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)

INTERIM RESULTS ANNOUNCEMENT FOR THE SIX MONTHS ENDED JUNE 30, 2023

The Board is pleased to announce the unaudited condensed consolidated interim results of the Group for the six months ended June 30, 2023, together with the comparative figures for the same period in 2022.

BUSINESS HIGHLIGHTS

During the Reporting Period, we have made significant progress in advancing our commercialization, product pipeline as well as business operations:

Commercialization

— The Group recorded revenue from product sales and research and development services of approximately RMB419.1 million for the six months ended June 30, 2023, representing an increase of 20% from RMB348.8 million in the corresponding period of last year, mainly attributable to robust year-on-year growth in sales revenue as a result of higher sales volume 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 tumours.

PRODUCT PIPELINE

Telitacicept (RC18, Brand Name: 泰爱®)

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

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

— In February 2023, the CDE officially approved the IND application for a Phase Ib/II clinical trial on disitamab vedotin (RC48, brand name: 爱地希®) 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 (RC48, brand name: 爱地希®) including:

- a Phase II clinical trial on disitamab vedotin (RC48, brand name: 爱地希®) 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;

- a Phase II clinical trial on disitamab vedotin (RC48, brand name: 爱地希®) 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 (RC48, brand name: 爱地希®) alone 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;

- a Phase II/III clinical study on disitamab vedotin (RC48, brand name: 爱地希®) 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 April 2023, the NMPA approved a Phase I IND application for disitamab vedotin (brand name: RC48, 爱地希®) in combination with radiotherapy to treat patients with HER2-expressing locally advanced solid tumors.

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 January 2023, the Company entered into a cooperation agreement on clinical development of drug combination with Shanghai Allist Pharmaceuticals Co., Ltd (stock code: 688578.SH) ("**Allist**"), pursuant to which the two parties will cooperate on clinical studies regarding the combination of RC108, a product of the Company and an ADC targeting cellular-mesenchymal epithelial transition factor (c-Met), with furmonertinib mesilate (brand name: 艾弗沙®), a product of Allist and a tyrosine kinase inhibitor (TKI).

— In March 2023, a Phase I/IIa IND application for the Company's product, 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, the application for a Phase I/IIa clinical study of the Company's product, 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 the Company's product RC198, a Fc fusion protein of interleukin-15 (IL-15) and interleukin 15 receptor alpha (IL15Rα). The Company will initiate a clinical study in Australia for patients with locally advanced unresectable or metastatic solid tumors. The Company's application for this clinical study was approved in July 2023 by the NMPA.

— In June 2023, an application for a Phase Ib/II clinical study of the Company's product, RC108, in combination with PD-1 for patients with c-Met-expressing advanced solid tumors was formally approved by the NMPA.

— In June 2023, the Company announced that it had entered into a clinical study and drug supply collaboration agreement with Innovent Biologics, Inc. (stock code: 01801.HK) to conduct drug combination studies for the Company's products, RC88 (targeting mesothelin (MSLN)) and RC108 (targeting c-Met), in combination with sintilimab injection (PD-1 inhibitor, brand name: 達伯舒®), respectively.

BUSINESS OPERATIONS

— In June 2023, Rules 18A.09 to 18A.11 of the Listing Rules ceased to be applied 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 name of the Company.

Following the Reporting Period,

— In July 2023, the NMPA approved an application for a Phase II clinical study of the Company's product disitamab vedotin (RC48, brand name: 爱地希®) 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 July 2023, the Phase I clinical study application for 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, the Phase I clinical study application for the Company's product, 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 our product RC28 for the treatment of patients with diabetic macular edema (DME).

FINANCIAL HIGHLIGHTS

— For the six months ended June 30, 2023, the total revenue of the Group reached approximately RMB419.1 million, and gross profit reached approximately RMB316.4 million.

— Bank balances and cash of the Group amounted to approximately RMB1,119.7 million as of June 30, 2023.

— The Group incurred total expenses of approximately RMB1,059.2 million for the six months ended June 30, 2023, including research and development expenses of approximately RMB540.5 million.

— The research and development expenses increased by approximately RMB90.8 million, or approximately 20.2%, to approximately RMB540.5 million.

— The loss before taxation increased by approximately RMB214.2 million, or approximately 43.8%, to approximately RMB703.4 million.

— Loss for the period increased by approximately RMB214.2 million, or approximately 43.8%, to approximately RMB703.4 million.

— The adjusted net loss* increased by approximately RMB182.2 million, or approximately 38.2%, to approximately RMB659.7 million.

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

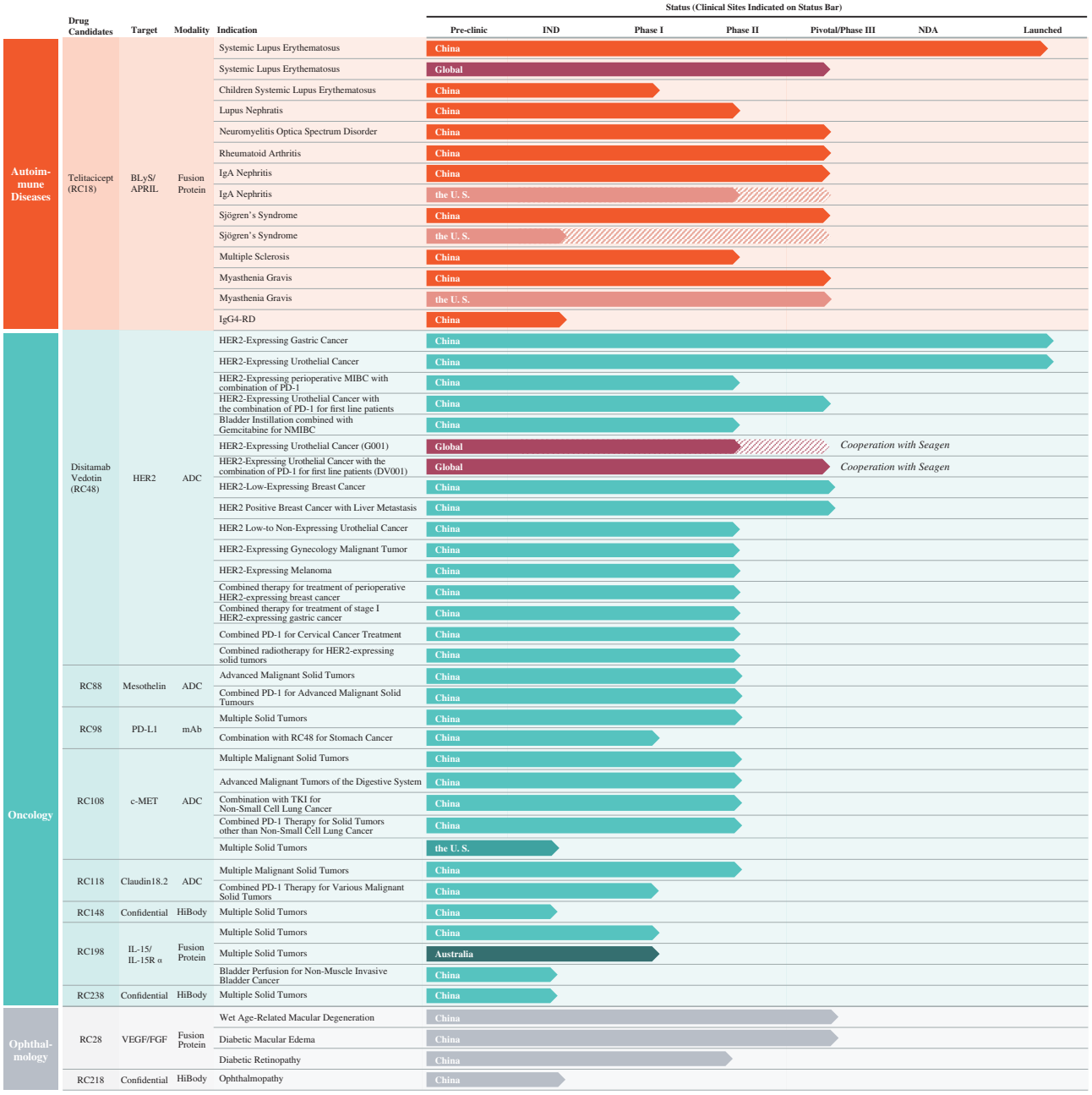
MANAGEMENT DISCUSSION AND ANALYSIS

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, seven are in clinical development stage targeting over 20 indications. Our two commercialization-stage drugs, telitacicept (RC18, brand name: 泰爱®) and disitamab vedotin (RC48, brand name: 爱地希®), are in clinical trials targeting 18 indications in China and the United States.

RICH PRODUCT PIPELINE

The following chart illustrates our pipeline and summarises the development status of our clinical-stage drug candidates and selected IND-enabling stage candidates as of June 30, 2023:



BUSINESS REVIEW

During the Reporting Period and up to the date of this announcement, the Group 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 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 order to explore its potential to address eight autoimmune diseases, in an attempt to address the significant unmet or underserved medical needs in this therapeutic area.

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 clinical findings 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 CDE earlier this Listing year.

- *China:* The IND application for telitacicept for the treatment of childhood systemic lupus erythematosus (cSLE) obtained the implied approval for a clinical trial from the CDE in April 2022. As of June 30, 2023, the first patient has been enrolled.

- *Global:* The FDA approved the IND application for Phase II trial on telitacicept in August 2019. We held an end-of-Phase II meeting with the FDA in January 2020 at which the FDA reviewed our drug candidate's data from the trials in China and discussed about the design of Phase III clinical trial. 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, with smooth progress currently.

- ***Lupus Nephritis (LN)***

  - *China:* The IND application for a Phase II trial on telitacicept for the treatment of active lupus nephritis obtained the implied approval from the CDE in September 2022. The Company has commenced this clinical study in China in the first half of 2023 and as of June 30, 2023, the first patient has been enrolled.

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

  We are conducting a multi-centre, double-blind, placebo-controlled Phase III clinical trial in China. We finished patient enrollment at the end of 2021 and completed the follow-up of the final subject at the end of 2022. We received positive results from this trial in the second quarter of 2023.

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

  - *China:* We completed a randomized, double-blind and placebo-controlled Phase II clinical trial to evaluate the efficacy and safety of telitacicept in IgAN patients, with positive results achieved. In September 2022, we reached a consensus with CDE on the protocol for a Phase III clinical trial on telitacicept for the treatment of IgAN. We further initiated this Phase III clinical study domestically in the first half of 2023, and as of June 30, 2023, the first patient has been enrolled.

  - *United States:* Telitacicept was approved by the FDA to conduct a Phase II clinical trial for the treatment of IgAN indication in the United States in December 2020. The planned total enrollment was approximately 30 patients. We communicated with the FDA regarding the use of telitacicept for the treatment of patients with IgAN in November 2022, and the FDA gave us permission to conduct an international, multi-centre Phase III clinical trial in the United States.

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

  - *China:* We communicated with the CDE regarding the protocol for a Phase III clinical trial on telitacicept for the treatment of pSS in June 2022 and reached consensus with it in August 2022. In the first half of 2023, we initiated this Phase III clinical study domestically and as of June 30, 2023, the first patient has been enrolled.

Previously, the Company completed a Phase II clinical trial in China for treatment of pSS, the results of which were published online in July 2023 in RHEUMATOLOGY, a leading international journal. This clinical trial was a randomized, double-blind and placebo-controlled Phase II clinical trial designed to evaluate the efficacy and safety of telitacicept for the treatment of adult patients with pSS. A total of 42 subjects were enrolled in the study and randomly assigned in a 1:1:1 ratio to receive placebo, 160mg of telitacicept, and 240mg of telitacicept subcutaneously once a week for 24 weeks. At week 24, the mean of the change from baseline in ESSDAI scores of each of the placebo, 160mg, and 240mg groups was 0.6±4.55 [mean (S.D.)], -3.3±2.73, -1.3±4.14, respectively. By Mixed Model for Repeated Measures (MMRM), the change in ESSDAI scores was significantly lower in the treatment group compared to the placebo group. According to placebo-adjusted least squares, the change from baseline in the ESSDAI scores at week 24 for the 160mg group was -4.3, with a p-value of 0.002. There were no deaths or serious adverse events (SAEs) in the telitacicept-treatment group throughout the treatment period.

The conclusion of the study suggests that telitacicept demonstrates a favorable clinical benefit in the treatment of patients with pSS. Compared with placebo, the telitacicept treatment group significantly improved ESSDAI scores and Multidimensional Fatigue Inventory (MFI-20) scores and reduced immunoglobulin levels in patients with pSS at weeks 12 and 24, was safely tolerated without SAEs, and there were no deaths in any of the groups during the trial period.

- *United States:* We communicated with the FDA regarding the use of telitacicept for the treatment of pSS patients in November 2022, and the FDA gave us permission to conduct an international, multi-centre Phase III clinical trial in the United States.

o 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 domestically in the first half of 2023, and as of June 30, 2023, the first patient has been enrolled.

- *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). The clinical trial is currently being initiated.

o ***Other Indications***

In addition to the above indications, we will continue to explore and evaluate the potential of telitacicept for new therapeutic areas such as IgG4-related diseases, antiphospholipid syndrome and membranous nephritis.

— Leveraging our experience in developing telitacicept for SLE globally, we will continue to explore the global path of approval and commercialization for the treatment of 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 ADC in China to have received IND approval for clinical trials. Disitamab vedotin is a novel ADC independently developed by us to treat 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).

— 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 and advanced melanoma.

o UC

- We completed a Phase II clinical trial on 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. The drug was included in the updated NRDL in January 2023.

- On June 3, 2023, the Company announced the latest results of its research on the combination with PD-1 for the treatment of locally advanced or metastatic uroepithelial cancer (la/mUC) in a poster presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting. This research is an open-label Phase Ib/II study to evaluate the safety and efficacy of disitamab vedotin in combination with toripalimab in la/mUC. This clinical study enrolled 41 patients with la/mUC, of whom 24% had liver metastases, 92.7% had HER2 expression of IHC1+ and above, and 32% were PD-L1 positive. Disitamab vedotin in combination with toripalimab demonstrated a manageable safety profile. The recommended dosage is disitamab vedotin of 2mg/kg + toripalimab of 3mg/kg every two weeks. As of November 18, 2022, the confirmed objective response rate (cORR) was 73.2% (95% confidence interval (CI): 57.1, 85.8), complete remission (CR) was 9.8%, ORR was 76.0% in primary patients, and median duration of response (DOR) was 8.2 months. In the HER2 IHC 3+/2+ and IHC 1+ subgroups, the ORR was 83.3% and 64.3%, respectively. Results showed a disease control rate (DCR) of 90.2% (95% CI: 76.9-97.3) and an overall median progress free survival (PFS) of 9.2 months (95% CI: 5.7-10.3), and the 2-year overall survival (OS) rate was 63.2%, demonstrating favorable efficacy and safety.

- 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 clinical trial on 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. At present, we are carrying out this clinical trial in China.

- We are conducting a multi-centre, randomized and 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. We planned to enroll 452 patients in this trial.

o GC

- The clinical study application of 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 CDE in April 2023.

o BC

— The Clinical Study application for the Phase II clinical study on disitamab vedotin in combination with toripalimab (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. Patient enrollment has been kicked off.

— The investigational new application for the Phase II clinical study on 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. Patient enrollment has been kicked off.

— The investigational new drug application for the Phase II clinical study on disitamab vedotin or in combination with toripalimab (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. Currently, the first patient has been enrolled.

— 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 of future cumulative net sales as Seagen subsequently continues global development and commercialization of disitamab vedotin.

- ***o UC***

  Seagen conducted an international, multi-centre, 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.

— **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

— RC28 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 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 in wAMD patients.

- ***o wAMD***

  Currently, we are conducting an open-label, single-arm Phase Ib dose-expansion trial to evaluate the efficacy and safety of RC28 in the patients with wAMD. As of December 31, 2021, we completed patient enrollment with 37 patients in this trial. The recent research results on the indication were presented at the 38th World Ophthalmology Congress (WOC 2022) in September 2022. We initiated the Phase III clinical study domestically in the first half of 2023.

- *o* ***DME***

  We are currently conducting a multi-centre, randomized, active-controlled Phase II clinical trial in China. As of December 31, 2022, we completed patient enrollment. We are now in the stage of follow-up and accumulation of clinical data. In the first half of this year, we further initiated the Phase III clinical trial.

- *o* ***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 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 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 investigational new drug application for the Phase I/II clinical study on RC88 in combination with sintilimab (brand name: 達伯舒®) for the treatment of patients with advanced malignant solid tumours was approved by the CDE in March 2023. Currently, the first patient has been enrolled.

— RC108 is our third ADC product developed in-house that has entered clinical studies. It targets c-Met-positive advanced solid tumours. c-Met is a receptor tyrosine kinase that, after binding a ligand, hepatocyte growth factor, activates a wide range of different cellular signaling pathways, including those involved in proliferation, motility, migration and invasion. It is a well-characterised oncogene that is associated with poor prognosis in many solid tumour types. We obtained clinical trial approval from the NMPA in November 2020 and have now started a Phase I clinical trial on c-Met positive advanced solid tumours in China. In addition, the FDA granted clinical trial approval in December 2022 to RC108 for the treatment of patients with c-Met-positive solid tumours. It is expanding for different indications currently.

— RC118 is our fourth ADC drug that has entered into clinical study, and it targets Claudin 18.2-positive locally advanced unresectable or metastatic malignant solid tumours. It is made by conjugating the recombinant humanised anti-Claudin18.2 monoclonal antibody and the small molecule microtubule inhibitor Monomethyl Auristatin E (MMAE) (a potent microtubule binding agent with its half-maximal inhibitory concentration (IC_{50}) in the subnanomolar range, as toxin payloads) with each other via cathepsin-cleavable linkers, and it has optimised drug-to-antibody ratio.

  • *China:* In September 2021, the Phase I clinical trial license for RC118 was obtained 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 high-dose escalation stage.

  • *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, as monotherapy for the treatment of advanced malignant solid tumors was formally approved by the CDE. This is a multi-center, open 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. Enrollment is primarily targeted at patients disease progression after standard therapy, or intolerance to standard therapy, or with locally advanced unresectable or metastatic malignant solid tumors where standard therapy is not available. RC148 is the Company's first clinically approved bispecific antibodies product.

— RC198: RC198 is an Fc fusion protein of interleukin-15 (IL-15) and IL-15 receptor alpha (IL-15R α). As a member of the interleukin common gamma chain receptor 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 clinical trial application for RC198 injection as monotherapy for the treatment of advanced malignant solid tumors was formally approved by the CDE.

— **Warning under Rule 18A.08(3) of the Listing Rules:** There is no assurance that the RC88, RC98, RC108, RC118, RC148, RC198, RC218 or RC228 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 conditional marketing by the NMPA in March 2021 and has entered into sales. This product for the treatment of SLE was included in the updated NRDL in December 2021. As of June 30, 2023, the commercialization team for autoimmune diseases had been admitted to over 600 hospitals.

Disitamab vedotin was approved for conditional marketing in June 2021, and has entered into sales in July 2021. This product for the treatment of HER2-expressing locally advanced or metastatic gastric cancer (GC) was included in the updated NRDL in December 2021. This product for the treatment of HER2-expressing locally advanced or metastatic urothelial carcinoma (UC) was included in the updated NRDL in January 2023. As of June 30, 2023, the commercialization team for autoimmune diseases had been admitted to over 600 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 and physicians in the respective therapeutic areas and further market penetration to promote the differentiated positioning and publicity of our products. In addition, we will utilise the existing clinical data to expand the promotion in the departments with approved indications and carry out extensive promotion work in departments with other indications.

KEY EVENTS AFTER THE REPORTING PERIOD

— In July 2023, the NMPA approved an application for a Phase II clinical study of the Company's product disitamab vedotin (RC48, brand name: 爱地希®) 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 July 2023, the Phase I clinical study application for 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, the Phase I clinical study application for the Company's product, 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 our product RC28 for the treatment of patients with diabetic macular edema (DME).

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 significant clinical needs worldwide.

Looking ahead to the second half of 2023, 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 for expansion in the international market, and 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 on telitacicept for the treatment of SLE indications and a phase II clinical trial for the treatment of IgAN in the United States. With regard to disitamab vedotin, we will continuously work with Seagen to support its global clinical trials.

FINANCIAL REVIEW

REVENUE

The Group's revenue increased from RMB348.8 million for the six months ended June 30, 2022 to RMB419.1 million for the six months ended June 30, 2023. The increase was mainly attributable to robust year-on-year growth in sales revenue as a result of 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 Group's other income and gains primarily consist of interest income, government grants, exchange income and wealth management income.

Our other income and gains increased from RMB53.7 million for the six months ended June 30, 2022 to RMB55.0 million for the six months ended June 30, 2023.

Selling and Distribution Expenses

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

Our selling and distribution expenses increased from RMB150.0 million for the six months ended June 30, 2022 to RMB350.2 million for the six months ended June 30, 2023, primarily due to there still being a need for continuous investment in team building costs, market development expenses, and academic promotion expenses, as a result of the expansion of the Company's sales scale and the corresponding increase in sales expenses, coupled with the fact that the commercialization capability of the Company is still in the early stage of development,

Administrative Expenses

The Group'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 RMB106.9 million for the six months ended June 30, 2022 to RMB168.6 million for the six months ended June 30, 2023, primarily due to an increase in employee expenses and depreciation of new plants after being transferred to fixed asset.

Research and Development Expenses

The Group'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 RMB449.7 million for the six months ended June 30, 2022 to RMB540.5 million for the six months ended June 30, 2023. The following table sets forth the components of our research and development expenses for the periods indicated.

	Six months ended June 30,			
	2023		2022	
	RMB'000	***%***	*RMB'000*	*%*
	(Unaudited)		(Unaudited)	
Employee benefits expenses	**206,661.6**	**38.2**	153,040.5	34.0
Raw material expenses	**73,286.7**	**13.6**	63,470.1	14.1
Clinical trial expenses	**124,038.3**	**23.0**	96,753.7	21.5
Testing expenses	**38,050.2**	**7.0**	44,158.6	9.8
Depreciation and amortisation expenses	**54,116.3**	**10.0**	47,524.1	10.6
Utilities	**10,314.8**	**1.9**	9,167.0	2.0
Others	**33,985.0**	**6.3**	35,557.8	8.0
Total	**540,452.9**	**100.0**	449,671.8	100.0

(i) Employee benefits expenses increased by RMB53.6 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 RMB9.8 million, mainly due to the continuous development of drug candidates;

(iii) Clinical trial expenses increased by RMB27.3 million, mainly due to the continuous clinical development of drug candidates;

(iv) Testing expenses decreased by RMB6.1 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 RMB6.6 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 decreased by RMB1.6 million.

Impairment Losses on Financial Assets, Net

The Group'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 RMB5.6 million for the six months ended June 30, 2022 and the net impairment loss on financial assets of RMB4.1 million for the six months ended June 30, 2023, mainly due to the timely collection of trade receivables from product sales at the end of last year in the current period and the decrease in the additional impairment loss for the period.

Other Expenses

The Group'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 RMB9.8 million for the six months ended June 30, 2022 to RMB5.5 million for the six months ended June 30, 2023, mainly due to a decline in donation expenditure of telitacicept and disitamab vedotin of RMB4.6 million but an increase in others of RMB0.3 million in total.

Finance costs

The Group's finance costs mainly comprise interest on lease liabilities, interest on discounted bankers' acceptances and interest on bank borrowings. Our financial costs increased from RMB2.2 million for the six months ended June 30, 2022 to RMB6.0 million for the six months ended June 30, 2023, mainly due to, during the Reporting Period, (i) an increase in interest on new lease; and (ii) an increase in interest on discounted bankers' acceptances.

Income Tax Expenses

For the six months ended June 30, 2022 and 2023, the Group's income tax expenses were nil.

Loss for the Period

Based on the factors described above, the Group's loss for the period increased from RMB489.1 million for the six months ended June 30, 2022 to RMB703.4 million for the six months ended June 30, 2023.

Liquidity and Financial Resources

Our primary use of cash is to fund research and development expenses. For the six months ended June 30, 2023, our net cash used in operating activities was RMB724.1 million. Our cash and cash equivalents decreased from RMB2,069.2 million as at December 31, 2022 to RMB1,119.7 million as at June 30, 2023, mainly due to the increase of daily operation and investment expenses.

Loans and Gearing Ratio

As of June 30, 2023, the Group's interest-bearing bank and other borrowings were RMB542.8 million.

The gearing ratio is calculated using the Group's total liabilities divided by its total assets. As of June 30, 2023, the Group's gearing ratio was 26.3% (December 31, 2022: 17.3%).

Significant Investments, Material Acquisitions and Disposal

The Group did not have any significant investments or material acquisitions or disposals of subsidiaries, associates and joint ventures for the six months ended June 30, 2023.

Capital Commitments

As of December 31, 2022 and June 30, 2023, the Group had capital commitments contracted for but not yet provided of RMB467.0 million and RMB233.3 million, respectively, primarily in connection with (i) contracts entered with contractors for the construction of our new manufacturing facilities; and (ii) contracts entered with suppliers for the purchase of equipment.

Contingent Liabilities

As of June 30, 2023, the Group 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 June 30, 2023, the Group had a total of 3,591 employees. The total remuneration cost for the six months ended June 30, 2023 was approximately RMB571.7 million, as compared to RMB335.3 million for the six months ended June 30, 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 Group provides continuing education and training programs, including internal and external training, for our employees to improve their technical, professional or management skills. The Group 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 the 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 six months ended June 30, 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 six months ended June 30, 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 six months ended June 30, 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 Interim Financial Results

The independent auditor of the Company, namely, Ernst & Young, has carried out a review of the interim financial information in accordance with the Hong Kong Standard on Review Engagements 2410, "Review of Interim Financial Information Performed by the Independent Auditor of the Entity" issued by the Hong Kong Institute of Certified Public Accountants. The Audit Committee has reviewed together with the Company's management and independent auditor the accounting principles and policies adopted by the Group and the Group's financial reporting matters (including reviewing of the unaudited condensed consolidated interim results for the six months ended June 30, 2023). The Audit Committee considered that the interim results are in compliance with the applicable accounting standards, laws and regulations, and the Company has made appropriate disclosures thereof.

Interim Dividend

The Board does not recommend the payment of an interim dividend for the six months ended June 30, 2023.

INTERIM CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS

For the six months ended 30 June 2023

	Notes	**2023 (Unaudited) *RMB'000***	2022 (Unaudited) *RMB'000*
REVENUE	*5*	**419,073**	348,779
Cost of sales		**(102,655)**	(167,505)
Gross profit		**316,418**	181,274
Other income and gains		**55,013**	53,676
Selling and distribution expenses		**(350,168)**	(149,961)
Administrative expenses		**(168,609)**	(106,919)
Research and development costs		**(540,453)**	(449,672)
Impairment losses on financial assets, net		**(4,108)**	(5,595)
Other expenses		**(5,458)**	(9,754)
Finance costs		**(5,997)**	(2,175)
LOSS BEFORE TAX		**(703,362)**	(489,126)
Income tax expense	*6*	**–**	–
LOSS FOR THE PERIOD		**(703,362)**	(489,126)
Attributable to:			
Owners of the parent		**703,362**	(489,126)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT	*8*		
Basic/diluted			
— For loss for the period		**(1.30)**	(0.96)

INTERIM CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

For the six months ended 30 June 2023

	2023	2022
	(Unaudited)	(Unaudited)
	RMB'000	*RMB'000*
LOSS FOR THE PERIOD	**(703,362)**	(489,126)
OTHER COMPREHENSIVE (LOSS)/INCOME		
Other comprehensive income that may be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	**1,469**	2,496
Other comprehensive (loss)/income that will not be reclassified to profit or loss in subsequent periods:		
Equity investments designated at fair value through other comprehensive income:	**(7,131)**	–
Changes in fair value	**(8,389)**	–
Income tax effect	**1,258**	–
OTHER COMPREHENSIVE (LOSS)/INCOME FOR THE PERIOD, NET OF TAX	**(5,662)**	2,496
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD	**(709,024)**	(486,630)
Attributable to:		
Owners of the parent	**(709,024)**	(486,630)

INTERIM CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

30 June 2023

	Notes	**30 June 2023 (Unaudited) *RMB'000***	31 December 2022 (Audited) *RMB'000*
NON-CURRENT ASSETS			
Property, plant and equipment		**2,588,379**	2,406,750
Right-of-use assets		**198,206**	204,778
Other intangible assets		**22,190**	17,461
Investment in an associate		**2,706**	1,500
Equity investments designated at fair value through other comprehensive income		**81,304**	79,693
Deferred tax assets		**1,218**	–
Pledged deposits		**639**	616
Other non-current assets		**175,586**	98,255
Total non-current assets		**3,070,228**	2,809,053
CURRENT ASSETS			
Inventories		**708,468**	522,673
Trade and bills receivables	*9*	**234,294**	281,187
Prepayments, other receivables and other assets		**293,233**	220,952
Financial assets at fair value through profit or loss		**261,111**	–
Pledged deposits		**144,118**	118,146
Cash and cash equivalents		**1,119,661**	2,069,180
Total current assets		**2,760,885**	3,212,138
CURRENT LIABILITIES			
Trade and bills payables	*10*	**262,042**	221,692
Other payables and accruals		**511,512**	585,840
Interest-bearing bank and other borrowings		**11,849**	–
Lease liabilities		**61,867**	60,154
Deferred income		**16,313**	15,348
Other current liabilities		**7,687**	9,267
Total current liabilities		**871,270**	892,301

	30 June 2023 (Unaudited) *RMB'000*	31 December 2022 (Audited) *RMB'000*
NET CURRENT ASSETS	**1,889,615**	2,319,837
TOTAL ASSETS LESS CURRENT LIABILITIES	**4,959,843**	5,128,890
NON-CURRENT LIABILITIES		
Interest-bearing bank and other borrowings	**530,929**	–
Lease liabilities	**96,925**	104,881
Deferred tax liabilities	**–**	40
Deferred income	**36,837**	43,669
Total non-current liabilities	**664,691**	148,590
Net assets	**4,295,152**	4,980,300
EQUITY		
Equity attributable to owners of the parent		
Share capital	**544,263**	544,263
Treasury shares	**(396,758)**	(463,028)
Reserves	**4,147,647**	4,899,065
Total equity	**4,295,152**	4,980,300

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

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 current period, the Company and its subsidiaries (the "Group") were principally engaged in biopharmaceutical research, biopharmaceutical services, 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") 14,000,000	100%	–	Research and development
RemeGen Medical Research (Shanghai) Co., Ltd. (榮昌生物醫藥研究(上海)有限公司)*#	Shanghai, PRC 20 May 2020	RMB8,000,000	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 names of these subsidiaries represent the best efforts made by the management of the Company to translate the Chinese names as they do not have official English names 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. BASIS OF PREPARATION

The interim condensed consolidated financial information for the six months ended 30 June 2023 has been prepared in accordance with IAS 34 *Interim Financial Reporting*. The interim condensed consolidated financial information does not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Group's annual consolidated financial statements for the year ended 31 December 2022.

3. CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The accounting policies adopted in the preparation of the interim condensed consolidated financial information are consistent with those applied in the preparation of the Group's annual consolidated financial statements for the year ended 31 December 2022, except for the adoption of the following new and revised International Financial Reporting Standards ("IFRSs") for the first time for the current period's financial information.

IFRS 17	*Insurance Contracts*
Amendments to IFRS 17	*Insurance Contracts*
Amendment to IFRS 17	*Initial Application of IFRS 17 and IFRS 9 — Comparative Information*
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 impact of the new and revised IFRSs that are applicable to the Group 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 HKFRS Practice Statement 2 provide non-mandatory guidance on how to apply the concept of materiality to accounting policy disclosures. The Group has applied the amendments since 1 January 2023. The amendments did not have any impact on the Group's interim condensed consolidated financial information but are expected to affect the accounting policy disclosures in the Group's annual consolidated 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. The Group has applied the amendments to changes in accounting policies and changes in accounting estimates that occur on or after 1 January 2023. Since the Group's policy of determining accounting estimates aligns with the amendments, the amendments did not have any impact on the financial position or performance of the Group.

(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 Group has applied the amendments on temporary differences related to leases as at 1 January 2022, with any cumulative effect recognised as an adjustment to the balance of retained profits or other component of equity as appropriate at that date. In addition, the Group has applied the amendments prospectively to transactions other than leases that occurred on or after 1 January 2022, if any.

The adoption of amendments to IAS 12 did not have any impact on the basic and diluted earnings per share attributable to ordinary equity holders of the parent, other comprehensive income and the interim condensed consolidated statements of cash flows for the six months ended 30 June 2023 and 2022.

(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. Entities are required to disclose the information relating to their exposure to Pillar Two income taxes in annual periods beginning on or after 1 January 2023, but are not required to disclose such information for any interim periods ending on or before 31 December 2023. The Group has applied the amendments retrospectively. Since the Group did not fall within the scope of the Pillar Two model rules, the amendments did not have any impact to the Group.

4. OPERATING SEGMENT INFORMATION

The Group is engaged in biopharmaceutical research, biopharmaceutical services, 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

	For the six months ended 30 June	
	2023	2022
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Mainland China	**416,118**	328,668
USA	**2,955**	20,111
	419,073	348,779

(b) Non-current assets

	30 June 2023	31 December 2022
	RMB'000	*RMB'000*
	(Unaudited)	(Audited)
Mainland China	**2,924,883**	2,660,910
USA	**63,402**	64,865
	2,988,285	2,725,775

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

5. REVENUE

An analysis of revenue is as follows:

	For the six months ended 30 June	
	2023	2022
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Revenue from contracts with customers		
Sales of goods	**416,118**	328,668
Service income	**2,955**	20,111
	419,073	348,779

Disaggregated revenue information for revenue from contracts with customers

	For the six months ended 30 June	
	2023	2022
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Geographical markets		
Mainland China	**416,118**	328,668
USA	**2,955**	20,111
	419,073	348,779

	For the six months ended 30 June	
	2023	2022
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Timing of revenue recognition		
Transferred at a point in time	**416,118**	348,779
Transferred over time	**2,955**	–
	419,073	348,779

6. INCOME TAX EXPENSES

The provision for corporate income tax in Mainland China 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 a High New Tech Enterprise 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 Mainland China were subject to preferential tax at a rate of 20%, because they were regarded as "small-scaled minimal profit enterprises" during the corresponding period.

The subsidiary incorporated in the USA is subject to America federal and California state income taxes. America federal income tax was provided at the rate of 21% and California income tax was provided at the rate of 8.84% during the six months ended 30 June 2023 on the estimated assessable profits arising in the USA.

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 during the six months ended 30 June 2023. No provision for Hong Kong profits tax has been made as the Group has no assessable profits derived from or earned in Hong Kong during the six months ended 30 June 2023.

The subsidiary incorporated in South Australia is subject to South Australia profits tax at the rate of 25% when the aggregated turnover is under the threshold of AUD50 million, or at the rate of 30% when the aggregated turnover is over AUD50 million. No provision for South Australia profits tax has been made as the Group had no assessable profits derived from or earned in South Australia during the six months ended 30 June 2023.

No current income tax and deferred income tax was charged for the six months ended 30 June 2023 (six months ended 30 June 2022: nil).

7. DIVIDENDS

No dividend has been declared and paid by the Company during the six months ended 30 June 2023 (six months ended 30 June 2022: nil).

8. 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 reporting period attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares in issue during the reporting period.

The calculation of the diluted earnings per share amounts is based on the loss for the period 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 period, 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:

	For the six months ended 30 June	
	2023	2022
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Loss		
Loss attributable to ordinary equity holders of the parent, used in the basic loss per share calculation	**(703,362)**	(489,126)
Dilutive potential conversion expenses	**–**	–
Loss attributable to ordinary equity holders of the parent Attributable to continuing operations	**(703,362)**	(489,126)

	Number of shares For the six months ended 30 June	
	2023	2022
	(Unaudited)	(Unaudited)
Shares		
Weighted average number of ordinary shares in issue during the period used in the basic loss per share calculation	**539,347,672**	511,374,317
Effect of dilution — weighted average number of ordinary shares:		
Share awards	**256,603**	–
	539,604,275	511,374,317

9. TRADE AND BILLS RECEIVABLES

	30 June 2023	31 December 2022
	RMB'000	*RMB'000*
	(Unaudited)	(Audited)
Trade receivables	**161,013**	212,664
Impairment	**(8,051)**	(10,633)
Trade receivables, net	**152,962**	202,031
Bills receivable	**81,332**	79,156
	234,294	281,187

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 3 months.

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

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:

	30 June 2023	31 December 2022
	RMB'000	*RMB'000*
	(Unaudited)	(Audited)
Within 1 year	**152,962**	202,031

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

	For the six months ended 30 June	
	2023	2022
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
At 1 January	**10,633**	121
Impairment losses, net	**298**	5,070
Amount written off as uncollectible	**(2,880)**	–
At 30 June	**8,051**	5,191

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.

10. TRADE AND BILLS PAYABLES

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

	30 June 2023	31 December 2022
	RMB'000	*RMB'000*
	(Unaudited)	(Audited)
Within 3 months	**192,348**	152,195
3 to 6 months	**64,354**	57,255
6 months to 1 year	**3,019**	12,242
Over 1 year	**2,321**	–
	262,042	221,692

11. EVENTS AFTER THE REPORTING PERIOD

There are no material subsequent events undertaken by the Company or by the Group after 30 June 2023.

PUBLICATION OF INTERIM RESULTS ANNOUNCEMENT AND INTERIM REPORT

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

The interim report for the six months ended June 30, 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.

DEFINITIONS AND GLOSSARY

"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 tumour cell surface antigens linked, via chemical linkers, to highly potent anti-tumour small molecule agents
"Audit Committee"	the audit committee of the Board
"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 as set out in Appendix 14 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
"Director(s)"	the director(s) of the Company
"CDE"	the Center for Drug Evaluation of China's National Medical Products Administration
"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 hydridization (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 (-)
"GC"	gastric cancer
"Group", "we", "us" 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 our Company, with a nominal value of RMB1.00 each, which are listed on the Stock Exchange
"HK$"	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
"Listing Rules"	the Rules Governing the Listing of Securities on the Stock Exchange, as amended or supplemented from time to time
"Model Code"	the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix 10 to the Listing Rules
"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
"PD-L1"	PD-1 ligand 1, which is a protein on the surface of a normal cell or a cancer cell that binds to its receptor, PD-1, on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell
"Reporting Period"	the six months ended June 30, 2023
"RMB" or "Renminbi"	Renminbi, the lawful currency of the PRC
"Shareholder(s)"	holder(s) of the Share(s)

"Share(s)"	ordinary share(s) in the capital of the Company with a nominal value of RMB1.00 each, comprising 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
"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
August 21, 2023

As at the date of this announcement, the Board 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*