RemeGen Co., Ltd.*

榮昌生物製藥(煙台)股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

(Stock Code: 9995)

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

The Board is pleased to announce the consolidated results of the Company for the year ended December 31, 2024, together with the comparative figures for the year ended December 31, 2023.

BUSINESS HIGHLIGHTS

During the past year, the Company has made significant progress in advancing commercialization, product pipeline as well as business operations:

COMMERCIALIZATION

– The Company recorded revenue from product sales of approximately RMB1,699.1 million for the year ended December 31, 2024, representing an increase of 61.9% from RMB1,049.2 million in the corresponding period of last year, mainly attributable to robust sales growth of telitacicept (RC18, brand name: 泰爱®), a commercial-stage product of the Company for the treatment of autoimmune diseases, and disitamab vedotin (RC48, brand name: 爱地希®), a commercial-stage product of the Company for the treatment of tumors.

PRODUCT PIPELINE

Telitacicept (RC18, Brand Name: 泰爱®)

– In March 2024, the FDA granted telitacicept fast track designation (FTD) for the treatment of patients with primary Sjögren's Syndrome (pSS).

– In May 2024, patient enrollment was completed in both domestic Phase III clinical trials of telitacicept for the treatment of active primary Sjögren's Syndrome (pSS) in adults and IgA (immunoglobulin A) nephropathy.

– In May 2024, the domestic Phase II clinical study data for telitacicept for the treatment of adults with generalized myasthenia gravis (gMG) was published in the European Journal of Neurology (EJN) (IF=5.1), a top international journal.

– In July 2024, telitacicept was granted full approval by the NMPA to be marketed in China for the treatment in combination with methotrexate of adult patients with moderate-to-severe active rheumatoid arthritis (RA) who have not responded well to methotrexate.

– In July 2024, the clinical study of telitacicept for the treatment of adult patients with primary membranous nephropathy was granted approval for clinical trials by the CDE.

– In August 2024, a global multi-center Phase III clinical trial of telitacicept for the treatment of generalized myasthenia gravis (gMG) enrolled the first patient in the U.S. and a Phase III clinical trial of telitacicept for the treatment of generalized myasthenia gravis (gMG) in China reached its primary study endpoints.

– In October 2024, the marketing application for telitacicept for the treatment of generalized myasthenia gravis (gMG) was accepted by the CDE in China.

Disitamab Vedotin (RC48, Brand Name: 爱地希®)

– In January 2024, Phase I data for disitamab vedotin in combination with toripalimab injection for the treatment of patients with HER2-expressing gastric cancer or gastroesophageal junction adenocarcinoma (GC/GEJ) was published in eClinicalMedicine, a sub-journal of The Lancet. The results of the study showed that disitamab vedotin in combination with toripalimab injection had a manageable safety profile and significant efficacy.

– In March 2024, Phase II clinical data for disitamab vedotin for the treatment of patients with HER2-expressing cervical cancer was reported via an oral presentation at the 2024 European Society of Gynaecological Oncology (ESGO) Congress.

– In June 2024, results of 15 studies of disitamab vedotin were presented at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting.

– In June 2024, the randomized, open-label, parallel-controlled, multi-center Phase III clinical study of disitamab vedotin for the treatment of patients with HER2-positive advanced breast cancer with liver metastasis achieved positive results and met the primary endpoint of the clinical trial. The project has been granted breakthrough therapy designation by the NMPA in June 2021.

— In August 2024, patient enrollment was completed in the Phase III clinical trial of disitamab vedotin in combination with PD-1 for the treatment of advanced stage I urothelial cancer in China.

— In October 2024, results of Phase II clinical study of disitamab vedotin in combination with cadonilimab for the treatment of recurrent or metastatic cervical cancer were announced at the 23rd International Gynecologic Cancer Society (IGCS) Annual Global Meeting.

— In December 2024, Phase III clinical data for disitamab vedotin for the treatment of HER2-positive advanced breast cancer patients with liver metastasis were presented publicly for the first time at Poster Spotlight Sessions regarding novel HER2 therapies of the 47th San Antonio Breast Cancer Symposium (SABCS).

Other Products

– In June 2024, Phase I/II results of RC88 for the treatment of platinum-resistant and recurrent epithelial ovarian cancer were presented at the 2024 ASCO Annual Meeting.

– In July 2024, a Phase Ib clinical study of RC28-E for the treatment of Wet Age-Related Macular Degeneration (wAMD) was published in Ophthalmology and Therapy, an internationally renowned ophthalmology journal.

Following the Reporting Period,

– In January 2025, Phase Ib/II clinical results of disitamab vedotin in combination with toripalimab for the treatment of locally advanced or metastatic urothelial cancer (UC) (RC48-C014) were published in the Annals of Oncology (IF: 56.7), a top international oncology journal.

– In February 2025, the updated results of neoadjuvant therapy of disitamab vedotin in combination with PD-1 for the treatment of HER2-expressing muscles invasive bladder cancer (MIBC) patients were presented during an oral presentation at the American Society of Clinical Oncology Urogenital Oncology Symposium (ASCO GU).

FINANCIAL HIGHLIGHTS

- For the year ended December 31, 2024, the Company's revenue was RMB1,710.2 million and its gross profit was RMB1,367.4 million.
- The Company's bank balances and cash amounted to RMB763.1 million as of December 31, 2024.
- The Company incurred total expenses (including selling and distribution expenses, administrative expenses and research and development expenses) of RMB2,820.8 million for the year ended December 31, 2024, of which RMB1,539.8 million was research and development expenses.
- The research and development expenses increased by RMB233.5 million, or 17.9%, to RMB1,539.8 million in 2024.
- The loss before tax decreased by RMB42.9 million, or 2.8%, to RMB1,468.4 million in 2024.
- Loss for the year decreased by RMB42.9 million, or 2.8%, to RMB1,468.4 million in 2024.
- The adjusted net loss* decreased by RMB26.0 million, or 1.8%, to RMB1,399.6 million in 2024.

* *Adjusted net loss is not a financial measurement as defined under IFRS, but a financial measurement after deducting loss before tax for the year and adding back share-based payments.*

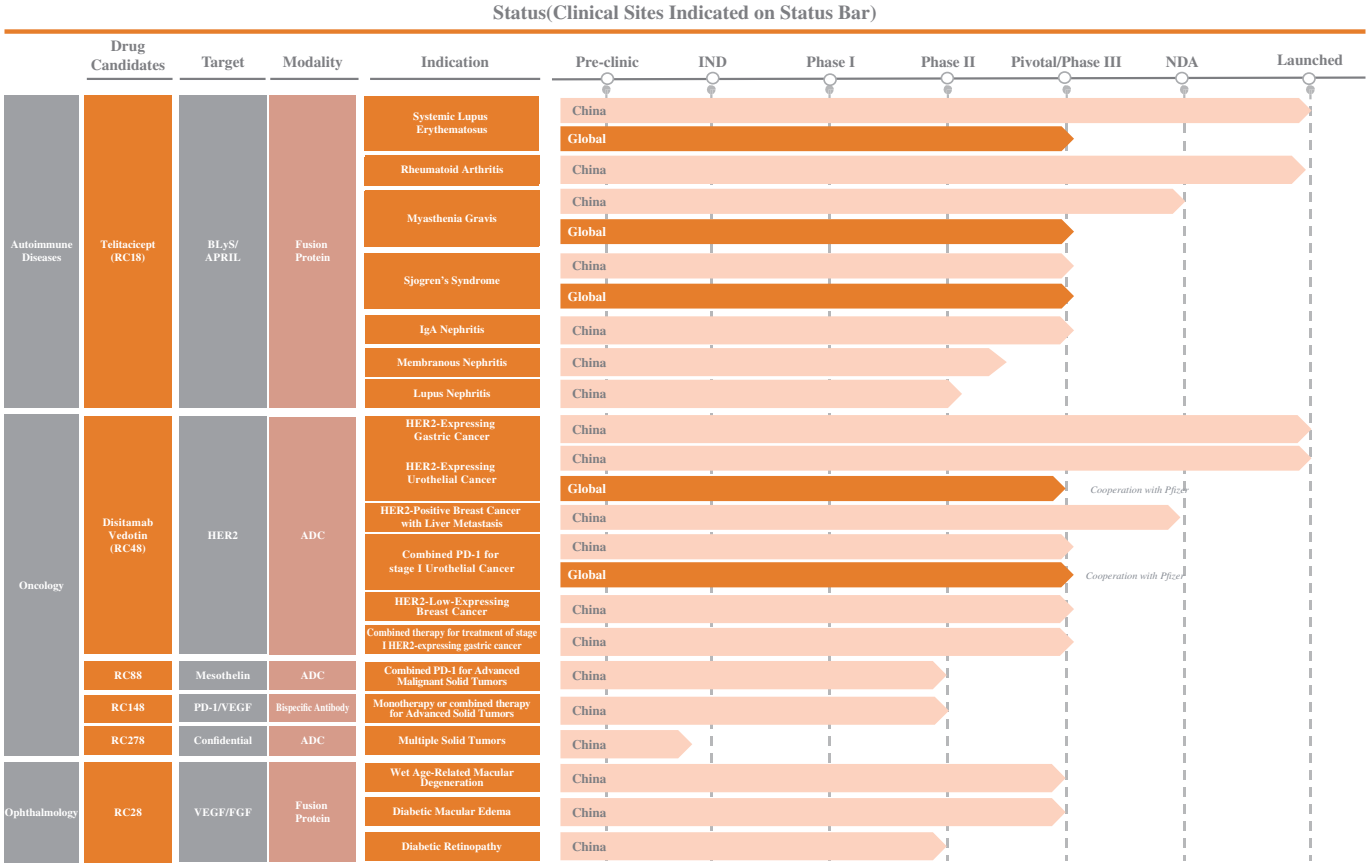
MANAGEMENT DISCUSSION AND ANALYSIS

OVERVIEW

We are a fully-integrated biopharmaceutical company committed to the discovery, development and commercialization of innovative and differentiated biologics for the treatment of autoimmune, oncology and ophthalmic diseases with unmet medical needs in China and globally. Our vision is to become a leading player in the global biopharmaceutical industry. We are one of the few Chinese biotechnology enterprises that have commercialized two products. Since our inception in 2008, we have been dedicated to the research and development of biologics with novel targets, innovative design and breakthrough potential to address global unmet clinical needs. Through more than ten years of efforts, we have built fully-integrated, end-to-end therapeutics development capabilities encompassing all the key biologics development functionalities, including discovery, preclinical pharmacology, process and quality development, clinical development, and manufacturing in compliance with global good manufacturing practice (GMP). Leveraging our strong research and development platforms, we have discovered and developed a robust pipeline of more than ten drug candidates. Among our drug candidates, seven are in clinical development stage targeting over 20 indications. Our two commercialized drugs, telitacicept (RC18, brand name: 泰爱®) and disitamab vedotin (RC48, brand name: 爱地希®), are in clinical trials targeting over 20 indications in China and globally.

PRODUCT PIPELINE

The following chart illustrates our pipeline and summarises the development status of our clinical-stage drug candidates and selected IND-enabling stage drug candidates as of December 31, 2024:



BUSINESS REVIEW

For the year ended December 31, 2024 and up to the date of this announcement, the Company has made the following significant progress:

Telitacicept (RC18, brand name: 泰爱®)

– Telitacicept is our proprietary novel fusion protein for treating autoimmune diseases. It is constructed with the extracellular domain of the human transmembrane activator and calcium modulator and cyclophilin ligand interactor (TACI) receptor and the fragment crystallizable (Fc) domain of human immunoglobulin G (IgG). Telitacicept targets and acts on two cell-signaling molecules critical for B-lymphocyte development: B-cell lymphocyte stimulator (BLyS) and a proliferation inducing ligand (APRIL), which allows it to effectively reduce B-cell mediated autoimmune responses that are implicated in several autoimmune diseases.

– We are currently evaluating telitacicept in late-stage clinical trials, in an attempt to address the significant unmet or underserved medical needs.

o Systemic Lupus Erythematosus (SLE)

- *China:* We have received full marketing approval from the NMPA in November 2023 and have successfully renewed telitacicept in the National Reimbursement Drug List (NRDL) at the end of 2023.

- *Global:* The international, multi-center Phase III clinical study is ready.

o Lupus Nephritis (LN)

- *China:* The IND application for a Phase II clinical trial on telitacicept for the treatment of active lupus nephritis obtained the approval from the CDE in September 2022. The Company has commenced this clinical study in China in the first half of 2023, with smooth progress currently.

o Rheumatoid Arthritis (RA)

We have completed a multi-center, double-blind, placebo-controlled Phase III clinical trial in China. We received positive results from this trial in the second quarter of 2023 and submitted BLA to the NMPA in August 2023 and presented the data at the American College of Rheumatology (ACR) Annual Meeting in November 2023. In July 2024, the NMPA approved the marketing of telitacicept for the treatment of this indication in China.

- ***Immunoglobulin A Nephropathy (IgAN)***

  In the first half of 2023, we initiated a Phase III clinical study of telitacicept for the treatment of IgAN in China, and in May 2024, patient enrollment for the Phase III study has been completed.

- ***Primary Sjögren's Syndrome (pSS)***

  - *China:* We communicated with the CDE regarding the protocol of a Phase III clinical study of telitacicept for the treatment of patients with pSS in June 2022 and reached consensus with the CDE in August 2022. In the first half of 2023, we initiated this Phase III clinical study in China, and in May 2024, patient enrollment has been completed.

  - *United States:* In December 2023, the FDA approved the IND application for the global multi-center Phase III clinical trial of telitacicept for the treatment of adult patients with pSS. In March 2024, telitacicept received a FTD from the FDA for the treatment of adult patients with pSS.

- ***Myasthenia Gravis (MG)***

  - *China:* In the first half of 2023, we initiated Phase III clinical trial of telitacicept for the treatment of generalized myasthenia gravis (gMG) in China, which is a multi-center, randomized, double-blind, placebo-controlled study. In August 2024, the clinical trial reached its primary study endpoints and the marketing application for this indication has been formally accepted by the CDE in October 2024 and included in the priority review and approval process. Previously, we received breakthrough therapy designation from the CDE for the treatment of generalized myasthenia gravis (gMG) in November 2022.

  - *United States:* The FDA granted orphan drug designation to telitacicept for the treatment of gMG in October 2022. In the first quarter of 2023, the FDA approved a global multi-center Phase III clinical trial of telitacicept for the treatment of patients with generalized myasthenia gravis (gMG) and granted it a FTD. In August 2024, the clinical trial enrolled the first patient in the U.S.

o Other Indications

In addition to the above indications, we also explore and evaluate telitacicept for the treatment of other autoimmune diseases, and plan to communicate with the CDE in respect of the Phase III clinical study of membranous nephritis and submit the IND application for interstitial lung disease study relating to connective tissue diseases. Moreover, telitacicept has garnered extensive attention and interests among researchers, and over one hundred studies such as antiphospholipid syndrome, primary immune thrombocytopenia and immune-mediated necrotizing myositis have been launched by researchers.

Warning under Rule 18A.08(3) of the Listing Rules: There is no assurance that telitacicept (RC18, brand name: 泰爱®) (for the treatment of other indications) will ultimately be successfully developed and marketed by the Company. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the Shares of the Company.

Disitamab Vedotin (RC48, brand name: 爱地希®)

– Disitamab vedotin is our leading antibody-drug conjugate (ADC) product candidate and is the first domestically developed ADC approved in China. Disitamab vedotin is a novel ADC independently developed by the Company for treating human epidermal growth factor receptor 2 (HER2)-expressing (including low-expressing) solid tumors. Disitamab vedotin is currently being studied in multiple late-stage clinical trials in China across a variety of solid tumor types. Among clinical trials in China, disitamab vedotin has demonstrated promising efficacy in patients with HER2-expressing advanced or metastatic gastric cancer (GC) and urothelial cancer (UC), and has also proved its potential as treatment for HER2-expressing (including low-expressing) breast cancer (BC) and other malignant tumors like gynecological cancers.

– We have been developing disitamab vedotin for a variety of HER2-expressing cancer types. Currently, we strategically focus on clinical studies on disitamab vedotin for the treatment of indications of GC, UC and BC in China, which suggest particularly significant unmet medical needs. We are also exploring the efficacy of disitamab vedotin in other prevalent cancer types with HER2 expression, such as gynecologic malignancies.

o Urothelial Cancer (UC)

- We completed a Phase II clinical trial of disitamab vedotin in patients with HER2-overexpressing (IHC 2+ or IHC 3+) UC in China. Based on the positive clinical results of this Phase II clinical trial and after communicating with the NMPA, we initiated a multi-center, single-arm, open-label Phase II registrational clinical trial. In December 2020, we received the breakthrough therapy designation from the NMPA for the treatment of UC. In September 2021, we were granted fast track designation by the NMPA for the treatment of UC. In December 2021, we received marketing approval for this indication. In November 2023, the clinical results were published online in the Journal of Clinical Oncology (JCO), a top international oncology journal. The drug was included in the updated NRDL in January 2023 and was successfully renewed by the end of 2023.

- We are now exploring the clinical potential of disitamab vedotin in combination with anti-PD-1 antibody for the treatment of HER2-expressing UC. The investigational new drug (IND) application for a Phase II trial of disitamab vedotin in combination with toripalimab injection (brand name: 拓益®) for the treatment of perioperative muscle invasive bladder cancer (MIBC) was accepted by the NMPA in February 2022. Such trial is progressing smoothly.

- In June 2024, the Company announced the preliminary results from a Phase II study of neoadjuvant therapy in combination with PD-1 for the treatment of HER2-expressing muscle invasive bladder cancer (MIBC) in a poster presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting. Among the 47 subjects enrolled, 31 patients underwent radical surgery. The results showed that the pathological complete response rate (pCR) was 61.3% (19/31); the pathological partial response rate (pPR) was 74.2% (23/31), and the safety profile was good.

- We are conducting a randomized, parallel-controlled and multi-center Phase III clinical trial in China to compare and evaluate the efficacy of disitamab vedotin in combination with toripalimab injection (brand name: 拓益®) and gemcitabine in combination with cisplatin/carboplatin for the treatment of patients with HER2-expressing locally advanced or metastatic UC (la/mUC) without prior systemic chemotherapy. In August 2024, patient enrollment was completed for such clinical trial.

o Gastric Cancer (GC)

- The IND application for a Phase II/III clinical trial of disitamab vedotin in combination with toripalimab and chemotherapy or disitamab vedotin for injection in combination with toripalimab and trastuzumab for first-line treatment of HER2-expressing or non-expressing locally advanced or metastatic gastric cancer (including gastroesophageal junction carcinoma) was approved by the NMPA in April 2023. This trial enrolled the first patient in the third quarter of 2023 and completed patient enrollment as of December 31, 2024.

- In June 2024, a multi-center, single-arm Phase II clinical study of disitamab vedotin in combination with tislelizumab and S-1 for the first-line treatment of HER2-overexpressing advanced gastric or gastroesophageal junction adenocarcinoma, led by Professor Liu Lian of Qilu Hospital of Shandong University, was presented at the 2024 ASCO Annual Meeting in the form of an oral communication of clinical science seminars. Among the 53 patients who could be evaluated for efficacy, the results showed that the first-line objective response rate (ORR) was 94.3%, and the disease control rate (DCR) was 98.1%. The 1-year progression-free survival (PFS) rate was 71.8%, and the 1-year overall survival (OS) rate was 97.6%, with benign safety profile.

- ***Breast Cancer (BC)***

  - In June 2024, the Phase III clinical trial of disitamab vedotin for the treatment of HER2-positive advanced breast cancer patients with liver metastasis achieved positive results and reached the primary study endpoints. The marketing application for this indication was accepted by the CDE in October 2024.

  - In December 2024, the clinical data of a randomized, open-label and multi-center Phase III clinical study of disitamab vedotin for the treatment of HER2-positive advanced breast cancer patients with liver metastasis were presented publicly for the first time at Poster Spotlight Sessions regarding novel HER2 therapies of the 47th San Antonio Breast Cancer Symposium (SABCS). According to the independent review committee (IRC) assessment, compared with lapatinib in combination with capecitabine, disitamab vedotin significantly prolonged patients' progression-free survival (PFS) and reduced the risk of disease progression or death by 44%. The median PFS was 9.9 vs 4.9 months; hazard ratio (HR) = 0.56, 95% CI: 0.35-0.90; two-sided P = 0.0143. Its safety data were similar to known risks and had a manageable safety profile. Overall survival (OS) data were immature. Although 21 patients in the lapatinib in combination with capecitabine group received disitamab vedotin after disease progression, a favourable trend of overall survival (OS) has been noticeably observed in the disitamab vedotin group, with median OSs as Not Evaluable (NE) vs 25.92 months in each of the two groups (HR = 0.56, 95% CI: 0.25-1.29).

- ***Gynecologic Cancers***

  - The IND application for a Phase II trial of disitamab vedotin in combination with zimberelimab injection (brand name: 譽妥®) for the treatment of patients with HER2-expressing recurrent or metastatic cervical cancer who have failed at least one line of platinum-containing chemotherapy was approved by the NMPA in October 2023. In March 2024, the Phase II clinical data for disitamab vedotin for the treatment of HER2-expressing cervical cancer patients were disclosed in the form of an oral report at the 2024 European Society of Gynaecological Oncology (ESGO) Congress. In May 2024, disitamab vedotin was included in the Guidelines for the Clinical Application of Antibody-Drug Conjugates for Gynecological Malignancies (2024 Edition) and was recommended for the treatment of patients with HER2-expressing recurrent metastatic cervical cancer, recurrent ovarian epithelial cancer, fallopian tube cancer or primary peritoneal cancer and recurrent metastatic uterine tumors (grade 2B recommendation).

  - In October 2024, results of Phase II clinical study of disitamab vedotin in combination with cadonilimab for the treatment of recurrent or metastatic cervical cancer were announced at the 23rd International Gynecologic Cancer Society (IGCS) Annual Global Meeting. The results of the study showed that in the HER2 expression (IHC 1+2+3+) cohort, the objective response rate (ORR) of disitamab vedotin in combination with cadonilimab was as high as 50%. In terms of safety, no deaths due to adverse events (AEs) were reported in this study, showing good tolerability.

– In August 2021, we entered into an exclusive worldwide license agreement with Seagen Inc. ("**Seagen**") to develop and commercialize disitamab vedotin. Pursuant to the license agreement, Seagen has been granted an exclusive license to develop and commercialize disitamab vedotin in global regions excluding Asia (Japan and Singapore excluded). We received an upfront payment of USD200 million in October 2021. Under the agreement, we will receive additional milestone payments of up to USD2.4 billion thereafter and the royalties amounting to a high single-digit to mid-teens percentage of future cumulative net sales as Seagen subsequently continues global development and commercialization of disitamab vedotin. Pfizer Inc. ("**Pfizer**")/Seagen are conducting various clinical trials of disitamab vedotin for different indications. Please refer to Pfizer's/Seagen's public information for more details.

o UC

- Pfizer/Seagen conducted an international multi-center, open-label Phase II pivotal trial in the United States in the first half of 2022 to evaluate the efficacy of disitamab vedotin in patients with HER2-expressing UC after the failure of first-line chemotherapy.

- In September 2024, the European Society for Medical Oncology (ESMO) Annual Meeting announced the Cohort C data of the RC48-G001 study. The conclusions of the study showed that disitamab vedotin in combination with pembrolizumab demonstrated encouraging preliminary antitumor activity in untreated HER2-expressing la/mUC patients. 15 patients (75%) achieved ORR confirmed by Blind Independent Central Review (BICR), and 7 patients (35%) achieved complete remission (CR). The median duration of response (DOR) was not reached. Both HER2-overexpressing and HER2-lowexpressing la/mUC patients showed responses to disitamab vedotin in combination with pembrolizumab. Disitamab vedotin in combination with pembrolizumab had a manageable safety profile, which is consistent with the results of previous disitamab vedotin monotherapy studies.

– **Warning under Rule 18A.08(3) of the Listing Rules:** There is no assurance that disitamab vedotin (RC48, brand name: 爱地希®) (for the treatment of other indications) will ultimately be successfully developed and marketed by the Company. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the Shares of the Company.

RC28-E

– RC28-E is an innovative fusion protein targeting both vascular endothelial growth factor (VEGF) and fibroblast growth factor (FGF). We are evaluating, and planning to evaluate, the efficacy of RC28-E in clinical studies for several ophthalmic diseases, including wet age-related macular degeneration (wAMD), diabetic macular edema (DME) and diabetic retinopathy (DR). In the Phase I clinical trial, no safety concerns were detected for up to 2.0mg injection of RC28-E in wAMD patients.

- ***Wet Age-Related Macular Degeneration (wAMD)***

  Currently, we have completed an open-label, single-arm Phase Ib dose-expansion trial to evaluate the efficacy and safety of RC28-E in the treatment of the patients with wAMD. The results of the study of this indication were presented at the 38th World Ophthalmology Congress (WOC 2022) in September 2022. We initiated the Phase III clinical study in China in the first half of 2023, and patient enrollment has been completed as of December 31, 2024.

  On July 20, 2024, a Phase Ib clinical study of RC28-E for the treatment of Wet Age-Related Macular Degeneration (wAMD) was published in Ophthalmology and Therapy, an internationally renowned ophthalmology journal. The results showed that RC28-E (0.5mg~2.0mg) demonstrated good safety and tolerability in patients with wAMD. Most of the adverse events (AEs) that occurred in the trial were mild or moderate, with the most common being mild injection-related subconjunctival hemorrhage (16.2%). At week 48, the best corrected visual acuity (BCVA) and central subfield thickness (CST) for the RC28-E injection at 0.5mg, 1.0mg and 2.0mg were significantly improved after 1 year of treatment. In addition, 46% of patients with polypoid choroidal vasculopathy (PCV) were enrolled in the study, 73% of whom were retreated (having received other anti-VEGF therapies before enrollment), and the results of the study indicated that RC28-E was effective in these relatively refractory patients.

- ***Diabetic Macular Edema (DME)***

  In the first half of 2023, we further initiated the Phase III clinical trial, and as of December 31, 2024, patient enrollment has been completed.

- ***Diabetic Retinopathy (DR)***

  We are currently conducting a multi-center, randomized, positive-controlled Phase II clinical trial in China, and as of December 31, 2024, patient enrollment has been completed.

– **Warning under Rule 18A.08(3) of the Listing Rules:** There is no assurance that the RC28-E will ultimately be successfully developed and marketed by the Company. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the Shares of the Company.

Other Clinical-stage Drug Candidates

– **RC88** is a novel mesothelin-targeting ADC drug that we developed for the treatment of solid tumors. The IND application for the Phase I/II trial of RC88 in combination with sintilimab (brand name: 達伯舒®) for the treatment of patients with advanced malignant solid tumors was approved by the NMPA in March 2023. Currently, the first patient has been enrolled.

– **RC148:** We are conducting a Phase II clinical study of RC148 in combination with docetaxel for the treatment of advanced lung cancer patients in China. As of December 31, 2024, the clinical trial is well advanced. At the same time, we are also conducting a multi-center phase I/II clinical study of RC148 in combination with ADC for patients with locally advanced unresectable or metastatic malignant solid tumors in China. As of December 31, 2024, the clinical trial is making progress smoothly.

– **RC278**: RC278 is a novel ADC drug for the treatment of various tumors. It is under preclinical study stage, with the target under confidentiality currently.

– **Warning under Rule 18A.08(3) of the Listing Rules:** There is no assurance that the RC88, RC148 or RC278 will ultimately be successfully developed and marketed by the Company. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the Shares of the Company.

Commercial-stage Product Portfolio

We have established our sales and marketing department dedicated to the commercialization of our pipeline products. According to the indications of our products, we have established two independent sales teams in the areas of autoimmune diseases and oncology respectively.

As the world's first innovative dual-target biological agent for the treatment of SLE, telitacicept was approved for marketing by the NMPA in March 2021 and has commenced sales. This product for the treatment of SLE was included in the NRDL in December 2021 and was successfully renewed by the end of 2023. As of December 31, 2024, telitacicept has been listed in over 1,000 hospitals.

Disitamab vedotin was approved for marketing by the NMPA in June 2021, and has commenced sales in July 2021. This product for the treatment of HER2-expressing advanced gastric cancer (GC) indication was included in the updated NRDL at the end of 2021. This product for the treatment of HER2-expressing urothelial carcinoma (UC) indication was included in the updated NRDL in January 2023. As of December 31, 2024, disitamab vedotin has been listed in over 1,000 hospitals.

Leveraging the expertise and industry connections of our teams, and the greatly improved accessibility of the two Core Products following their inclusion into the NRDL, we market the products primarily through a physician-targeted marketing strategy, focusing on direct and interactive communication with key opinion leaders (KOL) and physicians in the respective therapeutic areas to further expand the market penetration and establish the differentiated positioning of our products.

KEY EVENTS AFTER THE REPORTING PERIOD

– On January 7, 2025, the results of the Phase Ib/II study (RC48-C014) of "disitamab vedotin in combination with toripalimab for the treatment of locally advanced or metastatic urothelial carcinoma" conducted by the team led by Professor Guo Jun and Professor Sheng Xinan from Peking University Cancer Hospital were published in full in the Annals of Oncology (IF: 56.7), a top international oncology journal. This study is the first published long-term follow-up data of HER2-targeted ADC in combination with PD-1 inhibitor in the field of advanced urothelial carcinoma. The follow-up data of the past three years showed that the objective response rate (ORR) of disitamab vedotin in combination with toripalimab for the treatment of advanced urothelial carcinoma reached 73.2%, and the median overall survival (OS) reached 33.1 months. These are the highest ORR and the longest OS data reported in the prospective clinical study data of ADC in combination with PD-1 for the treatment of advanced urothelial carcinoma so far.

– In February 2025, the updated results of neoadjuvant therapy of disitamab vedotin in combination with PD-1 for the treatment of HER2-expressing (IHC 1+/2+/3+) muscles invasive bladder cancer (MIBC) patients from the RC48-C017 study were presented during an oral presentation at the American Society of Clinical Oncology Urogenital Oncology Symposium (ASCO GU) with a pathological complete response (pCR) rate of 63.6%.

FUTURE DEVELOPMENT

The Company is committed to becoming China's leading and world-class biopharmaceutical company to discover, develop, manufacture and commercialise first-in-class and best-in-class biopharmaceuticals in the major therapeutic areas of autoimmune diseases, oncology and ophthalmology, so as to create clinical value, maximise Shareholders' benefits and provide patients with high-quality drugs to address unmet clinical needs worldwide.

Looking ahead to 2025, we will endeavour to commercialise telitacicept and disitamab vedotin and actively expand the market in China. At the same time, we will continuously accelerate the application and clinical trials for the expansion of the indications for products in the pipeline.

On the international front, we will further step up our efforts to quickly advance and initiate clinical studies of our Core Products in the international market. We are conducting an international multi-center Phase III clinical trial of telitacicept for the treatment of MG indication. With regard to disitamab vedotin, we will continue to work with Pfizer/Seagen to support its global clinical trials/regulatory filings.

FINANCIAL REVIEW

Revenue

The Company's revenue increased from RMB1,076.1 million in 2023 to RMB1,710.2 million in 2024. The increase was mainly attributable to robust year-on-year growth in sales revenue driven by higher sales volume of telitacicept, a commercial-stage product of the Company for the treatment of autoimmune diseases, and disitamab vedotin, a commercial-stage product of the Company for the treatment of tumors.

Other Income and Gains

The Company's other income and gains primarily consist of interest income, government grants, exchange gains and wealth management income.

Our other income and gains decreased from RMB110.6 million in 2023 to RMB105.2 million in 2024, with an insignificant change.

Selling and Distribution Expenses

The Company's selling and distribution expenses mainly consist of employee benefits expenses and market development expenses.

Our selling and distribution expenses increased from RMB775.2 million in 2023 to RMB948.8 million in 2024, primarily due to an increase in marketing expenditure.

Administrative Expenses

The Company's administrative expenses mainly consist of employee benefits expenses, consulting service expenses, general office expenses, depreciation and amortisation expenses, and other administrative expenses.

Our administrative expenses increased from RMB313.7 million in 2023 to RMB332.3 million in 2024, primarily due to an increase in depreciation and amortisation expenses.

Research and Development Expenses

The Company's research and development expenses consist of employee benefits expenses, expenses for procuring raw materials used in the research and development, clinical trial expenses for our drug candidates, testing expenses for preclinical programs, depreciation and amortization expenses, utilities used for research and development activities, and other research and development expenses. Our research and development expenses increased from RMB1,306.3 million in 2023 to RMB1,539.8 million in 2024. The following table sets forth the components of our research and development expenses for the years indicated.

	Year ended December 31,			
	2024		2023	
	RMB'000	***%***	*RMB'000*	*%*
Employee benefits expenses	**458,269**	**29.8**	459,134	35.1
Raw material expenses	**216,390**	**14.1**	232,614	17.8
Clinical trial expenses	**547,771**	**35.6**	313,355	24.0
Testing expenses	**64,884**	**4.2**	89,628	6.9
Depreciation and amortisation expenses	**125,810**	**8.1**	113,522	8.7
Utilities	**31,962**	**2.1**	25,919	2.0
Others	**94,692**	**6.1**	72,135	5.5
Total	**1,539,778**	**100.0**	1,306,307	100.0

(i) Employee benefits expenses decreased by RMB0.87 million;

(ii) Raw material expenses decreased by RMB16.22 million, mainly due to the differences in project development progress;

(iii) Clinical trial expenses increased by RMB234.42 million, mainly due to the continuous clinical development of drug candidates, especially overseas clinical trials;

(iv) Testing expenses decreased by RMB24.74 million, mainly due to the differences in project development progress;

(v) Depreciation and amortisation expenses increased by RMB12.29 million, mainly due to an increase in depreciation after new plants and equipment being transferred to fixed asset;

(vi) Utilities increased by RMB6.04 million, mainly due to an increase in water, electricity and gas consumption;

(vii) Other expenses increased by RMB22.56 million, mainly due to an increase in various expenses such as software royalty, external purchases of non-patented technologies and repair and maintenance fees.

Impairment Losses on Financial Assets, Net

The Company's net impairment losses on financial assets mainly consist of the impairment losses in relation to other receivables and receivables. We recorded the net impairment loss on financial assets of RMB11.3 million for the year ended December 31, 2023 and the net impairment loss on financial assets of RMB11.1 million for the year ended December 31, 2024, with an insignificant change.

Other Expenses

The Company's other expenses primarily consist of (i) rental related expenses relating to the leases of our facilities to related parties; (ii) expenses incurred for sales of materials; (iii) losses from changes in foreign currency exchange rates; (iv) discounted interest on derecognized bank notes; and (v) other expenses, including our donation to a charity organisation. Our other expenses increased from RMB15.2 million in 2023 to RMB36.5 million in 2024, mainly due to an increase in losses from changes in foreign currency exchange rates and discounted interest on derecognized bank notes.

Finance Costs

The Company's finance costs mainly comprise interest on bank borrowings, interest on discounted bankers' acceptances and interest on lease liabilities. Our finance costs increased from RMB23.1 million in 2023 to RMB72.4 million in 2024, mainly due to an increase in interest on bank borrowings during the Reporting Period.

Income Tax Expenses

For the years ended December 31, 2023 and 2024, the Company's income tax expenses were nil.

Loss for the Year

Based on the factors described above, the Company's loss decreased from RMB1,511.2 million in 2023 to RMB1,468.4 million in 2024.

Liquidity and Financial Resources

Our primary use of cash is to fund research and development expenses. For the year ended December 31, 2024, our net cash used in operating activities was RMB1,176.6 million. Our cash and cash equivalents increased from RMB726.6 million as of December 31, 2023 to RMB759.5 million as of December 31, 2024.

Loans and Gearing Ratio

As of December 31, 2024, the Company's interest-bearing bank borrowings were RMB2,566.1 million.

The gearing ratio is calculated using the Company's total liabilities divided by its total assets. As of December 31, 2024, the Company's gearing ratio was 63.9% (December 31, 2023: 37.8%).

Significant Investments, Material Acquisitions and Disposal

The Company did not have any significant investments or material acquisitions or disposals of subsidiaries, associates and joint ventures for the year ended December 31, 2024.

Capital Commitments

For the years ended December 31, 2023 and 2024, the Company had capital commitments contracted for but not yet provided of RMB201.9 million and RMB210.8 million, respectively, primarily in connection with (i) contracts entered with contractors for the construction of our manufacturing facilities; and (ii) contracts entered with suppliers for the purchase of equipment.

Contingent Liabilities

As of December 31, 2024, the Company did not have any contingent liabilities.

Foreign Exchange Exposure

Our financial statements are expressed in RMB, but our assets such as certain of our cash and cash equivalents and time deposits are denominated in foreign currencies, and are exposed to foreign currency risk. We currently do not have a foreign currency hedging policy. However, the management monitors foreign exchange exposure and will consider hedging significant foreign currency exposure should the need arise.

Employees and Remuneration

As of December 31, 2024, the Company had a total of 3,497 employees. The total remuneration cost for 2024 was RMB1,175.2 million, as compared to RMB1,152.3 million for 2023.

To maintain the quality, knowledge and skill levels of our workforce, the Company provides continuing education and training programs, including internal and external training, for our employees to improve their technical, professional or management skills. The Company also provides training programs to our employees from time to time to ensure their awareness of and compliance with our policies and procedures in various aspects.

We provide various incentives and benefits to our employees. We offer competitive salaries, bonuses and share-based compensation to our employees, especially key employees. We have made contributions to social security insurance funds (including pension plans, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance) and housing provident funds for our employees in accordance with applicable PRC laws.

OTHER INFORMATION

Purchase, Sale or Redemption of Listed Securities of the Company

Neither the Company nor any of its subsidiaries had purchased, sold or redeemed any of the Company's listed securities during the year ended December 31, 2024.

Compliance with the CG Code

The Company has adopted the principles and code provisions as set out in the CG Code, and has complied with all applicable code provisions during the year ended December 31, 2024.

Compliance with the Model Code for Securities Transactions

The Company has adopted the Model Code as its own code of conduct regarding securities transactions by the Directors and Supervisors. Having made specific enquiries with all Directors and Supervisors, each of them has confirmed that he/she has complied with the Model Code for the year ended December 31, 2024. No incident of non-compliance of the Model Code by the employees who are likely to be in possession of inside information of the Company was noted by the Company.

Review of Financial Statements

The Audit Committee has jointly reviewed with the management and external auditor the accounting principles and policies adopted by the Company and the consolidated financial statements for the year ended December 31, 2024. The Audit Committee considered that the annual results are in compliance with the applicable accounting standards, laws and regulations, and the Company has made appropriate disclosures thereof.

Scope of Work of Ernst & Young

The financial information in respect of the preliminary results announcement of the Company for the year ended December 31, 2024 has been reviewed and agreed by the Company's auditor, Ernst & Young, to the amounts set out in the Company's draft consolidated financial statements for the year. The work performed by Ernst & Young in this respect did not constitute an assurance engagement in accordance with Hong Kong Standards on Auditing, Hong Kong Standards on Review Engagements or Hong Kong Standards on Assurance Engagements issued by the Hong Kong Institute of Certified Public Accountants and consequently no assurance has been expressed by Ernst & Young on the preliminary results announcement.

Final Dividend

The Board does not recommend the payment of a final dividend for the year ended December 31, 2024.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS

Year ended 31 December 2024

	Notes	**2024** ***RMB'000***	2023 *RMB'000*
REVENUE	*4*	**1,710,152**	1,076,130
Cost of sales		**(342,796)**	(253,136)
Gross profit		**1,367,356**	822,994
Other income and gains	*4*	**105,170**	110,564
Selling and distribution expenses		**(948,755)**	(775,185)
Administrative expenses		**(332,284)**	(313,673)
Research and development costs		**(1,539,778)**	(1,306,307)
Impairment losses on financial assets, net		**(11,088)**	(11,276)
Other expenses		**(36,500)**	(15,210)
Finance costs		**(72,379)**	(23,091)
Share of the associate's loss for the year		**(104)**	(45)
LOSS BEFORE TAX		**(1,468,362)**	(1,511,229)
Income tax expense	*5*	**–**	–
LOSS FOR THE YEAR		**(1,468,362)**	(1,511,229)
Attributable to:			
Owners of the parent		**(1,468,362)**	(1,511,229)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT	*6*		
Basic/diluted			
– For loss for the year		**RMB (2.73)**	RMB (2.80)

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

Year ended 31 December 2024

	2024	2023
	RMB'000	*RMB'000*
LOSS FOR THE YEAR	**(1,468,362)**	(1,511,229)
OTHER COMPREHENSIVE INCOME		
Other comprehensive income that may be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	**1,819**	(2,230)
Other comprehensive loss that will not be reclassified to profit or loss in subsequent periods:		
Equity investments designated at fair value through other comprehensive income:		
Changes in fair value	**(34,208)**	(55,217)
Income tax effect	**1,511**	(1,471)
	(32,697)	(56,688)
OTHER COMPREHENSIVE INCOME FOR THE YEAR, NET OF TAX	**(30,878)**	(58,918)
TOTAL COMPREHENSIVE INCOME FOR THE YEAR	**(1,499,240)**	(1,570,147)
Attributable to:		
Owners of the parent	**(1,499,240)**	(1,570,147)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

31 December 2024

	Notes	**31 December 2024** ***RMB'000***	31 December 2023 *RMB'000*
NON-CURRENT ASSETS			
Property, plant and equipment		**2,743,704**	2,833,055
Right-of-use assets		**210,742**	251,736
Other intangible assets		**26,143**	24,294
Investment in an associate		**8,851**	2,705
Equity investments designated at fair value through other comprehensive income		**59,313**	93,522
Financial assets at fair value through profit or loss		**4,037**	2,000
Pledged deposits		**638**	638
Other non-current assets		**155,293**	91,360
Total non-current assets		**3,208,721**	3,299,310
CURRENT ASSETS			
Inventories		**659,369**	741,560
Trade and bills receivables	*8*	**598,787**	420,419
Prepayments, other receivables and other assets		**269,150**	323,561
Pledged deposits		**2,805**	16,841
Interest receivable		**157**	–
Cash and cash equivalents		**759,530**	726,552
Total current assets		**2,289,798**	2,228,933
CURRENT LIABILITIES			
Trade and bills payables	*9*	**162,250**	139,331
Other payables and accruals		**565,184**	632,196
Interest-bearing bank borrowings		**1,370,240**	286,349
Lease liabilities		**62,299**	58,371
Deferred income		**9,799**	9,417
Other current liabilities		**18,324**	11,877
Total current liabilities		**2,188,096**	1,137,541

	31 December 2024 *RMB'000*	31 December 2023 *RMB'000*
NET CURRENT ASSETS	**101,702**	1,091,392
TOTAL ASSETS LESS CURRENT LIABILITIES	**3,310,423**	4,390,702
NON-CURRENT LIABILITIES		
Interest-bearing bank borrowings	**1,195,878**	840,588
Lease liabilities	**42,094**	74,675
Deferred tax liabilities	**–**	1,511
Deferred income	**86,250**	36,659
Total non-current liabilities	**1,324,222**	953,433
Net assets	**1,986,201**	3,437,269
EQUITY		
Equity attributable to owners of the parent		
Share capital	**544,332**	544,263
Treasury shares	**(445,329)**	(440,310)
Reserves	**1,887,198**	3,333,316
Total equity	**1,986,201**	3,437,269

NOTES TO FINANCIAL STATEMENTS

1. CORPORATE AND GROUP INFORMATION

RemeGen Co., Ltd. (the "**Company**") was incorporated in the People's Republic of China (the "**PRC**") on 4 July 2008 as a limited liability company. On 12 May 2020, the Company was converted into a joint stock company with limited liability under the Company Law of the PRC. The registered office of the Company is located at 58 Middle Beijing Road, Yantai Development Zone, Yantai Area of Shandong Pilot Free Trade Zone, PRC.

During the year, the Company and its subsidiaries (the "**Group**") were principally engaged in the biopharmaceutical research, biopharmaceutical service, and biopharmaceutical production and sale.

Information about subsidiaries

Particulars of the Company's principal subsidiaries are as follows:

Name	Place and date of registration/ incorporation and place of operations	Nominal value of issued ordinary/ registered paid-in capital	Percentage of equity attributable to the Company		Principal activities
			Direct	Indirect	
RemeGen Biosciences, Inc. (previously known as "**RC Biotechnologies, Inc.**")	Delaware, United States of America ("**USA**") 18 April 2011	1,500 ordinary shares	100%	–	Research and development, registration and business development
Ruimeijing (Beijing) Pharmaceutical Technology Co., Ltd. (瑞美京(北京)醫藥科技有限公司)*	Beijing, PRC 14 August 2019	RMB1,000,000	100%	–	Research and development
RemeGen Hong Kong Limited	Hong Kong 26 September 2019	United States dollars ("**USD**") 32,000,000	100%	–	Research and development
RemeGen Australia Pty Ltd	South Australia 3 March 2021	100 ordinary shares	–	100%	Research and development and business development
Shanghai Rongchang Biotechnology Co. Ltd. (上海榮昌生物科技有限公司)	Shanghai, PRC 7 May 2022	RMB500,000,000	100%	–	Research and development

* The English name of these subsidiaries represents the best efforts made by the management of the Company to translate the Chinese name as they do not have official English name registered in the PRC. These subsidiaries were registered as domestic limited liability companies under PRC law.

2. ACCOUNTING POLICIES

2.1 Basis of Preparation

These financial statements have been prepared in accordance with IFRS accounting standards, (which include all IFRS accounting standards, International Accounting Standards and Interpretations) as issued by the Hong Kong Institute of Certified Public Accountants ("**HKICPA**"), and the disclosure requirements of the Hong Kong Companies Ordinance. They have been prepared under the historical cost convention, except for equity investments designated at fair value through other comprehensive income and bills receivable which have been measured at fair value. These financial statements are presented in Renminbi ("**RMB**") and all values are rounded to the nearest thousand ("**RMB'000**") except when otherwise indicated.

The Group has been focusing on the research and development of drugs since its establishment and has gradually entered into the commercialization stage. A full marketing application of the telitacicept developed by the Group was officially approved by the NMPA in November 2023; a conditional marketing application of the disitamab vedotin was officially approved by the NMPA on 8 June 2021, and other drug candidates are in different preclinical and clinical development stages. As at 31 December 2024, the Group had accumulated losses of RMB4,321,871,000 and net current assets of RMB101,702,000. The Group has prepared these financial statements on a going concern basis as at 31 December 2024. Management of the Group believes that the cash and cash equivalents together with the unutilised bank facilities are sufficient to meet the cash requirements to fund operations, research and development and production activities of the Group for at least, but not limited to, twelve months from 31 December 2024.

Basis of consolidation

The consolidated financial statements include the financial statements of the Company and its subsidiaries for the year ended 31 December 2024. A subsidiary is an entity (including a structured entity), directly or indirectly, controlled by the Company. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee (i.e., existing rights that give the Group the current ability to direct the relevant activities of the investee).

Generally, there is a presumption that a majority of voting rights results in control. When the Company has less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, including:

(a) the contractual arrangement with the other vote holders of the investee;

(b) rights arising from other contractual arrangements; and

(c) the Group's voting rights and potential voting rights.

The financial statements of the subsidiaries are prepared for the same reporting period as the Company, using consistent accounting policies. The results of subsidiaries are consolidated from the date on which the Group obtains control, and continue to be consolidated until the date that such control ceases.

Profit or loss and each component of other comprehensive income are attributed to the owners of the parent of the Group. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control described above. A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

If the Group loses control over a subsidiary, it derecognises the related assets (including goodwill), liabilities, any non-controlling interest and the exchange fluctuation reserve; and recognises the fair value of any investment retained and any resulting surplus or deficit in profit or loss. The Group's share of components previously recognised in other comprehensive income is reclassified to profit or loss or retained profits, as appropriate, on the same basis as would be required if the Group had directly disposed of the related assets or liabilities.

2.2 Changes in Accounting Policies and Disclosures

The Group has adopted the following revised IFRS accounting standards for the first time for the current year's financial statements.

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

The nature and the impact of the revised IFRS accounting standards are described below:

(a) Amendments to IFRS 16 specify the requirements that a seller-lessee uses in measuring the lease liability arising in a sale and leaseback transaction to ensure the seller-lessee does not recognize any amount of the gain or loss that relates to the right of use it retains. Since the Group has no sale and leaseback transactions with variable lease payments that do not depend on an index or a rate occurring from the date of initial application of IFRS 16, the amendments did not have any impact on the financial position or performance of the Group.

(b) The 2020 Amendments clarify the requirements for classifying liabilities as current or non-current, including what is meant by a right to defer settlement and that a right to defer must exist at the end of the reporting period. Classification of a liability is unaffected by the likelihood that the entity will exercise its right to defer settlement. The amendments also clarify that a liability can be settled in its own equity instruments, and that only if a conversion option in a convertible liability is itself accounted for as an equity instrument would the terms of a liability not impact its classification. The 2022 Amendments further clarify that, among covenants of a liability arising from a loan arrangement, only those with which an entity must comply on or before the reporting date affect the classification of that liability as current or non-current. Additional disclosures are required for non-current liabilities that are subject to the entity complying with future covenants within 12 months after the reporting period.

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

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

2.3 Issued But Not Yet Effective IFRS accounting standards

The Group has not applied the following new and revised IFRS accounting standards, that have been issued but are not yet effective, in these financial statements. The Group intends to apply these new and revised IFRS accounting standards, if applicable, when they become effective.

IFRS 18	*Presentation and Disclosure in Financial Statements*[3]
IFRS 19	*Subsidiaries without Public Accountability: Disclosures*[3]
Amendments to IFRS 9 and IFRS 7	*Amendments to the Classification and Measurement of Financial Instruments*[2]
Amendments to IFRS 10 and IAS 28	*Sale or Contribution of Assets between an Investor and its Associate or Joint Venture*[4]
Amendments to IAS 21	*Lack of Exchangeability*[1]
Annual Improvements to IFRS Accounting Standards – Volume 11	Amendments to IFRS 1, IFRS 7, IFRS 9, IFRS 10 and IAS 7[2]

[1] Effective for annual periods beginning on or after 1 January 2025

[2] Effective for annual periods beginning on or after 1 January 2026

[3] Effective for annual/reporting periods beginning on or after 1 January 2027

[4] No mandatory effective date yet determined but available for adoption

Further information about those IFRS accounting standards that are expected to be applicable to the Group is described below.

IFRS 18 replaces IAS 1 *Presentation of Financial Statements*. While a number of sections have been brought forward from IAS 1 with limited changes, IFRS 18 introduces new requirements for presentation within the statement of profit or loss, including specified totals and subtotals. Entities are required to classify all income and expenses within the statement of profit or loss into one of the five categories: operating, investing, financing, income taxes and discontinued operations and to present two new defined subtotals. It also requires disclosures about management-defined performance measures in a single note and introduces enhanced requirements on the grouping (aggregation and disaggregation) and the location of information in both the primary financial statements and the notes. Some requirements previously included in IAS 1 are moved to IAS 8 *Accounting Policies, Changes in Accounting Estimates and Errors*, which is renamed as IAS 8 *Basis of Preparation of Financial Statements*. As a consequence of the issuance of IFRS 18, limited, but widely applicable, amendments are made to IAS 7 *Statement of Cash Flows*, IAS 33 *Earnings per Share* and IAS 34 *Interim Financial Reporting*. In addition, there are minor consequential amendments to other IFRS accounting standards. IFRS 18 and the consequential amendments to other IFRS accounting standards are effective for annual periods beginning on or after 1 January 2027 with earlier application permitted. Retrospective application is required. The Group is currently analysing the new requirements and assessing the impact of IFRS 18 on the presentation and disclosure of the Group's financial statements.

IFRS 19 allows eligible entities to elect to apply reduced disclosure requirements while still applying the recognition, measurement and presentation requirements in other IFRS accounting standards. To be eligible, at the end of the reporting period, an entity must be a subsidiary as defined in IFRS 10 *Consolidated Financial Statements*, cannot have public accountability and must have a parent (ultimate or intermediate) that prepares consolidated financial statements available for public use which comply with IFRS accounting standards. Earlier application is permitted. As the Company is a listed company, it is not eligible to elect to apply IFRS 19. Some of the Company's subsidiaries are considering the application of IFRS 19 in their specified financial statements.

Amendments to IFRS 9 and IFRS 7 clarify the date on which a financial asset or financial liability is derecognised and introduce an accounting policy option to derecognise a financial liability that is settled through an electronic payment system before the settlement date if specified criteria are met. The amendments clarify how to assess the contractual cash flow characteristics of financial assets with environmental, social and governance and other similar contingent features. Moreover, the amendments clarify the requirements for classifying financial assets with non-recourse features and contractually linked instruments. The amendments also include additional disclosures for investments in equity instruments designated at fair value through other comprehensive income and financial instruments with contingent features. The amendments shall be applied retrospectively with an adjustment to opening retained profits (or other component of equity) at the initial application date. Prior periods are not required to be restated and can only be restated without the use of hindsight. Earlier application of either all the amendments at the same time or only the amendments related to the classification of financial assets is permitted. The amendments are not expected to have any significant impact on the Group's financial statements.

Amendments to IFRS 10 and IAS 28 address an inconsistency between the requirements in IFRS 10 and in IAS 28 in dealing with the sale or contribution of assets between an investor and its associate or joint venture. The amendments require a full recognition of a gain or loss resulting from a downstream transaction when the sale or contribution of assets constitutes a business. For a transaction involving assets that do not constitute a business, a gain or loss resulting from the transaction is recognised in the investor's profit or loss only to the extent of the unrelated investor's interest in that associate or joint venture. The amendments are to be applied prospectively. The previous mandatory effective date of amendments to IFRS 10 and IAS 28 was removed by the HKICPA. However, the amendments are available for adoption now.

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. Earlier application is permitted. When applying the amendments, an entity cannot restate comparative information. Any cumulative effect of initially applying the amendments shall be recognised as an adjustment to the opening balance of retained profits or to the cumulative amount of translation differences accumulated in a separate component of equity, where appropriate, at the date of initial application. The amendments are not expected to have any significant impact on the Group's financial statements.

Annual Improvements to *IFRS Accounting Standards – Volume 11* set out amendments to IFRS 1, IFRS 7 (and the accompanying *Guidance on implementing IFRS 7*), IFRS 9, IFRS 10 and IAS 7. Details of the amendments that are expected to be applicable to the Group are as follows:

IFRS 7 *Financial Instruments: Disclosures:* The amendments have updated certain wording in paragraph B38 of IFRS 7 and paragraphs IG1, IG14 and IG20B of the *Guidance on implementing IFRS 7* for the purpose of simplification or achieving consistency with other paragraphs in the standard and/or with the concepts and terminology used in other standards. In addition, the amendments clarify that the *Guidance on implementing IFRS 7* does not necessarily illustrate all the requirements in the referenced paragraphs of IFRS 7 nor does it create additional requirements. Earlier application is permitted. The amendments are not expected to have any significant impact on the Group's financial statements.

IFRS 9 *Financial Instruments*: The amendments clarify that when a lessee has determined that a lease liability has been extinguished in accordance with IFRS 9, the lessee is required to apply paragraph 3.3.3 of IFRS 9 and recognise any resulting gain or loss in profit or loss. In addition, the amendments have updated certain wording in paragraph 5.1.3 of IFRS 9 and Appendix A of IFRS 9 to remove potential confusion. Earlier application is permitted. The amendments are not expected to have any significant impact on the Group's financial statements.

IFRS 10 *Consolidated Financial Statements*: The amendments clarify that the relationship described in paragraph B74 of IFRS 10 is just one example of various relationships that might exist between the investor and other parties acting as de facto agents of the investor, which removes the inconsistency with the requirement in paragraph B73 of IFRS 10. Earlier application is permitted. The amendments are not expected to have any significant impact on the Group's financial statements.

IAS 7 *Statement of Cash Flows*: The amendments replace the term "cost method" with "at cost" in paragraph 37 of IAS 7 following the prior deletion of the definition of "cost method". Earlier application is permitted. The amendments are not expected to have any impact on the Group's financial statements.

3. OPERATING SEGMENT INFORMATION

The Group is engaged in biopharmaceutical research, biopharmaceutical service, biopharmaceutical production and sale, which are regarded as a single reportable segment in a manner consistent with the way in which information is reported internally to the Group's senior management for purposes of resource allocation and performance assessment. Therefore, no analysis by operating segment is presented.

Geographical information

(a) Revenue from external customers

	2024	2023
	RMB'000	*RMB'000*
Chinese Mainland	**1,699,143**	1,049,195
United States of America	**11,009**	26,935
Total revenue	**1,710,152**	1,076,130

The revenue information above is based on the locations of the customers.

(b) Non-current assets

	2024	2023
	RMB'000	*RMB'000*
Chinese Mainland	**3,088,349**	3,129,739
United States of America	**43,171**	57,329
Total non-current assets	**3,131,520**	3,187,068

The non-current asset information above is based on the locations of the assets and excludes equity investments designated at fair value through other comprehensive income and other financial instruments.

Information about a major customer

During the year ended 31 December 2024, no revenue derived from a single customer accounted for 10% or more of the Group's total revenue (2023: Nil).

4. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	2024	2023
	RMB'000	*RMB'000*
Revenue from contracts with customers	**1,710,152**	1,076,130

Revenue from contracts with customers

(a) Disaggregated revenue information

	2024	2023
	RMB'000	*RMB'000*
Types of revenue		
Sales of goods	**1,699,143**	1,049,195
Service income	**11,009**	26,935
Total	**1,710,152**	1,076,130
Geographical markets		
Chinese Mainland	**1,699,143**	1,049,195
United States of America	**11,009**	26,935
Total	**1,710,152**	1,076,130
Timing of revenue recognition		
Goods transferred at a point in time	**1,699,143**	1,049,195
Services transferred over time	**11,009**	26,935
Total	**1,710,152**	1,076,130

(b) Performance obligations

Information about the Group's performance obligations is summarised below:

Sales of goods

The performance obligation is satisfied upon delivery of the goods and payment is generally due within 90 days from the delivery.

Service income

The Group earns revenue by providing research service to its customers through contracts. Revenue from service is recognised over time, using an input method to measure progress towards complete satisfaction of the service, because the customer simultaneously receives and consumes the benefits provided by the Group. The Group determines the progress of performance of services rendered based on labour hours spent and costs incurred in accordance with the input method. When the progress of performance is not reasonably determinable, the Group recognises revenue based on the amount of costs incurred until the progress of performance is reasonably determinable, provided that the costs incurred by the Group are expected to be reimbursed.

Licence revenue

The time when the intellectual property licence is delivered is the time when the performance obligation is fulfilled, and the customer obtains the control of the intellectual property licence at this time, can use and benefit from it, and the Group recognises the income for the part of the down payment amount at the time when the control of the intellectual property licence is transferred. Subsequent milestone payments are variable consideration, and their payment depends on future uncertain events and is difficult to estimate reasonably at this stage. The Group will re-estimate the amount of variable consideration that should be included in the transaction price at the end of the reporting period. For the royalties charged, revenue shall be recognised at the later point of time when the customer's subsequent sales or use behaviour actually occurs and the Company performs the relevant performance obligations.

The amounts of transaction prices allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at 31 December are as follows:

	2024	2023
	RMB'000	*RMB'000*
Amounts expected to be recognised as revenue:		
Within one year	**3,144**	11,398

The amounts disclosed above do not include variable consideration which is constrained.

	2024	2023
	RMB'000	*RMB'000*
Other income		
Government grants*	**78,835**	65,669
Rental income	**2,790**	2,667
Bank interest income	**10,239**	28,143
Gain on disposal of financial assets at fair value through profit or loss	**2,601**	7,020
Changes in fair value of financial assets at fair value through profit or loss	**1,537**	–
Sales of materials	**3,798**	4,156
Total other income	**99,800**	107,655
Gains		
Foreign exchange gains	**4,850**	2,819
Gain on disposal of property, plant and equipment	**–**	4
Others	**520**	86
Total gains	**5,370**	2,909
Total other income and gains	**105,170**	110,564

* The government grants mainly represent subsidies received from government authorities for the purpose of compensation for expenditure arising from research activities and clinical trials, awards for new drug development and capital expenditure incurred on certain projects. There are no unfulfilled conditions or contingencies relating to these government grants.

5. INCOME TAX

The provision for corporate income tax in Chinese Mainland is based on the statutory rate of 25% of the assessable profits as determined in accordance with the PRC Corporate Income Tax ("**CIT**") Law which was approved and became effective on 1 January 2008.

The Company has been recognised as High New Tech Enterprise since 2022 and entitled to a reduced corporate income tax rate of 15% according to the tax incentives of the CIT Law for High New Tech Enterprises.

Ruimeijing (Beijing) Pharmaceutical Technology Co., Ltd. was subject to preferential tax rates of 20%, because it was regarded as "small-scaled minimal profit enterprise" during the corresponding period in 2024. The subsidiaries incorporated in Chinese Mainland were subject to preferential tax rates of 25% in 2023.

The subsidiary incorporated in the United States of America is subject to America federal income tax at a rate of 21% and California state income tax at a rate of 8.84%.

The subsidiary incorporated in Hong Kong is subject to Hong Kong profits tax at the rate of 16.5% on any estimated assessable profits arising in Hong Kong.

The subsidiary incorporated in Australia is subject to Australia profits tax at the rate of 25% on any estimated assessable profits arising in Australia.

The income tax expense of the Group for the year is analysed as follows:

	2024	2023
	RMB'000	*RMB'000*
Current		
Charge for the year	**–**	–
Deferred	**–**	–
Total	**–**	–

A reconciliation of the tax expense charged/(credit) applicable to loss before tax at the statutory tax rates for the jurisdictions in which the Company and the majority of its subsidiaries are domiciled to the tax expense at the effective tax rate is as follows:

	2024	2023
	RMB'000	*RMB'000*
Loss before tax	**(1,468,362)**	(1,511,229)
Tax at the statutory tax rates	**(365,219)**	(264,513)
Lower tax rates enacted by local authority	**143,068**	173,842
Expenses not deductible for tax	**17,436**	14,583
Additional deductible allowance for research and development expenses*	**45,965**	(236,831)
Share of the associate's loss for the year	**16**	7
Effect of deemed sales	**4,978**	802
Deductible temporary difference and tax losses not recognised	**153,756**	312,110
Tax charge at the Group's effective rate	**–**	–

* Taxable amount of RMB163,091,000 is included as research and development expenses from prior periods that did not meet the requirements of additional deductible allowance in accordance with the tax policy.

The share of tax attributable to the associate's loss for the year amounting to RMB16,000 (2023: RMB7,000), is included in "Share of the associate's loss for the year" in the consolidated statement of profit or loss.

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

The calculation of the basic loss per share amount is based on the loss for the year attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 537,393,410 (2023: 538,914,230) outstanding during the year, as adjusted to reflect the rights issue during the year.

The calculation of the diluted loss per share amounts is based on the loss for the year attributable to ordinary equity holders of the parent. The weighted average number of ordinary shares used in the calculation is the number of ordinary shares outstanding during the year, as used in the basic loss per share calculation, and the weighted average number of ordinary shares assumed to have been issued at no consideration on the deemed exercise or conversion of all dilutive potential ordinary shares into ordinary shares.

Because the diluted loss per share amount is decreased when taking share awards into account, the share awards had an anti-dilutive effect on the basic loss per share for the year and were ignored in the calculation of diluted loss per share.

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

	2024	2023
	RMB'000	*RMB'000*
Loss		
Loss attributable to ordinary equity holders of the parent, used in the basic loss per share calculation	**(1,468,362)**	(1,511,229)
Dilutive potential conversion expenses	**–**	–
Loss attributable to ordinary equity holders of the parent	**(1,468,362)**	(1,511,229)
Attributable to:		
Continuing operations	**(1,468,362)**	(1,511,229)

	2024	2023
Shares		
Weighted average number of ordinary shares in issue during the year used in the basic loss per share calculation	**537,393,410**	538,914,230
Effect of dilution – weighted average number of ordinary shares:		
Share awards	**131,728**	959,160
Total	**537,525,138**	539,873,390

7. DIVIDENDS

No dividend has been declared and paid by the Company during the year (2023: Nil).

8. TRADE AND BILLS RECEIVABLES

	2024	2023
	RMB'000	*RMB'000*
Trade receivables	**403,567**	313,345
Impairment	**(20,178)**	(15,667)
Trade receivables, net	**383,389**	297,678
Bills receivable	**215,398**	122,741
Total	**598,787**	420,419

Trade receivables mainly consist of receivables of sales of goods.

For receivables of sales of goods, the Group's trading terms with its customers are mainly on credit. The credit period offered by the Group is generally one month and major customers can extend up to three months.

The Group does not hold any collateral or other credit enhancements over these balances. Trade receivables are non-interest-bearing.

At 31 December 2024, the Group has pledged bills receivable of approximately RMB141,186,000 (2023: RMB28,437,000) to secure a bank loan granted to a major supplier.

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

	2024	2023
	RMB'000	*RMB'000*
Within 1 year	**383,389**	297,678

The movements in the loss allowance for impairment of trade receivables are as follows:

	2024	2023
	RMB'000	*RMB'000*
At beginning of year	**15,667**	10,633
Impairment losses, net	**4,511**	7,914
Amount written off as uncollectible	**–**	(2,880)
At end of year	**20,178**	15,667

The expected loss rate for the trade receivables generated from the sales of goods not past due is assessed to be 5% based on the time of past due. The directors of the Company are of the opinion that the expected credit loss in respect of these balances is sufficient.

9. TRADE AND BILLS PAYABLES

An ageing analysis of the trade and bills payables as at the end of the year, based on the invoice date, is as follows:

	2024	2023
	RMB'000	*RMB'000*
Within 3 months	**114,296**	92,711
3 to 6 months	**29,284**	39,945
6 months to 1 year	**17,102**	5,425
Over 1 year	**1,568**	1,250
Total	**162,250**	139,331

The Group's trade payables included RMB12,634,000 due to the Group's related parties as at 31 December 2024 (31 December 2023: RMB1,906,000).

Other than the trade payables due to the Group's related parties, trade and bills payables are normally settled on terms of one to six months.

10. EVENTS AFTER THE REPORTING PERIOD

There is no significant event after the reporting period.

PUBLICATION OF ANNUAL RESULTS ANNOUNCEMENT AND ANNUAL REPORT

This announcement is published on the websites of the Stock Exchange at www.hkexnews.hk and the Company at www.remegen.com.

The annual report for the year ended December 31, 2024 containing all the information required by the Listing Rules will be dispatched to the Shareholders and published on the websites of the Stock Exchange and the Company in due course.

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

DEFINITION

"A Share(s)"	domestic Renminbi-denominated ordinary share(s) in the ordinary share capital of the Company, with a nominal value of RMB1.00 each, listed on the Science and Technology Innovation Board of the Shanghai Stock Exchange
"ADC"	antibody-drug conjugates, a class of biopharmaceutical drug composed of monoclonal antibodies targeted against specific tumor cell surface antigens linked, via chemical linkers, to highly potent anti-tumor small molecule agents
"Audit Committee"	the audit committee of the Board
"BLA"	biologics license application
"Board"	the board of Directors of the Company
"Company"	RemeGen Co., Ltd.* (榮昌生物製藥(煙台)股份有限公司), a company incorporated in the PRC with limited liability, the H Shares and A Shares of which are listed on the Main Board of the Stock Exchange (stock code: 9995) and the Science and Technology Innovation Board of the Shanghai Stock Exchange (stock code: 688331), respectively
"CG Code"	the Corporate Governance Code contained in Appendix C1 to the Listing Rules
"China" or "PRC"	the People's Republic of China excluding, for the purpose of this announcement, Hong Kong, Macau Special Administrative Region and Taiwan

"Core Product(s)"	has the meaning ascribed to it in Chapter 18A of the Listing Rules and in this context, our core products include telitacicept (RC18, brand name: 泰爱®), disitamab vedotin (RC48, brand name: 爱地希®) and RC28-E
"Director(s)"	the director(s) of the Company
"CDE"	the Center for Drug Evaluation of China's National Medical Products Administration
"DME"	diabetic macular edema
"DR"	diabetic retinopathy
"ESGO"	European Society of Gynaecological Oncology
"FDA"	U.S. Food and Drug Administration
"FTD"	fast track designation
"GC"	gastric cancer
"we" or "our"	the Company and its subsidiaries
"HER2"	human epidermal growth factor receptor 2
"H Share(s)"	share(s) in the ordinary share capital of the Company, with a nominal value of RMB1.00 each, which are listed on the Stock Exchange
"Hong Kong"	the Hong Kong Special Administrative Region of the People's Republic of China
"IgAN"	an autoimmune kidney disease that occurs when immunoglobulin A (IgA) deposits build up in the kidneys, causing localised inflammation that, over time, can hamper your kidneys' ability to filter waste from your blood
"IHC"	immunohistochemistry, a test that uses a chemical dye to stain and measure specific proteins. IHC staining for HER2 status is the most widely used initial approach for evaluating HER2 as a predictor of response to anti-HER2 therapy. The HER2 IHC test gives a score of 0 to 3+ that measures the amount of HER2 proteins on the surface of cells in a tissue sample
"IND"	investigational new drug application
"Listing Rules"	the Rules Governing the Listing of Securities on the Stock Exchange, as amended or supplemented from time to time

"LN"	lupus nephritis
"Model Code"	the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix C3 to the Listing Rules
"MG"	myasthenia gravis
"NMPA"	the National Medical Products Administration of the PRC (國家藥品監督管理局), successor to the China Food and Drug Administration or CFDA (國家食品藥品監督管理總局)
"PD-1"	programmed cell death protein 1, an immune checkpoint receptor expressed on T cells, B cells and macrophages
"pSS"	primary Sjögren's Syndrome
"RA"	rheumatoid arthritis
"Reporting Period"	the year ended December 31, 2024
"RMB"	Renminbi, the lawful currency of China
"Shareholder(s)"	holder(s) of the Shares
"Share(s)"	ordinary share(s) in the share capital of the Company, with a nominal value of RMB1.00 each, comprising the A Shares and H Shares
"SLE"	systemic lupus erythematosus, a systemic autoimmune disease in which the body's immune system attacks normal, healthy tissue and can result in symptoms such as inflammation and swelling
"wAMD"	wet age-related macular degeneration
"Stock Exchange"	The Stock Exchange of Hong Kong Limited
"Supervisor(s)"	supervisor(s) of the Company
"U.S." or "United States"	the United States of America

"USD"	United States dollars, the lawful currency of the United States
"%"	percent

By order of the Board
RemeGen Co., Ltd.*
Mr. Wang Weidong
Chairman and executive Director

Yantai, the People's Republic of China
March 27, 2025

As at the date of this announcement, the Board comprises Mr. Wang Weidong, Dr. Fang Jianmin and Mr. Lin Jian as the executive Directors, Dr. Wang Liqiang and Dr. Su Xiaodi as the non-executive Directors, and Mr. Hao Xianjing, Mr. Chen Yunjin and Mr. Huang Guobin as the independent non-executive Directors.

* *For identification purposes only*