01): a randomised, open-label, phase 2 trial”. The oral presentation at the 2025 ASCO Annual Meeting was titled “Claudin18.2-specific CAR T cells (Satri-cel) versus treatment of physician’s choice (TPC) for previously treated advanced gastric or gastroesophageal junction cancer (G/GEJC): Primary results from a randomized, open-label, phase II trial (CT041-ST-01)”. Among all 108 patients who received satri-cel infusion (88 patients in satri-cel arm and 20 patients in treatment of physicians’ choice (TPC) arm (one of apatinib, paclitaxel, docetaxel, irinotecan or nivolumab)), the median overall survival (mOS) reached 9.17 months, while the mOS of 28 patients in TPC arm who did not receive satri-cel treatment was only 3.98 months (HR 0.288; 95% CI: 0.169-0.492). Satri-cel demonstrated significant progression-free survival (PFS) improvement and a clinically meaningful OS benefit with a manageable safety profile in Claudin18.2 positive G/GEJA patients with failure to at least 2 prior lines of treatment, compared to standard therapy. It is worth noting that randomized controlled trials (RCTs) for autologous CAR-T products present differences and significant challenges in efficacy evaluation compared to single-arm trials. In single-arm trials, the baseline is the pre-lymphodepletion imaging, and the first tumor assessment compares post-CAR-T infusion results with pre-lymphodepletion imaging, allowing for a more intuitive demonstration of actual efficacy. In randomized controlled trials, both arms use pre-randomization imaging as the baseline. Due to the time interval between randomization and lymphodepletion, tumor burden worsens in more than half of the patients before CAR-T infusion. As a result, the first tumor assessment (comparing post-CAR-T infusion imaging with pre-randomization imaging) often leads to an underestimation of the true therapeutic effect. Since CAR-T cell manufacturing requires time, factors such as disease progression during the waiting period may prevent some patients from receiving CAR-T cell infusion but these patients are still included in the final efficacy analysis.

The Company is actively expanding satri-cel application in early-line treatment and perioperative treatment of cancer: including an ongoing Phase I clinical trial for PC adjuvant therapy in China (CT041-ST-05, NCT05911217) and an IIT for consolidation treatment following adjuvant therapy in patients with resected G/GEJA (CT041-CG4010, NCT06857786).

The final results of the investigator-initiated trial CT041-CG4006 have been published in *Nature Medicine* on June 3, 2024, which was titled “Claudin18.2-specific CAR T Cells in gastrointestinal cancers: Phase 1 trial final results”. Data were presented as an oral presentation at the 2024 ASCO Annual Meeting in June 2024. Satri-cel as sequential treatment after the first-line therapy, the median PFS and mOS were 15.2 months (95% CI: 6.8, not reached) and 16.4 months (95% CI: 7.0, not reached), respectively, and the OS rate at 12 months was 60.0% (95% CI: 12.6, 88.2).

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.

An article titled “Metastatic gastric cancer target lesion complete response with Claudin18.2-CAR T cells” was published in February 2024 in *Journal for ImmunoTherapy of Cancer* reporting a patient with metastatic gastric cancer, who had progressed on four lines of combined systemic chemotherapy and immunotherapy after receiving two satricabtagene autoleucel infusions achieved target lesion complete response and sustained an 8-month overall partial response with only minimal ascites.

Two metastatic pancreatic cancer patients administrated with satri-cel 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.

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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 July 2023, an article titled “Combined local therapy and CAR-GPC3 T-cell therapy in advanced hepatocellular carcinoma: a proof-of-concept treatment strategy” was published in *Cancer Communication*. Two advanced HCC patients who received local therapy followed by sequential infusions of CAR-GPC3 T-cells achieved more than 7-year disease-free survival.

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

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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 can shorten CT071's manufacturing time to approximately 30 hours and therefore, resulting CAR-T cells are younger and possibly more potent compared to conventional manufacturing. The improved manufacturing efficiency aims to expedite availability of the product to patients, enhances the supply capacity, and reduces manufacturing costs.

The results of CT071 for the treatment of newly diagnosed multiple myeloma (NDMM) in an investigator-initiated trial (NCT06407947), were presented in a poster session at the 30th EHA Congress, which was titled "A phase I study of GPRC5D targeting CAR T-cell therapy CT071 for high-risk newly diagnosed multiple myeloma". The overall response rate (ORR) was 100%, including stringent complete response (sCR) rate of 70% (7/10).

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

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Allogeneic CAR T-cell Product

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

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

CT0596 is an allogeneic CAR T-cell product candidate, targeting BCMA deploying our THANK-u Plus™ technology. An IIT has been initiated in China to evaluate the safety and efficacy of CT0596 for the treatment of R/R MM and R/R PCL. As of May 6, 2025, 8 patients with R/R MM who had received at least three prior lines of therapy were enrolled and infused with CT0596 following lymphodepletion with the FC regimen (fludarabine 22.5-30 mg/m² and cyclophosphamide 350-500 mg/m²). Among 5 patients who completed the first efficacy assessment at Week 4, 3 patients (60%) achieved sCR/CR, and 4 patients (80%) achieved minimal residual disease (MRD)-negativity in the bone marrow. All sCR/CR patients remained in ongoing responses, including the first patient who completed the four-month follow-up. No dose-limiting toxicities (DLTs), ≥Grade 3 cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS), or graft-versus-host disease (GvHD) were reported. Based on the preliminary safety and efficacy data, CT0596 demonstrated favorable tolerability and encouraging efficacy signals in R/R MM patients across all predefined dose levels, with CAR-T expansion observed.

KJ-C2219 is an allogeneic CAR T-cell product candidate targeting CD19/CD20 deploying our THANK-u Plus™ technology, for hematologic malignancies and autoimmune diseases. An IIT for relapsed/refractory B-cell non-Hodgkin lymphoma (R/R B-NHL) has been initiated at the end of 2024. A separate IIT for systemic lupus erythematosus (SLE) and systemic sclerosis (SSc) has been initiated in the first half of 2025. KJ-C2219 has administered the first dose to a patient in an investigator-initiated trial for R/R B-NHL and to another patient in an IIT for SLE and SSc.

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

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

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

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

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

Continuous Discovery and Technology Development

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

We have established an integrated research and development platform covering the full CAR T development cycle including target discovery, vector design, manufacturing, quality assurance, and quality control. Our integrated cell therapy platform is composed of target discovery, immune cell function evaluation platform, plasmid and lentiviral vector preparation platforms, cell therapy process development platform, analytical platforms with molecular, flow cytometry, biochemical, physical-chemical, and cell-based analytical capabilities, biological samples tests platform, clinical-scale and commercial-scale CAR T manufacturing platform, and platform for clinical studies.

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

(1) Better patient access with allogeneic CAR-T:

To reduce the cost and increase accessibility of CAR T-cell therapies, we continue to develop our market-differentiating allogeneic THANK-uCAR[®] technology. THANK-uCAR[®] is our proprietary technology to generate allogeneic CAR T cells with improved expansion and persistence by modifying donor-derived T cells. To minimize graft versus host disease (GvHD) and host versus graft response (HvGR) from allogeneic T cells, we disrupt the genomic loci encoding TRAC 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 TRAC-/B2M- T cells with a CAR that recognizes NKG2A to hinder the NKG2A-positive NK cell rejection of the CAR T cells and therefore allow the THANK-uCAR T cells to resist the attack by NK cells. Our in vitro and in vivo studies demonstrated that armoring the TRAC-/B2M T cells with the anti-NKG2A CAR resulted in improved expansion in the presence of NK cells. Based on the clinical data, it is found that baseline NKG2A expression levels on NK cells may be related to treatment outcomes. To address the potential impact of NKG2A expression levels on therapeutic efficacy, we developed THANK-u Plus[™] platform. CARsgen has developed the THANK-u Plus[™] platform as an enhanced version of its proprietary THANK-uCAR[®] allogeneic CAR-T technology to further improve therapeutic efficacy. THANK-u Plus[™] demonstrates sustained expansion regardless of varying NKG2A expression levels on NK cells and exhibits significantly improved expansion compared to THANK-uCAR[®]. Preclinical studies show that THANK-u Plus[™] delivers superior antitumor efficacy in the presence of NK cells compared to THANK-uCAR[®]. Allogeneic BCMA or dual-targeting CD19/CD20 CAR-T cells developed using this platform exhibit robust antitumor activity in the presence of NK cells, indicating that THANK-u Plus[™] has broad potential for developing diverse allogeneic CAR-T therapies. We are developing allogeneic CAR T-cell products using THANK-u Plus[™] platform, which we believe could increase CAR T cell expansion, persistence and efficacy.

(2) Improve manufacturing efficiency:

We have developed a proprietary platform that can shorten the manufacturing time for the CAR T cells to approximately 30 hours. The CARcelerate® platform produces CAR T cells that are younger, more likely to remain in a ‘naïve’ state and less likely to be exhausted. CAR T cells from the CARcelerate® platform are expected to exhibit more potent antitumor activity. The improved manufacturing efficiency is expected to enhance the supply capacity, reduce the manufacturing costs, and expedite the availability of the product to the patients. We are using CARcelerate® to manufacture CT071 for the treatment of patients with MM and pPCL.

(3) Enhance efficacy in solid tumors:

- To enhance efficacy against solid tumors, we developed CycloCAR® which features the co-expression of cytokine IL-7 and chemokine CCL21 in CAR T cells to potentially improve clinical efficacy and reduce the requirement of lymphodepletion conditioning. Preclinical results showed that IL-7 enhanced the proliferation and survival of CAR T cells and inhibited the apoptosis of CAR T cells, and CCL21 could drive infiltration of T cells and dendritic cells into tumor sites. The preclinical CycloCAR T cells improved the therapeutic effects against solid tumors in mice compared to conventional CAR T cells. Moreover, even without preconditioning chemotherapy, the CycloCAR T cells could potently suppress the tumor growth with a significantly better efficacy than CAR T cells co-expressing IL-7 and CCL19 (7×19 CAR T, a previously reported design by other researchers). Our studies demonstrated that, independent of lymphodepletion chemotherapy, CycloCAR T cells exerted potent antitumor effects which were facilitated by infiltration of T cells and dendritic cells into tumor tissues, CycloCAR T cells exhibited increased survival, and potential anti-angiogenesis effect. We are using CycloCAR® to develop CAR T-cell therapies against several targets including Claudin18.2, GPC3, and mesothelin. We continue to explore potential combination approaches to boost the therapeutic effects of single agents and identify new targets and approaches to tackle new indications.
- The Company continues investigating combinatorial approaches to enhance clinical outcomes of CAR-T therapies. For example, our collaboration with Moderna to explore satricabtagene autoleucel in combination with Claudin18.2 encoding mRNA vaccines to help boost T cell activation, proliferation and persistence.

(4) Target availability:

- In development of cancer therapies, the expression of tumor-associated antigens in normal tissues poses a significant challenge, as this expression pattern leads to on-target off-tumor toxicities. To resolve the challenge with target availability, we continue to explore innovative technologies to enhance drug target availability and therefore turn undruggable antigens into promising targets. We developed LADAR™ technology (local action driven by artificial receptor), in which an artificial receptor is triggered by a LADAR ligand to induce the transcription of the gene(s) of interest (e.g., the tumor antigen-targeted CAR, plus any cytokines or other therapeutic mediators). Through the LADAR™ artificial receptor, the antitumor CAR transcription is only triggered when the LADAR binds to a LADAR ligand, making it possible to precisely control when and where immune cells act against cancer cells.
- The LADAR-CAR signaling circuits require both antigens for LADAR™ and CAR recognition to kill target cells, thus reducing on-target off-tumor effects when these two antigens are not simultaneously expressed in the same normal tissues. In our in vitro studies, the LADAR™ system induced strong therapeutic gene expression in response to antigen engagement and, importantly, negligible leakage expression in resting cells. LADAR-CAR T cells executed killing function only if both antigens were present.
- We are also working on other applications of LADAR™ system, such as LADAR-cytokine circuits. We believe that the establishment of LADAR™ system is the key step to developing CAR T cells with powerful and precise killing of cancer.
- To develop effective CAR T-cell products for more cancer types and further enhance the antitumor effect, we have been expanding our research to more promising oncology targets for cell therapies. In addition, leveraging our proprietary antibody platforms, we have successfully developed humanized or fully human antibodies against these targets, such as B7-H3, etc. These antibodies, together with our CAR T-cell technology platforms, will help further enhance the product pipeline.

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

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

As of June 30, 2025, we had more than 300 patents of which 140 patents had been issued globally including China, the United States, Europe, and Japan, with an increase of 11 issued patents and 16 patent applications compared with that of January 1, 2025. 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-cells production. The vertically integrated production contributes to increased efficiency and enhanced control, resulting in improved drug product consistency and aiming for faster turnaround times for patients. The integrated manufacturing is also expected to help significantly reduce costs and improve margins for more advantageous commercialization. To further improve the manufacture efficiency, we developed a proprietary platform CARcelerate[®] that can shorten the manufacturing time for the CAR T cells to around 30 hours, as compared to the conventional CAR T manufacturing process. The CARcelerate[®] platform produces CAR T cells that are younger and are more likely to remain in a ‘naïve’ state and less likely to be exhausted; as such, these CAR T cells from the CARcelerate[®] platform are thought to exhibit more potent tumor killing activity.

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

In December 2023, FDA did an inspection on our Research Triangle Park GMP manufacturing facility in Durham, North Carolina (“**RTP Manufacturing Facility**”), with a total gross floor area of approximately 3,300 sq.m, completed technology transfer and provided CARsgen with additional manufacturing capacity of autologous CAR T-cell products of 700 patients annually. During its inspection, FDA found that certain procedures related to the manufacturing of the CAR T products were not conducted in accordance with Current Good Manufacturing Practices (CGMP) or other procedural controls and requirements associated with the manufacturing facility, and a Form 483 was issued and clinical holds were subsequently initiated for the three INDs active in the U.S.. In September 2024, the FDA did a follow-up inspection of the RTP Manufacturing Facility. The inspection was positive, and no observation (Form 483) was issued. On October 31, 2024, U.S. time, FDA lifted the clinical holds on clinical trials of zevorcabtagene autoleucel, satricabtagene autoleucel, and CT071 in the United States.

By building vertically integrated manufacturing capabilities in-house, we expect to significantly increase manufacturing sustainability, reduce manufacturing costs, and shorten the vein-to-vein time. In addition, we have a GMP-compliant manufacturing facility capable of high yield production of lentiviral vectors. With large scale lentiviral vectors production, we expect to reduce the CAR T manufacturing costs noticeably.

Industry Overview

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

Future and Outlook

With CARsgen's mission of "making cancer curable", we devote ourselves to develop innovative products for the treatment of cancer patients worldwide. Building on the milestones achieved, we will continue to focus on rapid clinical development of zevorcabtagene autoleucel and satricabtagene autoleucel both in China and overseas. We plan to expand these products in earlier line treatment as well as advance development of other products in clinical and preclinical stages. With continuous development of innovative CAR T technologies, we strive to further optimize efficacy, safety and affordability of CAR T-cell therapies to patients. We will continue to expand our manufacturing capacity in China and in the United States to support our clinical trials and future commercialization. We will continue to establish additional external partnerships with leading research institutes and pharmaceutical companies on technology and product licensing as a means to maximize the application of our technology platform and the value of our product, bringing more innovative cell therapy products to cancer patients worldwide and ultimately creating more value for our investors and the society.

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 not been profitable and have incurred operating losses in every year since inception, with operating losses of RMB77 million and RMB362 million for the six months ended June 30, 2025 and 2024, respectively. Substantially all of our operating losses resulted from research and development expenses, administrative expenses and net foreign exchange gains for the six months ended June 30, 2025.

Loss for the Period

Net loss was RMB75 million for the six months ended June 30, 2025, representing a decrease of RMB277 million from RMB352 million for the six months ended June 30, 2024. The decrease in loss was primarily due to lower research and development expenses, lower administrative expenses, higher net foreign exchange gains and higher gross profit for the six months ended June 30, 2025.

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,	
	2025	2024
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Loss for the periods	(75,483)	(351,558)
Add:		
Share-based compensation	3,684	9,190
Adjusted net loss	<u>(71,799)</u>	<u>(342,368)</u>

	Six months ended June 30,	
	2025	2024
	RMB	RMB
	(Unaudited)	(Unaudited)
Loss per share for the periods	(0.14)	(0.63)
Add:		
Share-based compensation per share	<u>0.01</u>	<u>0.02</u>
Adjusted net loss per share	<u>(0.13)</u>	<u>(0.61)</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,	
	2025	2024
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Revenue	<u>50,961</u>	<u>6,340</u>
Total	<u>50,961</u>	<u>6,340</u>

Research and Development Expenses

	Six months ended June 30,	
	2025	2024
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Employee benefit expenses	68,170	121,842
Testing and clinical expenses	28,514	79,035
Depreciation of property, plant and equipment	8,019	15,503
Research and development consumables	14,607	10,287
Utilities	5,619	8,359
Amortization of intangible assets	910	3,343
Short-term lease and low-value lease expenses	1,030	1,945
Travelling and transportation expenses	807	1,871
Depreciation of right-of-use assets	1,221	1,777
Office and other expenses	1,324	1,593
Total	130,221	245,555

Research and development expenses decreased to RMB130 million for the six months ended June 30, 2025, representing a decrease of RMB116 million from RMB246 million for the six months ended June 30, 2024, primarily due to the decreases in employee benefit expenses, depreciation of property, plant and equipment, and testing and clinical expenses.

Administrative Expenses

	Six months ended June 30,	
	2025	2024
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Employee benefit expenses	21,620	32,447
Professional service fees	5,816	22,863
Depreciation of property, plant and equipment	533	15,346
Depreciation of right-of-use assets	204	4,074
Office expenses	1,689	3,340
Travelling and transportation expenses	642	1,994
Auditors' remuneration	2,130	1,944
– audit service	1,916	1,944
– non-audit service	214	–
Utilities	475	634
Amortization of intangible assets	60	588
Short-term lease and low-value lease expenses	510	248
Other expenses	5,350	2,835
Total	39,029	86,313

Administrative expenses are RMB39 million for the six months ended June 30, 2025, representing a decrease of RMB47 million from RMB86 million for the six months ended June 30, 2024, primarily due to the decreases in employee benefit expenses, professional service expenses and depreciation of property, plant and equipment.

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,	
	2025	2024
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Wages and salaries	65,036	121,937
Pension costs	7,546	10,367
Share-based compensation	3,644	9,106
Other employee benefits	13,564	12,879
	<hr/>	<hr/>
Total	89,790	154,289
	<hr/> <hr/>	<hr/> <hr/>
Amount included in research and development expenses	68,170	121,842
Amount included in administrative expenses	21,620	32,447
	<hr/> <hr/>	<hr/> <hr/>

The decrease in employee benefit expenses was mainly due to less headcount and the decrease in staff salary, and share-based compensation, which was partially offset by the annual growth of salaries and the increase in other employee benefits due to lay off compensation.

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,	
	2025	2024
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Administrative expenses	779	2,398
Research and development expenses	2,865	6,708
Cost of sales	40	84
	<hr/>	<hr/>
Total	3,684	9,190
	<hr/> <hr/>	<hr/> <hr/>

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,	
	2025	2024
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Net cash used in operating activities	(196,308)	(255,947)
Net cash generated from investing activities	1,715	6,584
Net cash (used in)/generated from financing activities	(29,635)	24,688
Net decrease in cash and cash equivalents	(224,228)	(224,675)
Cash and cash equivalents at beginning of the period	1,479,058	1,849,752
Exchange gain on cash and cash equivalents	5,963	27,492
Cash and cash equivalents at end of the period	<u>1,260,793</u>	<u>1,652,569</u>

Net Cash used in Operating Activities

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

Our net cash used in operating activities were RMB196 million and RMB256 million for the six months ended June 30, 2025 and 2024, respectively.

We had one product, 赛恺泽®, approved on February 23, 2024 for commercial sale and have generated income in the first half of 2025. We believe our pipeline products have promising global market potential in the future. We intend to continue investing in our research and development efforts and aim to obtain marketing approvals for our product candidates as soon as feasible. As we launch and commercialize our product candidates, we expect to generate operating income and improve our net operating cash outflow position.

Net Cash Generated from Investing Activities

Our cash used in investing activities mainly reflects our cash used for our purchase of term deposits with original maturity between three and twelve months, property, plant and equipment and our cash generated from investing activities mainly reflects our net cash receipts from term deposits with original maturity between three and twelve months.

For the six months ended June 30, 2025, our net cash generated from investing activities was RMB1.7 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, 2024, our net cash generated from investing activities was RMB6.6 million, which was primarily attributable to interest receipts from term deposit with original maturity between three and twelve months.

Net Cash (used in)/generated from Financing Activities

For the six months ended June 30 2025, our net cash used in financing activities was RMB30 million primarily attributable to repayment of bank borrowings of RMB89 million, capital injection from the investor of a subsidiary of RMB80 million, payments for ordinary share repurchase of RMB31 million, proceeds from issue of shares to employees under Employee Incentive Schemes of RMB18 million and payment of lease expenses of RMB8 million. 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 share of RMB92 million and proceed from new bank loan of RMB130 million.

Cash and Bank Balances

	As at June 30, 2025 <i>RMB'000</i> (Unaudited)	As at December 31, 2024 <i>RMB'000</i> (Audited)
Cash at banks		
– RMB	1,182,826	1,358,145
– USD	62,117	120,778
– HKD	15,850	135
Subtotal	1,260,793	1,479,058

The Group's cash and bank balances as at June 30, 2025 were RMB1,261 million, representing a decrease of RMB218 million compared to RMB1,479 million as at December 31, 2024. The decrease was mainly due to the decreased 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, 2025 were NIL, representing a decrease of RMB89 million compared to RMB89 million as at December 31, 2024.

The gearing ratio (calculated by dividing the sum of borrowings and lease liabilities by total equity) of the Group as at June 30, 2025 was 7.2%, compared to 15.75% as at December 31, 2024.

Lease Liabilities

The Group leases offices and dormitory. Lease on offices and dormitory were measured at net present value of the lease payments to be paid during the lease terms.

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

Our lease liabilities decreased to RMB69 million as at June 30, 2025 from RMB77 million as at December 31, 2024.

Significant Investments

As at June 30, 2025, 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, 2025, we did not have material acquisitions or disposals of subsidiaries, associates and joint ventures.

Foreign Exchange Risk

The Group has entities operating in the United States of America and in the People's Republic of China and there are certain cash and bank balances, other receivables, accruals and other payables denominated in a currency that is not the functional currency of the relevant group entities. As at June 30, 2025, the Group had no foreign exchange hedging instruments and foreign currency hedging policy. However, our management constantly monitors the economic situation and our Group's foreign exchange exposure and will consider appropriate hedging measures in the future should the need arise.

Capital Expenditure

For the six months ended June 30, 2025, the Group's total capital expenditure amounted to approximately RMB2.8 million, which was mostly used in purchase of property, plant and equipment, and software.

Charge on Assets

As at June 30, 2025 and December 31, 2024, the Group did not have any charge on assets.

Contingent Liability

As at June 30, 2025, the Group did not have any material contingent liabilities.

Employees and Remuneration Policies

As of June 30, 2025, we had a total of 371 employees, compared to 468 employees at December 31, 2024.

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

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

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

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

Future Investment Plans and Expected Funding

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

Asset Impairment

Reference is made to the annual results announcement for the year ended December 31, 2024 of the Company dated March 18, 2025, and the annual report for the year ended December 31, 2024 of the Company dated April 16, 2025. The impairment losses on (i) property, plant and equipment of RMB162.3 million; (ii) right-of-use assets of RMB26.5 million; and (iii) intangible assets of RMB0.3 million (collectively, the “Impairments”) were recorded by the Company for the year ended 31 December 2024.

Background

Based on the superior allogeneic CAR-T data identified in October 2024, the Company determined impairment indicators existed. Following its data exchange sessions at ASH in November and early December 2024 and based on the focus shift from autologous pipelines to allogeneic pipelines, the Management formalized plans for pipeline adjustments and identified potential impairments. After confirming impairment indicators and completing International Accounting Standards 36 – impairment testing, including extensive and thorough discussions with the auditor, the Company recognized impairment losses on autologous assets deemed unusable for its allogeneic pipeline.

Key assumptions and inputs

Based on the above events and circumstances, the Management conducted internal impairment tests of long-term assets with the key assumptions below:

- (1). A strategic reduction in resource allocation will be implemented by the Group to certain autologous CAR-T pipelines without a clear commercialization plan. More specifically, despite the FDA lifted the clinical hold on October 31, 2024, the competitive landscape for autologous CAR-T products has already shifted. For instance, other BCMA-targeted CAR-T competitors have acquired approvals for the second prior lines of therapy in multiple myeloma. Given these market changes and the preliminary advantages shown by our allogeneic CAR-T data, the Company decided to reduce resources for autologous CAR-T products without clear commercialization plan and reallocate investment to allogeneic CAR-T products;
- (2). No clear commercialization plan can be projected for existing autologous pipelines, except for those already launched or in NDA preparation. Although CT053 NDA has been approved and CT041 NDA has been accepted in China, there is no clear commercialization timeline for the remaining autologous pipeline products, such as the autologous CAR-T product targeting GPRC5D. The Company determined that impairment testing should be performed on the assets used solely for the remaining autologous pipeline products mentioned above; and

- (3). No clear and measurable disposal plan can be identified for certain autologous pipeline assets without a clear commercialization plan. Specifically, the assets in the aforesaid item (2) which are only used for the remaining autologous pipelines lack measurable disposal options, which cannot be sold commercially due to absent market quotations and disposal plans. Consequently, the Management cannot determine their fair value and must turn to the value-in-use (“VIU”) method in accordance with accounting standards.

The Company had identified its property, plant and equipment, right of use assets and intangible assets related to autologous pipelines without a clear commercialization plan as obsolete assets (the “Assets”), subject to impairment test in accordance with International Accounting Standards 36.

Value-in-use approach was applied by the Group as the Management believes that there is no basis for making a reliable estimate of the fair price of the Assets given the lack of a commercial possibility for sale. The value in use of the Assets was determined based on the present value of the future cash flow expected to be derived from the Assets. The Management then compared the carrying amount of the Assets against the value in use and recognized impairment losses.

The fixed assets valued at RMB8,300,152 using the VIU method refer to those assets that can be used in both autologous and allogeneic pipelines in aspects such as production, quality control/testing, process development, and analytical method development. Such assets were valued at RMB8,300,152 (net book value), were assessed using the VIU method, representing the net book value of such assets.

Among the Assets, other than the fixed assets there are certain assets that could only be used for the remaining autologous pipelines. Such assets include (i) right-of-use assets such as building facility appendages; and (ii) intangible assets such as monitoring software. The VIU value of such assets was nil and therefore in accordance with the requirements of IAS 36, a full provision for impairment has been made.

INTERIM CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the six months ended June 30, 2025

	Notes	2025 (Unaudited) RMB'000	2024 (Unaudited) RMB'000
Revenue	4	50,961	6,340
Cost of sales	6	(21,592)	(4,723)
Gross profit		29,369	1,617
Other income	4	5,638	23,062
Selling and distribution expenses	6	(942)	(721)
Administrative expenses	6	(39,029)	(86,313)
Research and development expenses	6	(130,221)	(245,555)
Other gains/(losses) – net	5	58,481	(53,630)
Operating loss		(76,704)	(361,540)
Finance income	6	4,285	12,596
Finance costs	6	(3,064)	(2,614)
Finance income – net		1,221	9,982
Loss before income tax		(75,483)	(351,558)
Income tax expense	7	–	–
Loss for the period and attributable to owners of the parent		(75,483)	(351,558)
Other comprehensive (loss)/income for the period:			
<i>Items that may be reclassified to profit or loss</i>			
Exchange differences on translation of subsidiaries		79,679	(72,183)
<i>Items that will not be reclassified to profit or loss</i>			
Exchange differences on translation of the Company		(129,926)	158,609
Other comprehensive income for the period, net of tax		(50,247)	86,426
Total comprehensive loss for the period and attributable to the owners of the parent		(125,730)	(265,132)
Loss per share attributable to ordinary equity holders of the parent			
Basic and diluted loss per share (in RMB)	9	(0.14)	(0.63)

INTERIM CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

June 30, 2025

	Notes	June 30, 2025 (Unaudited) RMB'000	December 31, 2024 (Audited) RMB'000
NON-CURRENT ASSETS			
Property, plant and equipment		95,579	106,749
Right-of-use assets		15,297	17,200
Intangible assets		3,577	2,943
Other non-current assets and prepayments		19,045	15,867
Total non-current assets		133,498	142,759
CURRENT ASSETS			
Trade receivables	10	18,545	8,768
Inventories		11,121	6,926
Other receivables		41,284	19,344
Other current assets and prepayments		48,150	16,179
Cash and bank balances		1,260,793	1,479,058
Total current assets		1,379,893	1,530,275
CURRENT LIABILITIES			
Accruals and other payables	11	157,116	181,623
Interest-bearing bank borrowings		–	20,287
Lease liabilities		13,614	13,441
Deferred income		10,333	11,033
Contract liabilities	12	32,736	27,623
Total current liabilities		213,799	254,007
NET CURRENT ASSETS		1,166,094	1,276,268
TOTAL ASSETS LESS CURRENT LIABILITIES		1,299,592	1,419,027
NON-CURRENT LIABILITIES			
Interest-bearing bank borrowings		–	68,850
Lease liabilities		55,639	63,844
Deferred income		7,127	7,342
Other financial liability		71,602	–
Contract liabilities		203,091	222,284
Total non-current liabilities		337,459	362,320
Net assets		962,133	1,056,707
EQUITY			
Equity attributable to owners of the parent			
Share capital	13	1	1
Reserves		962,132	1,056,706
Total equity		962,133	1,056,707

NOTES TO FINANCIAL STATEMENTS

June 30, 2025

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 Mainland China (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, 2025 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 December 31, 2024.

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 December 31, 2024, except for the adoption of the following amended IFRS Accounting Standards for the first time for the current period’s financial information.

Amendments to IAS 21

Lack of Exchangeability

The nature and the impact of the amended IFRS Accounting Standards are described below:

Amendments to IAS 21 specify how an entity shall assess whether a currency is exchangeable into another currency and how it shall estimate a spot exchange rate at a measurement date when exchangeability is lacking. The amendments require disclosures of information that enable users of financial statements to understand the impact of a currency not being exchangeable. As the currencies that the Group had transacted with and the functional currencies of group entities for translation into the Group’s presentation currency were exchangeable, the amendments did not have any impact on the interim condensed consolidated financial information.

4. REVENUE AND OTHER INCOME

An analysis of revenue is as follows:

	For the six months ended June 30,	
	2025	2024
	RMB’000	RMB’000
	(Unaudited)	(Unaudited)
Revenue from contracts with customers		
Sale of pharmaceutical products	48,263	5,925
Provision of cryopreservation services	2,698	415
Total	50,961	6,340

Disaggregated revenue information for revenue from contracts with customers:

	For the six months ended June 30,	
	2025	2024
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Geographical market		
Mainland China	50,961	6,340
Timing of revenue recognition		
Goods transferred at a point in time	48,263	5,925
Services transferred over time	2,698	415
Total	50,961	6,340

An analysis of other income is as follows:

	For the six months ended June 30,	
	2025	2024
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Government grants (i)	1,143	2,907
Interest income on term deposits with original maturity between three and twelve months	4,495	20,155
Total	5,638	23,062

- (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 GAINS/(LOSSES) – NET

	For the six months ended June 30,	
	2025	2024
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Foreign exchange gains/(loss) – net	59,841	(53,476)
Others	(1,360)	(154)
Total	58,481	(53,630)

6. LOSS BEFORE TAX

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

<i>Notes</i>	For the six months ended June 30,	
	2025	2024
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Employee benefit expenses	99,370	154,288
Testing and clinical expenses	28,514	79,035
Depreciation of property, plant and equipment	9,307	31,708
Research and development consumables	14,607	10,287
Professional service expenses	5,816	22,664
Depreciation of right-of-use assets	1,425	6,008
Utilities	6,094	8,993
Office expenses	2,925	3,893
Travelling and transportation expenses	1,449	3,865
Amortization of intangible assets	1,962	3,976
Short term lease and low value lease expenses	1,540	2,456
Auditors' remuneration	2,130	1,944
– <i>Audit service</i>	1,916	1,944
– <i>Non-audit service</i>	214	–
Other expenses	4,446	2,751
Cost of inventories sold	11,257	4,723
Marketing service fees	942	721
Interest income	(4,285)	(12,596)
Interest expense on lease liabilities	1,533	1,679
Interest expense on financial liabilities	1,213	–
Interest expense on bank borrowings	318	935
Total	190,563	327,330
Cost of inventories sold	21,592	4,723
Selling and distribution expenses	942	721
Administrative expenses	39,029	86,313
Research and development expenses	130,221	245,555
Finance income	(4,285)	(12,596)
Finance costs	3,064	2,614
Total	190,563	327,330

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% (2024: 16.5%) as the Company has no estimated assessable profit.

(c) Mainland China corporate income tax

Subsidiaries in Mainland China are subject to income tax at a rate of 25%(2024: 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% (2024: 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% (2024: 21%) for the six months ended June 30, 2025. CARsgen USA was also subject to the state income tax during for the six months ended June 30, 2025 and 2024.

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% (2024: 12.5%) on the estimated assessable profit and 33% (2024: 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, 2025 (six months ended June 30, 2024: 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 and the put option over non-controlling interests of a subsidiary had anti-dilutive effects 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,	
	2025	2024
	(Unaudited)	(Unaudited)
Loss attributable to the ordinary equity holders of the parent (<i>RMB'000</i>)	(75,483)	(351,558)
Weighted average number of ordinary shares in issue during the period, used in the basic and diluted loss per share calculation (<i>'000</i>)	551,391	557,030
Basic and diluted loss per share (<i>RMB</i>)	(0.14)	(0.63)

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, 2025	December 31, 2024
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Audited)
Within 1 year	17,745	8,768
1 to 2 years	800	—
Net carrying amount	18,545	8,768

Trade receivables are non-interest-bearing. The Company had concentration of credit risk of RMB18,545,000 and RMB8,768,000 trade receivables that were due from one single customer as of June 30, 2025 and December 31, 2024 respectively. The Company seeks to maintain strict control over its outstanding receivables and overdue balances are reviewed regularly by management. Based on the customer's past repayment record and stable business relationship with the Group, management believes that the risk of expected credit loss is minimal.

11. ACCRUALS AND OTHER PAYABLES

	June 30, 2025 RMB'000 (Unaudited)	December 31, 2024 RMB'000 (Audited)
Accrued expenses (i)	109,017	121,830
Staff salaries and welfare payables	22,773	44,189
Other taxes payable	2,860	4,812
Payables for acquisition of property, plant and equipment	1,091	1,095
Payables for research and development consumables	453	539
Payables to employee for the disposal of stock under stock incentive plans due to stock sales	16,861	4,857
Others	4,061	4,301
Total	157,116	181,623

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

12. CONTRACT LIABILITIES

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

	June 30, 2025 RMB'000 (Unaudited)	December 31, 2024 RMB'000 (Audited)
<i>Advances received from a customer</i>		
Grant of an exclusive distribution agreement	235,827	249,907
Non-current	203,091	222,284
Current	32,736	27,623
Total	235,827	249,907

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.

13. SHARE CAPITAL

Authorized:

	Number of shares <i>In thousands</i>	Nominal value of shares <i>USD</i>	RMB equivalent value <i>RMB'000</i>
As at January 1, 2024, June 30, 2024, January 1, 2025 and June 30, 2025	200,000,000	50,000	349

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, 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
As at December 31, 2024 (audited)	571,671	1
Issue of shares held in trust (i)	1,698	—*
Issue of shares to employees under Employee Incentive Schemes (ii)	2,535	—*
As at June 30, 2025 (unaudited)	575,904	1

* The amounts are less than RMB1,000.

(i): On April 16, 2025, the Company allotted and issued 1,698,000 shares to Carfe Unity Limited, which was wholly owned by the Post-IPO RSU Scheme Trustee. Such shares are to be held in trust by the Post-IPO RSU Scheme Trustee to facilitate the transfer of shares to the grantees upon vesting of the relevant Share Options and Share Awards. The shares of the Company held in Carfe Unity Limited were accounted as “Reserve – Treasury shares held in trust”.

(ii): During the six months ended June 30, 2025, the Company issued 2,535,450 ordinary shares at the cost of HK\$28,180,000 (equivalent to RMB26,478,000 approximately) in total at the prices ranging from nil to HK\$16.32 per share to employees under Employee Incentive Schemes (six months ended June 30, 2024: 35,394 ordinary shares at HK\$97,000 (equivalent to RMB89,000 approximately)).

Movements in treasury shares during the period:

	Number of treasury shares <i>In thousands</i>	RMB equivalent value <i>RMB'000</i>
As at December 31, 2023 (audited)	18,407	—*
Transfer of treasury shares to employees related to employee share-based payment	(672)	—*
Share repurchase	9,052	—*
	<hr/>	<hr/>
As at June 30, 2024 (unaudited)	<u>26,787</u>	<u>—*</u>
As at December 31, 2024 (audited)	22,261	—*
Issue of shares held in trust	1,698	—*
Transfer of treasury shares to employees related to employee share-based payment (i)	(1,783)	—*
	<hr/>	<hr/>
As at June 30, 2025 (unaudited)	<u>22,176</u>	<u>—*</u>

* The amounts are less than RMB1,000.

(i): During the six months ended June 30, 2025, the Company transferred 1,783,150 treasury shares to employees under Employee Incentive Schemes at the cost of HK\$1,058,000 (equivalent to RMB994,000 approximately) in total at the prices ranging from nil to HK\$4.60 per share (During the six months ended June 30, 2024, the Company transferred 671,598 treasury shares to employees under Employee Incentive Schemes at the cost of HK\$37,000 (equivalent to RMB34,000 approximately) in total at the prices ranging from nil to HK\$4.60 per share).

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, 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)).

As of June 30, 2025, there were no treasury Shares (as defined under the Listing Rules) held by the Company and no Shares repurchased but pending cancellation.

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 as its own code of corporate governance practices.

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

Subsequent Event

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, 2025, as far as the Company is aware, the Company and its subsidiaries were not involved in any material litigation or arbitration and no material litigation or claim of material importance was pending or threatened against or by the Company.

Use of Proceeds from the Global Offering

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

- approximately HK\$902.4 million (US\$115.7 million) (or approximately 30% of the net proceeds) to fund further development of our Core Product, BCMA CAR-T (CT053);
- approximately HK\$932.5 million (US\$119.6 million) (or approximately 31% of the net proceeds) to fund ongoing and planned research and development of our other pipeline product candidates;
- approximately HK\$601.6 million (US\$77.2 million) (or approximately 20% of the net proceeds) for developing full-scale manufacturing and commercialization capabilities;
- approximately HK\$300.8 million (US\$38.6 million) (or approximately 10% of the net proceeds) for continued upgrading of CAR-T technologies and early-stage research and development activities; and
- approximately HK\$270.7 million (US\$34.7 million) (or approximately 9% of the net proceeds) will be used for our working capital and other general corporate purposes.

The net proceeds from the Global Offering have been utilized in accordance with the purposes set out in the Prospectus. The table below sets out the applications of the net proceeds and actual usage up to June 30, 2025:

Use of proceeds	Planned allocation of Net Proceeds (HKD million)	Planned allocation of Net Proceeds (RMB million)	Utilized amount (as at December 31, 2024) (RMB million)	Utilized for the six months ended June 30, 2025 (RMB million)	Utilized amount (as at June 30, 2025) (RMB million)	Remaining amount (as at June 30, 2025) (RMB million)
Further development of our Core Product, BCMA CAR-T (CT053)	902.4	851.7	851.7	0	851.7	0
Ongoing and planned research and development of our other pipeline product candidates	932.5	849.9	696.2	63.4	759.6	90.3
Developing full-scale manufacturing and commercialization capabilities	601.6	548.3	370.6	44.6	415.2	133.1
Upgrading of CAR-T technologies and early- stage research and development activities	300.8	274.1	174.6	40.1	214.7	59.4
Working capital and other general corporate purposes	270.7	255.5	255.5	0	255.5	0
Total	3,008.0	2,779.5	2,348.6	148.1	2,496.7	282.8

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 June 30, 2025 exchange rate of HK\$1 to RMB0.9114.

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, 2025. The Audit Committee considers that the interim financial results for the six months ended June 30, 2025 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 and Corporate Governance Report set out in Appendix C1 to the Listing Rules
“Director(s)”	the director(s) of the Company
“Global Offering”	the initial public offering of the Shares on the terms and subject to the conditions as described in the Prospectus
“Group”, “our Group”, “we”, “us” or “our”	our Company, its subsidiaries and consolidated affiliated entities from time to time or, where the context so requires, in respect of the period prior to our Company becoming the holding company of its present subsidiaries and consolidated affiliated entities, such subsidiaries and consolidated affiliated entities as if they were subsidiaries and consolidated affiliated entities of our Company at the relevant time
“HK\$”	Hong Kong dollars, the lawful currency of Hong Kong
“Hong Kong” or “HK”	the Hong Kong Special Administrative Region of the People’s Republic of China
“Huadong Medicine”	Huadong Medicine Co., Ltd. (Stock Code: 000963.SZ), a leading largescale comprehensive pharmaceutical listed company based in Hangzhou, China

“IFRS”	International Financial Reporting Standards
“Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time
“Model Code”	Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix C3 to the Listing Rules
“NMPA”	National Medical Products Administration (國家藥品監督管理局), the successor of the China Food and Drug Administration (國家食品藥品監督管理總局), or the CFDA, the State Food and Drug Administration (國家食品藥品監督管理局), or the SFDA and the State Drug Administration (國家藥品監督管理局), or the SDA
“Prospectus”	the prospectus issued by the Company on June 7, 2021 in connection with the Global Offering
“RMB”	Renminbi, the lawful currency of China
“Shareholder(s)”	holder(s) of shares of the Company
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“United States”, “U.S.” or “US”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“US\$”, “U.S. dollars” or “USD”	United States dollars, the lawful currency of the United States

GLOSSARY

“antigen”	the substance that is capable of stimulating an immune response, specifically activating lymphocytes, which are the body’s infection-fighting white blood cells
“ASCO”	American Society of Clinical Oncology
“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
“CD20”	cell-surface molecule expressed on the surface of normal B lymphocyte and B-cell malignancies
“CD38”	also named cyclic ADP ribose hydrolase, a glycoprotein expressed on the surface of many immune cells (white blood cells), including T/B lymphocytes and natural killer cells. And it also functions in cell adhesion, signal transduction and calcium signaling
“CGMP”	current good manufacturing practices
“chemotherapy”	a category of cancer treatment that uses one or more anti-cancer chemotherapeutic agents as part of its standardized regimen
“CMC”	chemistry, manufacturing, and controls processes in the development, licensure, manufacturing, and ongoing marketing of pharmaceutical products

“CRS”	cytokine release syndrome, a form of systemic inflammatory response syndrome that arises as a complication of some diseases or infections, and is also an adverse effect of some monoclonal antibody drugs, as well as adoptive T cell therapies
“CycloCAR®”	a next-generation CAR-T technology under development by the Company, which features co-expression of cytokines IL-7 and chemokine CCL21 in the CAR T-cells to potentially improve clinical efficacy and reduced requirement for lymphodepletion conditioning
“cytokine”	a broad and loose category of small proteins that are important in cell signaling. Their release affects the growth of all blood cells and other cells that help the body’s immune and inflammation responses
“EHA”	European Hematology Association
“EMA”	European Medicines Agency
“FDA”, “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. Zonghai LI
Chairman

Hong Kong, August 14, 2025

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

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