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, 2023

The Board is pleased to announce the consolidated results of the Company for the year ended December 31, 2023, together with the comparative figures for the year ended December 31, 2022.

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 RMB1,049.2 million for the year ended December 31, 2023, representing an increase of 42.1% from RMB738.2 million in the corresponding period of last year, mainly attributable to robust year-on-year growth in sales revenue driven by higher sales volume of telitacicept (RC18, brand name: 泰爱®), a commercial-stage product for the treatment of autoimmune diseases, and disitamab vedotin (RC48, brand name: 爱地希®), a commercial-stage product for the treatment of tumours.

– Telitacicept and disitamab vedotin have been successfully renewed in the National Drug Catalogue for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (2023 Edition) in December 2023 and continued to be included in the new Catalogue of the National Reimbursement Drug List (NRDL), which became effective from January 1, 2024.

PRODUCT PIPELINE

Telitacicept (RC18, Brand Name: 泰爱®)

– In January 2023, the FDA approved the investigational new drug (IND) application for the Phase III trial of telitacicept for the treatment of generalized myasthenia gravis (gMG) and granted it a fast track designation (FTD).

– In August 2023, telitacicept obtained positive outcome from a Phase III clinical trial for the treatment of rheumatoid arthritis (RA) in China and submitted a biologics license application (BLA) to the National Medical Products Administration (NMPA).

– In November 2023, telitacicept has been formally granted full approval for marketing by the NMPA for the treatment of systemic lupus erythematosus (SLE).

– In December 2023, FDA approved the IND application for the global, multi-center Phase III trial of telitacicept for the treatment of adult patients with active primary Sjögren's Syndrome (pSS).

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

– In February 2023, the NMPA officially approved the IND application for a Phase Ib/II trial of disitamab vedotin in combination with pyrotinib maleate tablets (brand name: 艾瑞妮®) for the treatment of patients with locally advanced or metastatic non-small cell lung cancer with HER2 mutations.

– In March 2023, the CDE approved a series of IND applications for disitamab vedotin including:

  • a Phase II clinical trial of disitamab vedotin in combination with toripalimab injection (brand name: 拓益®) or letrozole as a neoadjuvant therapy for patients with HR+, HER2 low-expressing breast cancer;

  • a Phase II clinical trial of disitamab vedotin with pertuzumab (brand name: Perjeta®) in combination with or without toripalimab injection (brand name: 拓益®) as a neoadjuvant therapy for patients with HER2-positive breast cancer;

  • a Phase II study on disitamab vedotin alone or in combination with toripalimab injection (brand name: 拓益®) or sequential chemotherapy as a neoadjuvant therapy for patients with HR-, HER2 low-expressing breast cancer;

  • a Phase II/III clinical study on disitamab vedotin in combination with toripalimab injection (brand name: 拓益®) and chemotherapy or trastuzumab for injection (Herceptin) as a first-line therapy for patients with HER2-expressing locally advanced or metastatic gastric cancer (including gastroesophageal junction carcinoma).

– In July 2023, the NMPA approved the IND application for a Phase II trial of disitamab vedotin in combination with zimberelimab (brand name: 譽妥®) for the treatment of PD-1/PD-L1-treated patients with recurrent or metastatic cervical cancer expressing HER2 who have failed at least one line of standard platinum-containing therapy.

– In October 2023, the NMPA approved the IND application for a Phase II trial of disitamab vedotin in combination with toripalimab injection (brand name: 拓益®) and with or without chemotherapy (capecitabine and oxaliplatin) versus chemotherapy for the perioperative treatment of patients with resectable and HER2-expressing gastric cancer/gastroesophageal junction (GC/GEJ) adenocarcinoma.

– In October 2023, the NMPA approved 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 recurrent or metastatic HER2-expressing cervical cancer who have failed at least one line of platinum-containing chemotherapy.

– In December 2023, the NMPA approved the IND application for a Phase II/III trial of disitamab vedotin in combination with cadonilimab injection (brand name: 開坦尼®) for the treatment of patients with HER2-expressing locally advanced or metastatic GC/GEJ adenocarcinoma who have failed one line of therapy.

Other Products

– In January 2023, the Company officially launched a Phase III clinical trial of **RC28-E** for injection for the treatment of wet age-related macular degeneration (wAMD) in China.

– In March 2023, an IND application for a Phase I/IIa trial of **RC88** for injection in combination with toripalimab injection (brand name: 拓益®) for the treatment of patients with advanced malignant solid tumours was approved by the CDE.

– In April 2023, an IND application for a Phase I/IIa trial of **RC118** for injection in combination with PD-1 monoclonal antibody in Claudin18.2 expression positive locally advanced unresectable or metastatic malignant solid tumors was formally approved by the NMPA.

– In April 2023, the Company received the ethics approval from the Australia's Human Research Ethics Committee for a Phase I clinical trial of **RC198**, a Fc fusion protein of interleukin-15 (IL-15) and interleukin 15 receptor alpha (IL15Rα). A clinical study has been initiated in Australia for patients with locally advanced unresectable or metastatic solid tumors. The application for this clinical study was also approved by the NMPA in July 2023.

– In July 2023, an IND application for a phase I trial of the Company's first bispecific antibody product **RC148** as monotherapy for the treatment of patients with advanced solid tumors was formally approved by the NMPA.

– In July 2023, an IND application for a phase I trial of RC198 as monotherapy for the treatment of patients with advanced solid tumors was formally approved by the NMPA.

– In August 2023, the first patient was enrolled in a domestic Phase III clinical trial of RC28-E for the treatment of patients with diabetic macular edema (DME).

– In December 2023, an IND application for a phase II trial of RC88 for the treatment of patients with gynecologic cancers was approved by the FDA.

BUSINESS OPERATIONS

– In June 2023, Rules 18A.09 to 18A.11 of the Listing Rules ceased to be applicable to the Company as the Company satisfied the market capitalization/revenue test under Rule 8.05(3) of the Listing Rules and therefore the "B" marker was no longer affixed to the short stock names of the Company.

Following the Reporting Period,

– In January 2024, RC88 was granted the FTD by the FDA for the treatment of patients with platinum-resistant and recurrent epithelial ovarian cancer, carcinoma tubae and primary peritoneal cancer.

– 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) were 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 controllable safety profile and significant efficacy.

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

– In March 2024, Telitacicept was granted the FTD by the FDA for the treatment of adult patients with pSS.

FINANCIAL HIGHLIGHTS

- For the year ended December 31, 2023, the Company's revenue was RMB1,076.1 million and its gross profit was RMB823.0 million.
- The Company's bank balances and cash amounted to RMB726.6 million as of December 31, 2023.
- The Company incurred total expenses (including selling and distribution expenses, administrative expenses and research and development expenses) of RMB2,395.2 million for the year ended December 31, 2023, of which RMB1,306.3 million was research and development expenses.
- The research and development expenses increased by RMB324.2 million, or 33.0%, to RMB1,306.3 million in 2023.
- The loss before tax increased by RMB512.4 million, or 51.3%, to RMB1,511.2 million in 2023.
- Loss for the year increased by RMB512.4 million, or 51.3%, to RMB1,511.2 million in 2023.
- The adjusted net loss increased by RMB482.7 million, or 51.2%, to RMB1,425.7 million in 2023.

* *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.*

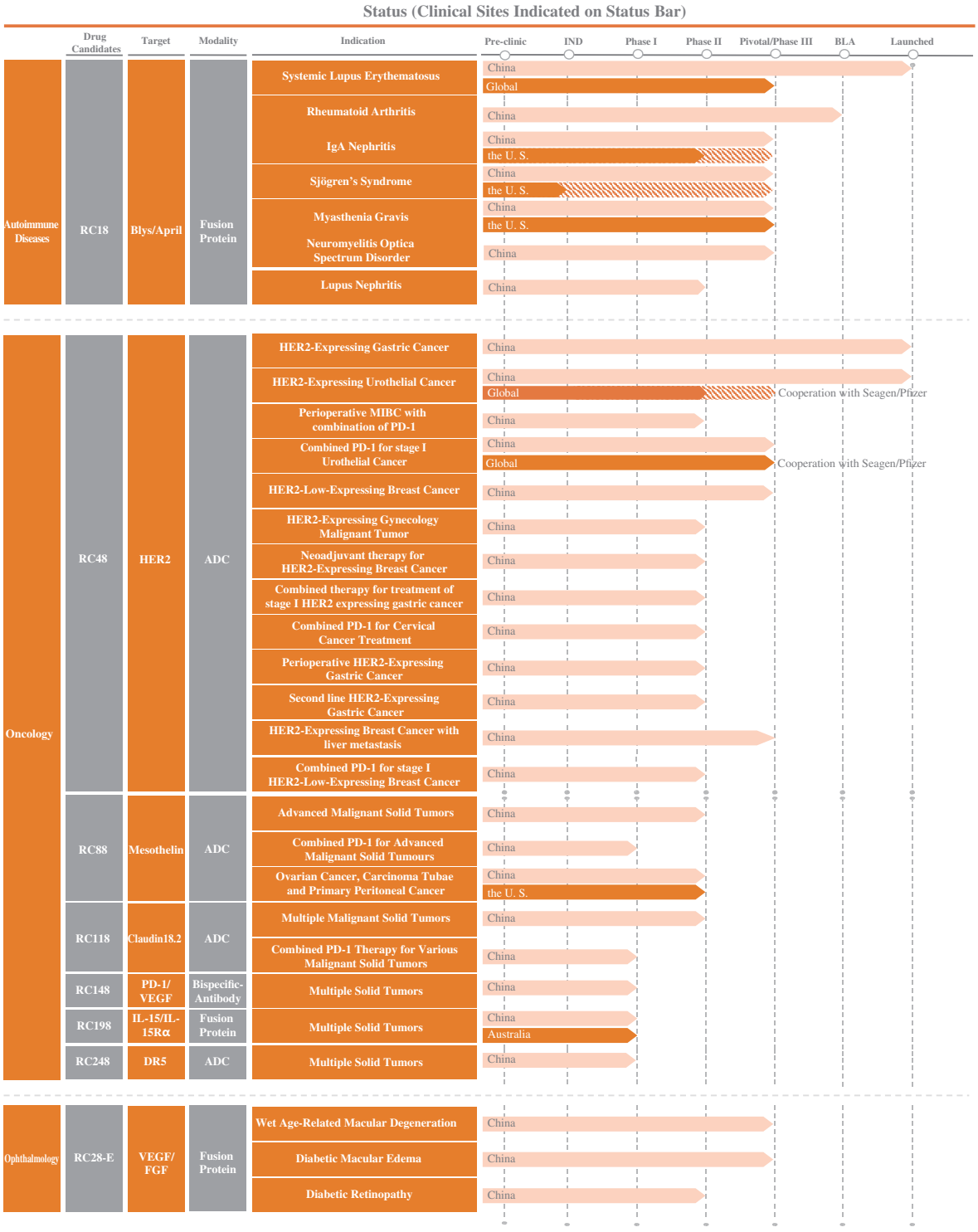
MANAGEMENT DISCUSSION AND ANALYSIS

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 commercialised 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 biologic drug 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, several are in clinical development stage targeting extensive 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 the United States.

PRODUCT PIPELINE

The following chart illustrates our pipeline and summarises the development status of our clinical-stage drug candidates as of December 31, 2023:



BUSINESS REVIEW

For the year ended December 31, 2023 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 to explore its potential in treating various autoimmune diseases that are with significant unmet medical needs.

o Systemic Lupus Erythematosus (SLE)

- *China:* We have initiated a Phase III confirmatory clinical trial in China in July 2019. We completed the trial in the third quarter of 2022 and obtained positive results. The results of the relevant clinical study were presented at the American College of Rheumatology (ACR) 2022 Annual Meeting. The supplemental information of new drug application submitted by the Company was accepted by the NMPA in early 2023 and granted full marketing approval by the NMPA in November 2023. In January 2022, telitacicept was included in the NRDL and was successfully renewed by the end of 2023. In December 2023, the results of the pivotal Phase IIb clinical study for this indication were published in the Annals of The Rheumatic Diseases, ARD, a journal with the highest impact factor in rheumatology.

- *Global:* We initiated the international, multi-centre Phase III clinical study in the United States in the first half of 2022 and received approvals from the European Union and CDE in September 2022 respectively.

- ***Rheumatoid Arthritis (RA)***

We have completed a multi-centre, 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 NMPA in August 2023 and presented the data at the ACR in November 2023.

This clinical trial was designed to evaluate the efficacy and safety of 160mg telitacicept versus placebo in RA patients with inadequate response to methotrexate (MTX). A total of 479 patients with rheumatoid arthritis were enrolled in the study, and the primary efficacy endpoint was the proportion of patients achieving an ACR20 response at week 24. The secondary efficacy endpoints include ACR50 and ACR70 response rates, components of the ACR response, DAS28-ESR, and radiological joint damage measured by mTSS at week 24.

The data showed that this Phase III clinical trial achieved the primary clinical endpoints and secondary endpoints. The results of the study demonstrated the efficacy and safety of telitacicept in patients with moderate to severe rheumatoid arthritis with inadequate response to MTX.

The data showed a significant increase in ACR20 response rate in the telitacicept group compared to the placebo group (60.0% vs 26.9%, P/span>) at week 24. ACR50 response rate in the telitacicept group was significantly higher than that in the placebo group (21.4% vs 5.9%, P/span>) at week 24. At the same time, the telitacicept group achieved better results than the placebo group in reducing DAS28-ESR from baseline and in components of the ACR response criteria. In addition, the proportion of patients without radiological progression (△mTSS≤0) was significantly higher in the telitacicept group than that in the placebo group (90.2% vs 66.4%, P/span>) at week 24. Compared with baseline, the progression of joint damage (as measured by mTSS, joint space narrowing score, and erosion score) was significantly reduced in patients in the telitacicept group at week 24.

As for the safety, the telitacicept group was similar to the placebo group in terms of treatment-related adverse events (TEAEs), serious adverse events (SAEs), TEAEs leading to discontinuation of study and treatment, and incidence of infections. There were no deaths during the study.

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

  - *China:* We completed a randomized, double-blind and placebo-controlled Phase II clinical trial, with positive results achieved. In September 2022, we reached a consensus with CDE on the protocol for a Phase III clinical trial of telitacicept for the treatment of IgAN. We initiated this Phase III clinical study in China in the first half of 2023, and the study is progressing smoothly.

  - *United States:* We communicated with the FDA regarding the use of telitacicept for the treatment of patients with IgAN in November 2022, and obtained FDA's permission to conduct a Phase III clinical trial.

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

  - *China:* We communicated with the CDE regarding the protocol of a Phase III clinical trial of telitacicept for the treatment of patients with pSS in June 2022 and reached consensus with CDE in August 2022. In the first half of 2023, we initiated this Phase III clinical study in China, and the study is progressing smoothly.

    Previously, the Company completed a Phase II clinical trial in China for treatment of pSS, and the trial results were published online in July 2023 in RHEUMATOLOGY, a leading international journal.

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

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

  - *China:* We completed a randomized, open-label Phase II clinical trial in China in the first quarter of 2022 and obtained positive results. We received breakthrough therapy designation from the CDE for the treatment of generalized myasthenia gravis (gMG) in November 2022. We initiated the Phase III clinical study in China in the first half of 2023, and as of December 31, 2023, patient enrollment has been completed.

  - *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 Phase III clinical trial study of telitacicept for the treatment of patients with generalized myasthenia gravis (gMG) and granted it an FTD.

o ***Other Indications***

In addition to the above indications, we will continue to explore and evaluate the potential of telitacicept in treating other autoimmune diseases.

– **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 tumours. Disitamab vedotin is currently being studied in multiple late-stage clinical trials in China across a variety of solid tumour types. In 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.

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-centre, 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 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 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.

- We are conducting a multi-centre, randomized and parallel controlled 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 without prior systemic chemotherapy. Such trial is progressing smoothly.

o Gastric Cancer (GC)

- The IND application for combining disitamab vedotin with PD-1 and chemotherapy or with PD-1 and Herceptin as first-line therapy for HER2-expressing locally advanced or metastatic gastric cancer (including gastroesophageal junction carcinoma) was approved by the NMPA in April 2023. This study is progressing smoothly.

- The IND application for a Phase II trial of disitamab vedotin in combination with toripalimab injection (brand name: 拓益®) and with or without chemotherapy (capecitabine and oxaliplatin) versus chemotherapy for the perioperative treatment of patients with resectable and HER2-expressing GC/GEJ adenocarcinoma was approved by the NMPA in October 2023.

- The IND application for a Phase II/III trial of disitamab vedotin in combination with cadonilimab injection (brand name: 开坦尼®) for the treatment of patients with HER2-expressing locally advanced or metastatic GC/GEJ adenocarcinoma who have failed one line of therapy was approved by the NMPA in December 2023.

o Breast Cancer (BC)

- The IND application for the Phase II trial of disitamab vedotin in combination with toripalimab injection (brand name: 拓益®) or letrozole as a neoadjuvant therapy for patients with HR-positive, HER2 low-expressing breast cancer was approved by the CDE in April 2023.

- The IND application for the Phase II trial of disitamab vedotin and pertuzumab (brand name: Perjeta®) in combination with or without toripalimab injection (brand name: 拓益®) as a neoadjuvant therapy for patients with HER2-positive breast cancer was approved by the CDE in April 2023.

- The IND application for the Phase II trial of disitamab vedotin or in combination with toripalimab injection (brand name: 拓益®) or sequential chemotherapy as a neoadjuvant therapy for patients with HR-negative, HER2 low-expressing breast cancer was approved by the CDE in April 2023.

o ***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 recurrent or metastatic cervical cancer expressing HER2 who have failed at least one line of platinum-containing chemotherapy was approved by the NMPA in October 2023.

– 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 trails of disitamab vedotin for different indications. Please refer to Pfizer's/Seagen's public information for more details.

– **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 plan to evaluate, 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.

o ***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. As of December 31, 2021, we completed patient enrollment with 37 patients in this trial. The latest 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.

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

  In the first half of 2023, we further initiated the Phase III clinical trial.

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

  We are currently conducting a multi-centre, randomized, positive-controlled Phase II clinical trial in China.

– **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. Phase I clinical trials are currently underway in patients with a variety of advanced solid tumors. It is currently in the expansion phase. 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 tumours was approved by the NMPA in March 2023. Currently, the first patient has been enrolled. In December 2023, the IND application for a Phase II trial of RC88 for the treatment of patients with gynecologic cancers was approved by the U.S. FDA.

– **RC118** is a novel Claudin18.2-targeting ADC drug that we developed to treat Claudin18.2-positive locally advanced resectable or metastatic malignant solid tumours patients. It is made by conjugating the recombinant humanised anti-Claudin18.2 monoclonal antibody and the small molecule microtubule inhibitor Monomethyl Auristatin E (MMAE) via cathepsin-cleavable linkers, and it has optimised drug-to-antibody ratio.

  - *China:* In September 2021, the Phase I clinical trial for RC118 was approved from the NMPA. We are conducting a Phase I clinical trial in patients with Claudin18.2-positive locally advanced unresectable or metastatic malignant solid tumours in China. It is currently in the expansion phase.

  - *United States:* In December 2022, the FDA granted two orphan drug designations for RC118 for the treatment of patients with gastric cancer (including gastroesophageal junction carcinoma) and pancreatic cancer.

– **RC148**: In July 2023, the Company's Phase I clinical trial study for its self-developed novel bispecific antibody RC148 (PD-1/VEGF), as monotherapy for the treatment of advanced malignant solid tumors was formally approved by the CDE. This is a multi-center, open-label Phase I clinical study designed to evaluate the safety, tolerability, maximum tolerated dose/maximum administered dose, pharmacokinetics (PK), immunogenicity, Phase II recommended dose, and preliminary antitumor efficacy of RC148. In September 2023, the first patient was enrolled.

– **RC198**: RC198 is an Fc fusion protein of interleukin-15 (IL-15) and IL-15 receptor alpha (IL-15Rα). As a member of the immuno-modulatory cytokine family, IL-15 is a potent initiator of lymphocytes and enhances the activation, proliferation, survival, cytolysis, and migration of NK cells, CD8+ effector T cells, natural killer T cells (NKT), and other lymphocytes, which has a broad-spectrum antitumor potential, and is expected to provide a new therapeutic option for cancer patients.

    • *Australia:* RC198 has received permission from Australia's Human Research Ethics Committee in April 2023 to initiate a clinical study in Australia in patients with locally advanced unresectable or metastatic solid tumors.

    • *China:* In July 2023, the Phase I IND application for RC198 injection as monotherapy for the treatment of advanced malignant solid tumors was formally approved by the CDE.

– **RC248**: RC248 is a novel DR5-targeting ADC drug for treatment of various tumors. It is under phase I dosage escalation stage. As of December 31, 2023, the first patient was enrolled.

– **Warning under Rule 18A.08(3) of the Listing Rules:** There is no assurance that the RC88, RC118, RC148, RC198 or RC248 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 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 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, 2023, telitacicept has been listed in over 800 hospitals.

Disitamab vedotin was approved for marketing by the NMPA in June 2021, and 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. Both indications were successfully renewed by the end of 2023. As of December 31, 2023, disitamab vedotin has been listed in over 650 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

– In January 2024, RC88 was granted the FTD by the FDA for the treatment of patients with platinum-resistant and recurrent epithelial ovarian cancer, carcinoma tubae and primary peritoneal cancer.

– 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) were 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 controllable 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 were disclosed via an oral presentation at the 2024 European Society of Gynaecological Oncology (ESGO) Congress.

– In March 2024, Telitacicept was granted the FTD by the FDA for the treatment of adult patients with pSS.

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 shareholder benefits and provide patients with high-quality drugs to address unmet clinical needs worldwide.

Looking ahead to 2024, 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-centre Phase III clinical trial of telitacicept for the treatment of SLE indication and initiating Phase III clinical trials for other indications in the United States. 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 RMB767.8 million in 2022 to RMB1,076.1 million in 2023. 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 tumours.

Other Income and Gains

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

Our other income and gains decreased from RMB232.5 million in 2022 to RMB110.6 million in 2023, primarily due to a decrease of RMB75.6 million in government grants, a decrease of RMB33.4 million in interest income, a decrease of RMB10.4 million in exchange income and a total decrease of RMB2.5 million in others.

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 RMB440.7 million in 2022 to RMB775.2 million in 2023, primarily due to the fact that the Company invested more in team building costs and academic promotion expenses in commercialization in order to expand the market.

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 RMB272.5 million in 2022 to RMB313.7 million in 2023, primarily due to an increase in depreciation of new plants after being transferred to fixed asset.

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 RMB982.1 million in 2022 to RMB1,306.3 million in 2023. The following table sets forth the components of our research and development expenses for the years indicated.

	Year ended December 31,			
	2023		2022	
	RMB'000	***%***	*RMB'000*	*%*
Employee benefits expenses	**459,134**	**35.1**	321,728	32.8
Raw material expenses	**232,614**	**17.8**	163,448	16.6
Clinical trial expenses	**313,355**	**24.0**	235,283	24.0
Testing expenses	**89,628**	**6.9**	86,031	8.8
Depreciation and amortisation expenses	**113,522**	**8.7**	99,271	10.1
Utilities	**25,919**	**2.0**	19,594	2.0
Others	**72,135**	**5.5**	56,725	5.7
Total	**1,306,307**	**100.0**	982,080	100.0

(i) Employee benefits expenses increased by RMB137.4 million, mainly due to an increase in the number of research and development employees and an increase in staff salary levels;

(ii) Raw material expenses increased by RMB69.2 million, mainly due to the continuous development of drug candidates;

(iii) Clinical trial expenses increased by RMB78.1 million, mainly due to the continuous clinical development of drug candidates;

(iv) Testing expenses increased by RMB3.6 million, mainly due to the differences between drug candidates development stages and the progress of research and development;

(v) Depreciation and amortisation expenses increased by RMB14.3 million, mainly due to an increase in depreciation expenses as a result of new purchases of research and development equipment due to the continuous development of drug candidates;

(vi) Other expenses increased by RMB15.4 million.

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 RMB11.1 million for the year ended December 31, 2022 and the net impairment loss on financial assets of RMB11.3 million for the year ended December 31, 2023.

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; and (iv) other expenses, including our donation to a charity organisation and the donation expenditure of telitacicept and disitamab vedotin. Our other expenses decreased from RMB16.0 million in 2022 to RMB15.2 million in 2023.

Finance Costs

The Company's finance costs mainly comprise interest on lease liabilities, interest on discounted bankers' acceptances and interest on bank borrowings. Our finance costs increased from RMB6.8 million in 2022 to RMB23.1 million in 2023, mainly due to, during the year, (i) an increase in interest on bank borrowings; (ii) an increase in interest on discounted bankers' acceptances; and (iii) an increase in interest on new lease.

Income Tax Expenses

For the years ended December 31, 2022 and 2023, the Company's income tax expenses were nil.

Loss for the Year

Based on the factors described above, the Company's loss increased from RMB998.8 million in 2022 to RMB1,511.2 million in 2023.

Liquidity and Financial Resources

Our primary use of cash is to fund research and development expenses. For the year ended December 31, 2023, our net cash used in operating activities was RMB1,501.8 million. Our cash and cash equivalents decreased from RMB2,069.2 million as of December 31, 2022 to RMB726.6 million as of December 31, 2023, mainly due to the increase of daily operation and investment expenses.

Loans and Gearing Ratio

As of December 31, 2023, the Company's interest-bearing bank borrowings were RMB1,126.9 million.

The gearing ratio is calculated using the Company's total liabilities divided by its total assets. As of December 31, 2023, the Company's gearing ratio was 37.8% (December 31, 2022: 17.3%).

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, 2023.

Capital Commitments

For the years ended December 31, 2022 and 2023, the Company had capital commitments contracted for but not yet provided of RMB467.0 million and RMB201.9 million, respectively, primarily due to completion of a majority of contracts signed in the early stage for the construction of the new plant.

Contingent Liabilities

As of December 31, 2023, 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, 2023, the Company had a total of 3,615 employees. The total remuneration cost for 2023 was RMB1,152.3 million, as compared to RMB810.7 million for 2022, primarily due to an increase in the number of employees, and an increase in their salaries and an increase in share-based compensation.

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 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, 2023.

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, 2023.

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, 2023. 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 reviewed together 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, 2023. 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, 2023 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, 2023.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS

Year ended 31 December 2023

	Notes	**2023** ***RMB'000***	2022 *RMB'000*
REVENUE	*4*	**1,076,130**	767,775
Cost of sales		**(253,136)**	(269,939)
Gross profit		**822,994**	497,836
Other income and gains	*4*	**110,564**	232,499
Selling and distribution expenses		**(775,185)**	(440,696)
Administrative expenses		**(313,673)**	(272,542)
Research and development costs		**(1,306,307)**	(982,080)
Impairment losses on financial assets, net		**(11,276)**	(11,128)
Other expenses		**(15,210)**	(15,962)
Finance costs		**(23,091)**	(6,757)
Share of the associate's profit/(loss) for the year		**(45)**	–
LOSS BEFORE TAX		**(1,511,229)**	(998,830)
Income tax expense	*5*	**–**	–
LOSS FOR THE YEAR		**(1,511,229)**	(998,830)
Attributable to:			
Owners of the parent		**(1,511,229)**	(998,830)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT	*6*		
Basic/Diluted			
– For loss for the year		**RMB(2.80)**	RMB(1.88)

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

Year ended 31 December 2023

	2023	2022
	RMB'000	*RMB'000*
LOSS FOR THE YEAR	**(1,511,229)**	(998,830)
OTHER COMPREHENSIVE INCOME		
Other comprehensive income that may be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	**(2,230)**	3,519
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	**(55,217)**	(1,799)
Income tax effect	**(1,471)**	270
	(56,688)	(1,529)
OTHER COMPREHENSIVE INCOME FOR THE YEAR, NET OF TAX	**(58,918)**	1,990
TOTAL COMPREHENSIVE INCOME FOR THE YEAR	**(1,570,147)**	(996,840)
Attributable to:		
Owners of the parent	**(1,570,147)**	(996,840)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

31 December 2023

	Notes	**31 December 2023** ***RMB'000***	31 December 2022 *RMB'000*
NON-CURRENT ASSETS			
Property, plant and equipment		**2,833,055**	2,406,750
Right-of-use assets		**251,736**	204,778
Other intangible assets		**24,294**	17,461
Investments in an associate		**2,705**	1,500
Equity investments designated at fair value through other comprehensive income		**93,522**	79,693
Pledged deposits		**638**	616
Financial assets at fair value through profit or loss		**2,000**	–
Other non-current assets		**91,360**	98,255
Total non-current assets		**3,299,310**	2,809,053
CURRENT ASSETS			
Inventories		**741,560**	522,673
Trade and bills receivables	*8*	**420,419**	281,187
Prepayments, other receivables and other assets		**323,561**	220,952
Pledged deposits		**16,841**	118,146
Cash and cash equivalents		**726,552**	2,069,180
Total current assets		**2,228,933**	3,212,138
CURRENT LIABILITIES			
Trade and bills payables	*9*	**139,331**	221,692
Other payables and accruals		**632,196**	585,840
Interest-bearing bank borrowings		**286,349**	–
Lease liabilities		**58,371**	60,154
Deferred income		**9,417**	15,348
Other current liabilities		**11,877**	9,267
Total current liabilities		**1,137,541**	892,301
NET CURRENT ASSETS		**1,091,392**	2,319,837

	31 December 2023	31 December 2022
	RMB'000	*RMB'000*
TOTAL ASSETS LESS CURRENT LIABILITIES	**4,390,702**	5,128,890
NON-CURRENT LIABILITIES		
Interest-bearing bank borrowings	**840,588**	–
Lease liabilities	**74,675**	104,881
Deferred tax liabilities	**1,511**	40
Deferred income	**36,659**	43,669
Total non-current liabilities	**953,433**	148,590
Net assets	**3,437,269**	4,980,300
EQUITY		
Equity attributable to owners of the parent		
Share capital	**544,263**	544,263
Treasury shares	**(440,310)**	(463,028)
Reserves	**3,333,316**	4,899,065
Total equity	**3,437,269**	4,980,300

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.

RemeGen Medical Research (Shanghai) Co., Ltd. was deregistered on 7 April 2023.

2. ACCOUNTING POLICIES

2.1 Basis of Preparation

These financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRSs"), (which include all International Financial Reporting Standards, International Accounting Standards ("IASB") and Interpretations) 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 stage. As at 31 December 2023, the Group had accumulated losses of RMB2,853,509,000 and net current assets of RMB1,091,392,000. The Group has prepared these financial statements on a going concern basis. 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 2023.

Basis of consolidation

The consolidated financial statements include the financial statements of the Company and its subsidiaries (collectively referred to as the "Group") for the year ended 31 December 2023. A subsidiary is an entity (including a structured entity), directly or indirectly, controlled by the Company. Control is achieved when the Company 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 Company 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 Company 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 Company'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 Company 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 Company. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Company are eliminated in full on consolidation.

The Company 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 Company 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 Company'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 Company had directly disposed of the related assets or liabilities.

2.2 Changes in Accounting Policies and Disclosures

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

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

The nature and the impact of the new and revised IFRSs that are applicable to the Company are described below:

(a) Amendments to IAS 1 require entities to disclose their material accounting policy information rather than their significant accounting policies. Accounting policy information is material if, when considered together with other information included in an entity's financial statements, it can reasonably be expected to influence decisions that the primary users of general purpose financial statements make on the basis of those financial statements. Amendments to IFRS Practice Statement 2 *Making Materiality Judgements* provide non-mandatory guidance on how to apply the concept of materiality to accounting policy disclosures. The Company has disclosed the material accounting policy information in note 2 to the financial statements. The amendments did not have any impact on the measurement, recognition or presentation of any items in the Company's financial statements.

(b) Amendments to IAS 8 clarify the distinction between changes in accounting estimates and changes in accounting policies. Accounting estimates are defined as monetary amounts in financial statements that are subject to measurement uncertainty. The amendments also clarify how entities use measurement techniques and inputs to develop accounting estimates. Since the Company's approach and policy align with the amendments, the amendments had no impact on the Company's financial statements.

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

The adoption of amendments to IAS 12 did not have any material impact on the basic and diluted earnings per share attributable to ordinary equity holders of the parent, other comprehensive income and the consolidated statements of cash flows for the years ended 31 December 2023 and 2022.

Upon the application of the amendments, the Company has determined the temporary differences arising from right-of-use assets and lease liabilities separately. However, they did not have any material impact on the overall deferred tax balances presented in the consolidated statement of financial position as the related deferred tax balances qualified for offsetting under IAS 12.

(d) Amendments to IAS 12 *International Tax Reform – Pillar Two Model Rules* introduce a mandatory temporary exception from the recognition and disclosure of deferred taxes arising from the implementation of the Pillar Two model rules published by the Organisation for Economic Co-operation and Development. The amendments also introduce disclosure requirements for the affected entities to help users of the financial statements better understand the entities' exposure to Pillar Two income taxes, including the disclosure of current tax related to Pillar Two income taxes separately in the periods when Pillar Two legislation is effective and the disclosure of known or reasonably estimable information of their exposure to Pillar Two income taxes in periods in which the legislation is enacted or substantively enacted but not yet in effect. The Company has applied the amendments retrospectively. Since the Company did not fall within the scope of the Pillar Two model rules, the amendments did not have any impact to the Company.

2.3 Issued But Not Yet Effective International Financial Reporting Standards

The Company has not applied the following revised IFRSs, that have been issued but are not yet effective, in these financial statements. The Company intends to apply these revised IFRSs, if applicable, when they become effective.

Amendments to IFRS 10 and IAS 28	*Sale or Contribution of Assets between an Investor and its Associate or Joint Venture*[3]
Amendments to IFRS 16	*Lease Liability in a Sale and Leaseback*[1]
Amendments to IAS 1	*Classification of Liabilities as Current or Non-current (the "2020 Amendments")*[1]
Amendments to IAS 1	*Non-current Liabilities with Covenants (the "2022 Amendments")*[1]
Amendments to IAS 7 and IFRS 7	*Supplier Finance Arrangements*[1]
Amendments to IAS 21	*Lack of Exchangeability*[2]

[1] Effective for annual periods beginning on or after 1 January 2024
[2] Effective for annual periods beginning on or after 1 January 2025
[3] No mandatory effective date yet determined but available for adoption

Further information about those IFRSs that are expected to be applicable to the Company is described below.

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 IFRS 16 specify the requirements that a seller-lessee uses in measuring the lease liability arising in a sale and leaseback transaction to ensure the seller-lessee does not recognise any amount of the gain or loss that relates to the right of use it retains. The amendments are effective for annual periods beginning on or after 1 January 2024 and shall be applied retrospectively to sale and leaseback transactions entered into after the date of initial application of IFRS 16 (i.e., 1 January 2019). Earlier application is permitted. The amendments are not expected to have any significant impact on the Company's financial statements.

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 to 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 amendments shall be applied retrospectively with early application permitted. An entity that applies the 2020 Amendments early is required to apply simultaneously the 2022 Amendments, and vice versa. The Company is currently assessing the impact of the amendments and whether existing loan agreements may require revision. Based on a preliminary assessment, the amendments are not expected to have any significant impact on the Company's financial statements.

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. Earlier application of the amendments is permitted. The amendments provide certain transition reliefs regarding comparative information, quantitative information as at the beginning of the annual reporting period and interim disclosures. The amendments are not expected to have any significant impact on the Company's financial statements.

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 Company's financial statements.

3. OPERATING SEGMENT INFORMATION

The Company is engaged in biopharmaceutical research, biopharmaceutical service, biopharmaceutical production and sale, which is regarded as a single reportable segment in a manner consistent with the way in which information is reported internally to the Company'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

	2023	2022
	RMB'000	*RMB'000*
Chinese Mainland	**1,049,195**	723,388
United States of America	**26,935**	44,387
Total revenue	**1,076,130**	767,775

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

(b) Non-current assets

	2023	2022
	RMB'000	*RMB'000*
Chinese Mainland	**3,129,739**	2,660,910
United States of America	**57,329**	64,865
Total non-current assets	**3,187,068**	2,725,775

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 2023, no revenue derived from a single customer accounted for 10% or more of the Company's total revenue (2022: Nil).

4. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	2023	2022
	RMB'000	*RMB'000*
Revenue from contracts with customers	**1,076,130**	767,775

Revenue from contracts with customers

(a) Disaggregated revenue information

	2023	2022
	RMB'000	*RMB'000*
Types of revenue		
Sales of goods	**1,049,195**	738,204
Service income	**26,935**	29,571
Total	**1,076,130**	767,775
Geographical markets		
Chinese Mainland	**1,049,195**	723,388
United States of America	**26,935**	44,387
Total	**1,076,130**	767,775
Timing of revenue recognition		
Goods transferred at a point in time	**1,049,195**	738,204
Services transferred over time	**26,935**	29,571
Total	**1,076,130**	767,775

(b) Performance obligations

Information about the Company'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 Company. The Company determines the progress of performance of services rendered based on labor hours spent and costs incurred in accordance with the input method. When the progress of performance is not reasonably determinable, the Company recognizes revenue based on the amount of costs incurred until the progress of performance is reasonably determinable, provided that the costs incurred by the Company 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 Company 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 Company 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 recognized at the later point of time when the customer's subsequent sales or use behavior 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:

	2023	2022
	RMB'000	*RMB'000*
Amounts expected to be recognised as revenue:		
Within one year	**11,398**	51

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

	2023	2022
	RMB'000	*RMB'000*
Other income		
Government grants*	**65,669**	141,221
Rental income	**2,667**	2,152
Bank interest income	**28,143**	61,543
Gain on disposal of financial assets at fair value through profit or loss	**7,020**	12,106
Sales of materials	**4,156**	2,182
Total other income	**107,655**	219,204
Gains		
Foreign exchange gains, net	**2,819**	13,234
Gain on disposal of property, plant and equipment	**4**	15
Others	**86**	46
Total gains	**2,909**	13,295
Total other income and gains	**110,564**	232,499

* 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 Law which was approved and became effective on 1 January 2008.

The Company has been recognised as High New Tech Enterprises in 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.

The subsidiaries incorporated in Chinese Mainland were subject to preferential tax rates of 20%, because they were regarded as "small-scaled minimal profit enterprises" during the corresponding period in 2022. 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 Company for the year is analysed as follows:

	2023	2022
	RMB'000	*RMB'000*
Current		
Charge for the year	**–**	–
Deferred	**–**	–
Total	**–**	–

A reconciliation of the tax expense applicable to (loss)/profit before tax at the statutory 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:

	2023	2022
	RMB'000	*RMB'000*
Loss before tax	**(1,511,229)**	(998,830)
Tax at the statutory tax rate	**(264,513)**	(254,487)
Lower tax rates enacted by local authority	**307,780**	148,072
Expenses not deductible for tax	**24,016**	10,180
Additional deductible allowance for research and development expenses	**(390,054)**	(194,727)
Share of the associate's profit/(loss) for the year	**11**	–
Effect of deemed sales	**1,336**	4,737
Income not subject to tax	**–**	(2,436)
Deductible temporary difference and tax losses not recognised	**321,424**	288,661
Tax charge at the Company's effective rate	**–**	–

The share of tax attributable to associates amounting to RMB11,000 (2022: Nil), is included in "Share of the associate's profit/(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 538,914,230 (2022: 530,120,137) in issue during the year, as adjusted to reflect the rights issue during the year.

The calculation of the diluted earnings per share amounts is based on the profit for the year attributable to ordinary equity holders of the parent, adjusted to reflect the interest on the convertible bonds, where applicable (see below). The weighted average number of ordinary shares used in the calculation is the number of ordinary shares in issue during the year, as used in the basic earnings 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.

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

	2023	2022
	RMB'000	*RMB'000*
Loss		
Loss attributable to ordinary equity holders of the parent, used in the basic loss per share calculation	**(1,511,229)**	(998,830)
Dilutive potential conversion expenses	**–**	–
Loss attributable to ordinary equity holders of the parent	**(1,511,229)**	(998,830)
Attributable to continuing operations	**(1,511,229)**	(998,830)

	2023	2022
Shares		
Weighted average number of ordinary shares in issue during the year used in the basic loss per share calculation	**538,914,230**	530,120,137
Effect of dilution-weighted average number of ordinary shares:		
Share awards	**959,160**	1,034,407
Total	**539,873,390**	531,154,544

7. DIVIDENDS

No dividend has been declared and paid by the Company during the year (2022:Nil).

8. TRADE AND BILLS RECEIVABLES

	2023	2022
	RMB'000	*RMB'000*
Trade receivables	**313,345**	212,664
Impairment	**(15,667)**	(10,633)
Trade receivables, net	**297,678**	202,031
Bills receivable	**122,741**	79,156
Total	**420,419**	281,187

Trade receivables mainly consist of receivables of sales of goods.

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

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

At 31 December 2023, the Company has pledged bills receivable of approximately RMB28,436,000 (2022: Nil) to secure a bank loan.

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:

	2023	2022
	RMB'000	*RMB'000*
Within 1 year	**297,678**	202,031

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

	2023	2022
	RMB'000	*RMB'000*
At beginning of year	**10,633**	121
Impairment losses, net	**7,914**	10,512
Amount written off as uncollectible	**(2,880)**	–
At end of year	**15,667**	10,633

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 are of the opinion that the ECL 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:

	2023	2022
	RMB'000	*RMB'000*
Within 3 months	**92,711**	152,195
3 to 6 months	**39,945**	57,255
6 months to 1 year	**5,425**	12,242
Over 1 year	**1,250**	–
Total	**139,331**	221,692

The Company's trade payables included RMB1,906,000 due to the Company's related parties as at 31 December 2023 (31 December 2022: RMB35,000).

Other than the trade payables due to the Company'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 important events 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, 2023 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
"A Share Offering"	the initial public offering of A Shares on March 31, 2022
"ADC"	antibody-drug conjugates, a class of biopharmaceutical drug composed of monoclonal antibodies targeted against specific tumour cell surface antigens linked, via chemical linkers, to highly potent anti-tumour small molecule agents
"Audit Committee"	the audit committee of the Board
"BLA"	biologics license application
"Board of Directors" or "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 "the 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 including 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
"ESSDAI score"	EULAR Sjögren's syndrome (SS) disease activity index, a systemic disease activity index that was designed to measure disease activity in patients with primary SS
"FDA"	U.S. Food and Drug Administration
"FISH"	fluorescence in situ hybridization, a type of in situ hybridization (ISH) test that detects the genetic material in human cells, including specific genes or portions of genes. In the case of HER2 FISH test, fluorescent labels are used to attach to the hybrid of HER2-genes and the probes and return a score of either positive (+) or negative (-)
"FTD"	fast track designation
"GC"	gastric cancer
"Group", "we", "us" or "our"	the Company and its subsidiaries
"HER2"	human epidermal growth factor receptor 2
"HR+"	hormone receptors positive
"HR-"	hormone receptors negative
"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
"HK$" or "Hong Kong dollars"	Hong Kong dollars, the lawful currency of Hong Kong
"Hong Kong"	the Hong Kong Special Administrative Region of the PRC

"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
"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, 2024

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

* *For identification purposes only*