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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, 2022

The Board is pleased to announce the consolidated results of the Group for the year ended December 31, 2022, together with the comparative figures for the year ended December 31, 2021.

FINANCIAL HIGHLIGHTS

- For the year ended December 31, 2022, the Group's revenue was approximately RMB767.8 million and its gross profit was approximately RMB497.8 million.
- Bank balances and cash amounted to approximately RMB2,069.2 million as of December 31, 2022.
- The Group incurred total expenses (including selling and distribution expenses, administrative expenses and research and development expenses) of approximately RMB1,695.3 million for the year ended December 31, 2022, of which approximately RMB440.7 million was selling and distribution expenses, approximately RMB272.5 million was administrative expenses and approximately RMB982.1 million was research and development expenses.
- The research and development expenses increased by approximately RMB271.1 million, or approximately 38.1%, to approximately RMB982.1 million in 2022.

- The (loss)/profit before tax changed from a profit before tax of approximately RMB276.3 million in 2021 to a loss of approximately RMB998.8 million in 2022.
- (Loss)/profit for the year changed from a profit of approximately RMB276.3 million in 2021 to a loss of approximately RMB998.8 million in 2022.
- The adjusted (loss)/profit changed from a profit of approximately RMB295.5 million in 2021 to a loss of approximately RMB943.0 million in 2022.

* *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 payment expenses.*

BUSINESS HIGHLIGHTS

We have made significant progress in our commercialisation, product pipeline and business operations last year:

COMMERCIALISATION

- The Group recorded sales revenue of RMB738.4 million for the year ended December 31, 2022, a year-on-year increase of 462.4% from RMB131.3 million in 2021, largely because of robust year-on-year growth in sales volume and sales revenue from 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, after the two drugs were included into the National Reimbursement Drug List (NRDL).
- As of December 31, 2022, the commercialisation teams of telitacicept (RC18, brand name: 泰爱®) and disitamab vedotin (RC48, brand name: 爱地希®) had 639 and 520 members respectively, versus 132 and 180 members as of the end of December 31, 2021.
- As of January 31, 2023, disitamab vedotin (RC48, brand name: 爱地希®) (i) for the treatment of patients with HER2-expressing locally advanced or metastatic gastric cancer (GC) (including gastroesophageal junction adenocarcinoma); and (ii) for the treatment of patients with HER2-expressing locally advanced or metastatic urothelial cancer (UC), have both been included in the updated NRDL. Disitamab vedotin for the treatment of UC was included into the NRDL for the first time following the grant of marketing approval from NMPA in China at the end of 2021. The new price will take effect from March 1, 2023.

PRODUCT PIPELINE

Telitacicept (RC18, Brand Name: 泰爱®)

- The Company initiated an international, multi-centre Phase III clinical trial on telitacicept for the treatment of systemic lupus erythematosus (SLE) in the United States in the first half of 2022 and received further European Union and CDE approval in September 2022. Global patient enrollment is currently underway.
- The Company completed the Phase III confirmatory clinical trial on telitacicept for the treatment of systemic lupus erythematosus in China in September 2022 and obtained positive results which were presented at the American College of Rheumatology (ACR) Annual Meeting in November 2022.
- The Company's investigational new drug (IND) application for telitacicept for the treatment of childhood-onset systemic lupus erythematosus (cSLE) obtained the implied approval for a clinical trial from the CDE in April 2022.
- The Company's IND application for a Phase II clinical trial on telitacicept for the treatment of active lupus nephritis obtained the implied approval from the CDE in September 2022.
- The Company filed an application for communication on the protocol for a Phase III clinical trial on telitacicept for the treatment of immunoglobulin A nephropathy (IgAN) to the CDE in June 2022 and reached consensus with the CDE in September 2022. The Company communicated with the FDA on this indication in November 2022, and the FDA gave it permission to conduct an international, multi-centre Phase III clinical trial in the United States.
- The Company had a discussion with the CDE about the protocol for a Phase III clinical trial on telitacicept for the treatment of primary Sjögren's Syndrome (pSS) in June 2022 and reached consensus with the CDE in August 2022. The Phase III clinical trial kicked off in China at the end of 2022. In addition, the Company communicated with the FDA on this indication in November 2022, and the FDA gave it permission to conduct an international, multi-centre Phase III clinical trial in the United States.

- The Company completed the Phase II clinical trial for telitacicept for the treatment of generalised myasthenia gravis (gMG) in China in February 2022 and obtained positive results. Its protocol for the Phase III clinical study was approved by NMPA’s Center for Drug Evaluation (CDE) in October 2022. The clinical study is currently being conducted in China. In October 2022, the U.S. Food and Drug Administration (FDA) granted orphan drug designation for telitacicept for the treatment of generalised myasthenia gravis (gMG). The product received breakthrough therapy designation for the treatment of gMG in November 2022.

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

- The IND application for disitamab vedotin in combination with toripalimab injection (brand name: 拓益®) for the treatment of perioperative muscle invasive bladder cancer (MIBC) obtained the implied approval for a clinical trial from the CDE in February 2022. The clinical trial kicked off in April 2022. Patient enrollment is now underway.
- The IND application for disitamab vedotin in combination with RC98 for injection for the treatment of HER2-expressing locally advanced or metastatic gastric cancer (including gastroesophageal junction adenocarcinoma) obtained the implied approval for a clinical trial from the CDE in April 2022. The clinical trial kicked off in August 2022. Patient enrollment is going on smoothly.
- In April 2022, disitamab vedotin was officially included into the Guidelines of Chinese Society of Clinical Oncology (CSCO) on Gastric Cancer (2022) as a Level II recommendation for the treatment of patients with HER2-positive gastric cancer who receive third-line and later-line therapies.
- The IND application for disitamab vedotin in combination with RC98 for injection for the treatment of HER2-expressing locally advanced or metastatic solid tumours obtained the implied approval for a clinical trial from the CDE in June 2022. The clinical trial kicked off in August 2022. Patient enrollment is going on smoothly.
- Disitamab vedotin was presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2022, with the latest advances in the treatment of patients with HER2-low-expressing locally advanced or metastatic urothelial cancer, HER2-overexpressing metastatic urothelial cancer, and locally advanced or metastatic urothelial cancer in combination with toripalimab in the form of wall posters.

- In November 2022, disitamab vedotin was officially recommended as a first-line therapy in the Guidelines of Chinese Society of Clinical Oncology (CSCO) on Urothelial Cancer (2022). At this point, disitamab vedotin was included into the Guidelines as a Level III recommendation for first-line therapy of advanced uroepithelial carcinoma (mUC) and a Level II recommendation for second and third line therapy, i.e., a full-line treatment recommendation.
- The IND application for disitamab vedotin for injection, given as an intravenous infusion, in combination with gemcitabine hydrochloride for injection, given through intravesical instillation, for the treatment of bacillus calmette-guerin (BCG)-unvaccinated or BCG-unresponsive patients with high-risk non-muscle invasive bladder cancer (NMIBC) obtained the implied approval for a clinical trial from the CDE in December 2022.

Other products

- RC28-E injection was presented at the 38th World Ophthalmology Congress (WOC 2022) in September 2022, with recent research results on its treatment of wet age-related macular degeneration (wAMD).
- The FDA granted clinical trial approval to RC108 for injection, an antibody-drug conjugate (ADC), for the treatment of patients with c-Met-positive solid tumours in December 2022.
- RC118 for injection, an ADC, received orphan drug designations from the FDA in December 2022 for the treatment of patients with gastric cancer (including gastroesophageal junction adenocarcinoma) and pancreatic cancer respectively.

BUSINESS OPERATIONS

- The Company completed A Share Offering, and A shares were listed and traded on the Science and Technology Innovation Board of the Shanghai Stock Exchange on March 31, 2022.

Following the reporting period,

- the FDA approved the IND application for the Phase III clinical trial on telitaccept for the treatment of gMG and granted fast-track designation to the drug in January 2023.
- The Company officially initiated a Phase III clinical trial on RC28-E injection for the treatment of wAMD in China in January 2023.
- 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), pursuant to which the parties will cooperate on clinical studies on the development of combinations consisting of RC108, an ADC targeting cellular-mesenchymal epithelial transition factor (c-Met), and furmonertinib mesilate tablets (brand name: 艾弗沙®), a tyrosine kinase inhibitor (TKI).
- In February 2023, the CDE officially approved the IND application for a Phase Ib/II clinical trial on a combination of disitamab vedotin (RC48, brand name: 爱地希®) and 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 range of IND applications for disitamab vedotin (RC48, brand name: 爱地希®) including:
 - 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®) 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;
- disitamab vedotin (RC48, brand name: 爱地希®) in combination with toripalimab injection (brand name: 爱地希®) and chemotherapy or trastuzumab for injection (Herceptin) as a first-line therapy for patients with HER2-expressing locally advanced or metastatic gastric cancer (GEJ carcinoma)

— In March, 2023, the CDE approved an IND application for the Phase I/IIa clinical trial on RC88 for Injection, the Company's product, in combination with toripalimab injection (brand name: 拓益®) for patients with advanced malignant solid tumors.

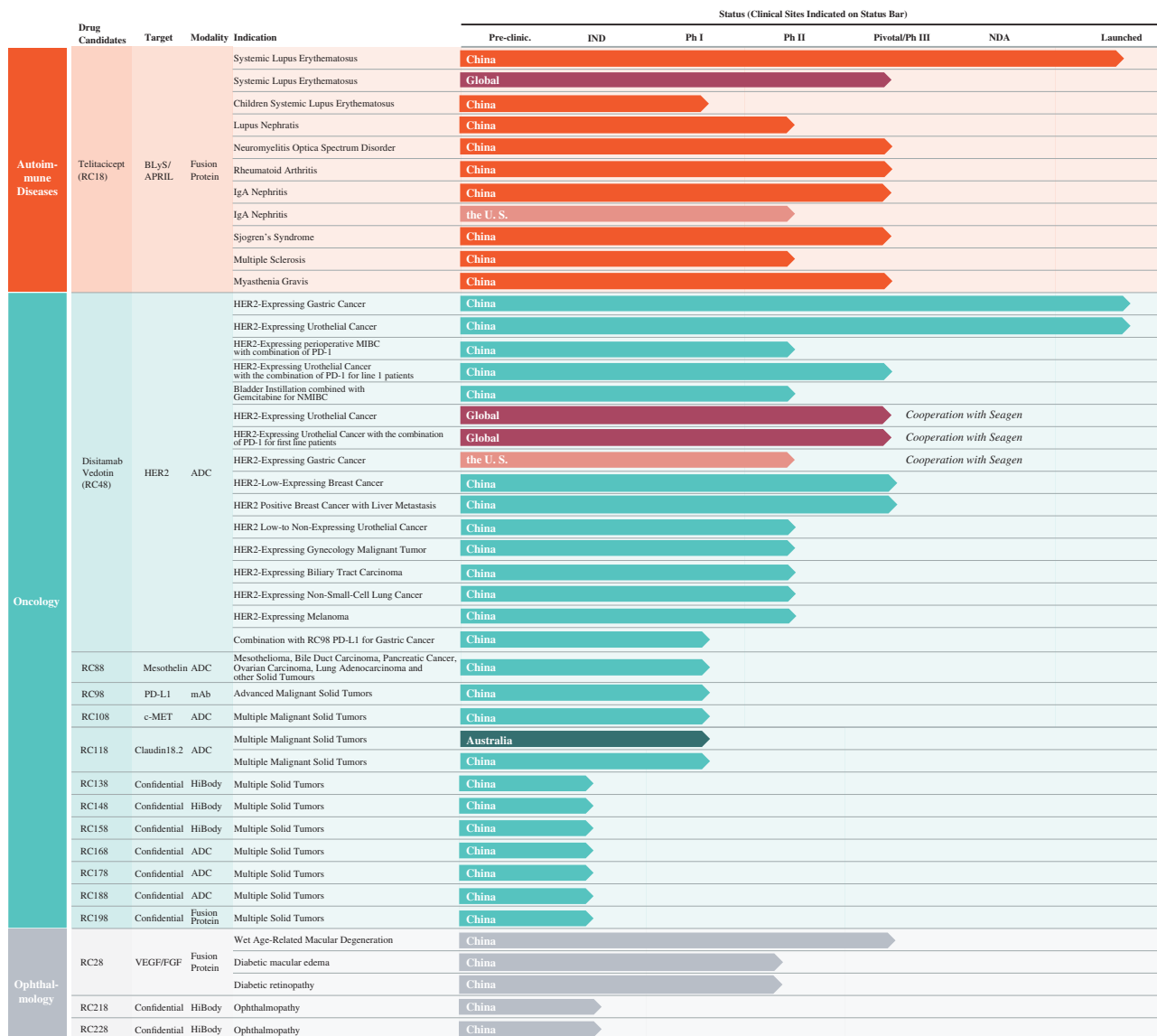
MANAGEMENT DISCUSSION AND ANALYSIS

OVERVIEW

We are a fully-integrated biopharmaceutical company committed to the discovery, development and commercialisation 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. Two of our commercialisation-stage drugs, telitacicept (RC18, brand name: 泰爱®) and disitamab vedotin (RC48, brand name: 爱地希®), are in clinical trials targeting eighteen 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 and selected IND-enabling stage candidates as of December 31, 2022:



BUSINESS REVIEW

For the year ended December 31, 2022 and up to the date of this announcement, the Group has made the following significant progress:

Telitacept (RC18 , brand name: 泰爱®)

- Telitacept 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). Telitacept 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 telitacept 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 SLE

- *China:* Telitacept for the treatment of moderate to severe SLE showing unsatisfactory response to standard therapy was granted the conditional marketing approval from the NMPA on March 9, 2021. Based on the completed Phase IIb registrational trial in 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.
- *China:* The IND application for telitacept for the treatment of cSLE obtained the implied approval for a clinical trial from the CDE in April 2022.

- *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 the drug candidate’s positive data from our trials in China and discussed the design for the Phase III clinical trial. Based on this meeting, the FDA allowed us to conduct the Phase III clinical study on telitacicept for the treatment of SLE in the United States. In April 2020, the FDA granted fast track designation to telitacicept, which could expedite the review and potential approval process with the FDA. We initiated the international, multi-centre Phase III clinical study in the United States in the first half of 2022 and received approval from the European Union and CDE in September 2022. Global patient enrollment is currently underway.
- o *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.
- o *Immunoglobulin A Nephropathy (IgAN)*
 - *China*: We completed a randomised, 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.
 - *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 enrolled 14 patients in the United States as of December 31, 2022.
- o *Primary Sjögren’s syndrome (pSS)*
 - *China*: We completed a Phase II clinical trial in China for primary Sjögren’s syndrome (pSS) with positive results. 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 the CDE in August 2022. Currently, we have initiated the clinical study.

- *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 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.

o Myasthenia gravis (MG)

- *China:* We completed a randomised, 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 gMG in November 2022.
- *United States:* The FDA granted orphan drug designation to telitacicept for the treatment of gMG in October 2022.

o Neuromyelitis optica spectrum disorder (NMOSD)

We are conducting a randomised, double-blind and placebo-controlled Phase III clinical trial in China to evaluate the efficacy and safety of telitacicept for the treatment of NMOSD. We initiated the Phase III clinical trial in September 2017 and enrolled the first patient in January 2018. We enrolled 149 patients in this trial as of 31 December 2022.

o Other indications

In addition to the indications described above, we are also evaluating telitacicept for other autoimmune diseases, namely multiple sclerosis (MS). We enrolled 8 patients in Phase II clinical trial on multiple sclerosis as of December 31, 2022.

- Leveraging our experience in developing telitacicept for SLE globally, we will continuously explore the global path of approval and commercialisation for the treatment of other autoimmune diseases.

- **Warning under Rule 18A.08(3) of the Listing Rules:** There is no assurance that telitacicept (RC18) (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 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 non-small cell lung cancer (NSCLC), biliary tract cancer (BTC), gynecologic malignancies and advanced melanoma.

o GC

- Disitamab vedotin received conditional marketing approval from the NMPA on June 9, 2021 and was included in the updated NRDL in December of the same year. Based on the completed Phase II clinical trial in China, we initiated a Phase III confirmatory clinical trial in China in October 2020, with a planned total enrollment of 351 patients. We enrolled 130 patients in the Phase III confirmatory clinical trial as of December 31, 2022.
- Moreover, we are exploring the clinical probability of combining disitamab vedotin with RC98 (PD-L1 antibody) for the treatment of HER2-expressing locally advanced or metastatic gastric cancer (including gastroesophageal junction adenocarcinoma). Our IND application was approved by the CDE in April 2022. The clinical trial kicked off in August 2022. One patient was enrolled in the study as of December 31, 2022.

- We are exploring the clinical probability 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 adenocarcinoma). Our IND application for Phase II/III trials was submitted to the CDE in December 2022.

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.
- In addition, in view of the promising efficacy of disitamab vedotin in patients with HER2-low-expressing UC, we initiated a single-centre, single-arm, open-label Phase II registrational clinical study in June 2019 to evaluate the efficacy and safety of disitamab vedotin in HER2-negative (IHC 1+ or IHC 0) locally advanced or metastatic UC. Approximately 18 patients were enrolled in this trial. Patient enrollment was completed in July 2021. We further presented the latest advances in the clinical study at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2022.
- 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 approved by the NMPA in February 2022. At present, we are carrying out this clinical trial in China. We enrolled 9 patients in the trial as of December 31, 2022.
- We are conducting a multi-centre, randomised 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 plan to enroll 452 patients in the trial. We enrolled 67 patients in the trial as of December 31, 2022.

o BC

- On June 28, 2021, the NMPA granted us the breakthrough therapy designation for disitamab vedotin in the treatment of patients with HER2-positive advanced breast cancer with liver metastases who had previously received trastuzumab and taxane therapy. We are conducting the Phase III clinical trial in China. As of December 31, 2022, we enrolled 104 patients in this trial.
- As we have observed preliminary efficacy of disitamab vedotin in patients with low-level HER2 expression, we have initiated the Phase III clinical trial in patients with HER2 low-expressing (IHC 2+ and FISH-) BC. As of December 31, 2022, we had enrolled 279 patients in this trial.

o NSCLC

We are conducting an open-label Phase Ib trial in China to evaluate disitamab vedotin as monotherapy for the treatment of HER2-overexpressing (IHC 2+ or IHC 3+) or HER2-mutant NSCLC. We enrolled 37 patients as of December 31, 2022.

o BTC

We are conducting a multi-centre, single-arm and open-label Phase II trial in China to evaluate disitamab vedotin as monotherapy in the patients with HER2-overexpressing (IHC 2+ or IHC 3+) BTC post to the failure of first-line chemotherapy. We enrolled 28 patients in this trial as of December 31, 2022.

o Gynecologic malignancies

At the end of 2021, we conducted an open, multi-cohort and multi-centre phase II clinical study in China on disitamab vedotin for the treatment of patients with HER2-expressing gynecologic malignancies, who were allocated to four cohorts of cervical cancer, ovarian epithelial cancer, fallopian tube cancer and primary peritoneal cancer, endometrial cancer and other gynecological malignancies, in a bid to evaluate the efficacy of disitamab vedotin in treatment of patients with HER2-expressing gynecologic malignancies. 60 patients were enrolled as of December 31, 2022.

o Advanced melanoma

In May 2022, we conducted a single-arm, open and single-centre Phase IIa clinical study in China to evaluate the efficacy of disitamab vedotin in the treatment of patients with HER2-expressing advanced melanoma (except for primary uveal melanoma) who have failed standard therapy. As of December 31, 2022, we enrolled 2 patients in this trial.

- Moreover, we are exploring the clinical probability of combining disitamab vedotin with RC98 (PD-L1 antibody) for the treatment of HER2-expressing locally advanced or metastatic solid tumours. Our IND application related thereto was approved by the CDE in June 2022.
- In August 2021, we entered into an exclusive worldwide license agreement with Seagen Inc. (“Seagen”) to develop and commercialise 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 US\$200 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 clinical 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) (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 2.0 mg 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.

- o DME*

- We are currently conducting a multi-centre, randomised, 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.

- o DR*

- We are currently conducting a multi-centre, randomised, active-controlled Phase II clinical trial in China. As of December 31, 2022, we had enrolled 89 patients in this trial.

- **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 we developed for the treatment of solid tumours. It is currently in a Phase I clinical trial in patients with multiple advanced solid tumours. We completed patient enrollment as of December 31, 2022. Data scrubbing and patient development are underway.

- RC98 is an innovative PD-L1 monoclonal antibody we developed for the treatment of solid tumours. We obtained the IND approval for RC98 from the NMPA in July 2019 and we have initiated a Phase I clinical trial in patients with multiple advanced solid tumours, including but not limited to lung cancer and urothelial cancer. We completed patient enrollment as of December 31, 2022. A patient development trial is being underway.
- 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 . We enrolled 18 patients as of December 31, 2022. In addition, the FDA granted clinical trial approval in December 2022 to RC108 for the treatment of patients with c-Met-positive solid tumours.
- 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 (IC₅₀) in the subnanomolar range, as toxin payloads) with each other via cathepsin-cleavable linkers, and it has optimised drug-to-antibody ratio.
 - *Australia:* We received the ethics approval to commence a Phase I clinical trial on the ADC RC118 from Australia’s Human Research Ethics Committee in July 2021. Currently, we are conducting a Phase I clinical trial in patients with Claudin18.2-positive locally advanced unresectable or metastatic malignant solid tumours in Australia. The clinical study site in Australia was officially launched in November 2021. As of December 31, 2022, dose escalation of three dose levels had been completed.
 - *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. As of December 31, 2022, we enrolled 12 patients in this trial.
 - *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 adenocarcinoma) and pancreatic cancer.

- **Warning under Rule 18A.08(3) of the Listing Rules:** There is no assurance that the RC88, RC98, RC108, RC118, RC138, RC148, RC158, RC168, RC178, RC188, 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 commercialisation 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.

As of December 31, 2022, our commercialisation team for autoimmune diseases had 639 members with rich experience in the commercialisation of autoimmune therapeutic drugs.

As the world's first innovative dual-target biologics agent for the treatment of SLE, telitacicept was approved for 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. In 2022, the commercialisation team has covered 1,876 hospitals nationwide. As of December 31, 2022, the commercialisation team for autoimmune diseases had been admitted to 495 hospitals and 1,015 direct-to-patient (DTP) pharmacies.

As of December 31, 2022, our commercialisation team for oncology diseases had 520 members with rich experience in the commercialisation of oncology therapeutic drugs. Disitamab vedotin was approved for 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. In 2022, the commercialisation has covered 1,419 hospitals nationwide. As of December 31, 2022, the commercialisation team for autoimmune diseases had been admitted to 472 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 promotion 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

- Disitamab vedotin for the treatment of patients with HER2-expressing locally advanced or metastatic UC was included in the updated NRDL in January 2023. The new price will take effect from March 1, 2023.
- The FDA approved the IND application for the Phase III clinical trial on telitacicept for the treatment of gMG and granted fast-track designation to the drug in January 2023.
- The Company officially initiated a Phase III clinical trial on RC28-E injection for the treatment of wAMD in China in January 2023.
- 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), pursuant to which the parties will cooperate on clinical studies on the development of combinations consisting of RC108, an ADC targeting cellular-mesenchymal epithelial transition factor (c-Met) of the Company, and furmonertinib mesilate tablets (brand name: 艾弗沙®), a tyrosine kinase inhibitor (TKI).
- In February 2023, the CDE officially approved the IND application for a Phase Ib/II clinical trial on a combination of disitamab vedotin (RC48, brand name: 爱地希®) and 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 range of IND applications for disitamab vedotin (RC48, brand name: 爱地希®) including:
 - disitamab vedotin (RC48, brand name: 爱地希®) in combination with toripalimab injection (brand name: 拓益®) or letrozole as neoadjuvant therapies 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®) 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;

- 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 GEJ carcinoma).
- In March, 2023, the CDE approved an IND application for the Phase I/IIa clinical trial on RC88 for Injection, the Company's product, in combination with toripalimab injection (brand name: 拓益®) for patients with advanced malignant solid tumors.

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 forward to 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 fell to RMB767.8 million in 2022 from RMB1,423.9 million in 2021. The Company granted Seagen an exclusive license to develop and commercialise disitamab vedotin in countries outside the RemeGen Territory in 2021, received an upfront payment of US\$200 million from Seagen and recognised the revenue. Despite the Company received no revenue in this regard in 2022, the sales revenue from telitacicept and disitamab vedotin saw fast growth in 2022 as the two drugs were included in the NRDL at the end of 2021 and smooth progress of commercialization.

Other Income and Gains

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

Our other income and gains increased from RMB186.0 million in 2021 to RMB232.5 million in 2022, primarily due to an increase of RMB18.2 million in interest income and an increase of RMB12.1 million in wealth management income from the proceeds raised in A Share Offering, an increase of RMB13.2 million in exchange gain, and a total increase of RMB3.0 million in others.

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 RMB263.0 million in 2021 to RMB440.7 million in 2022, primarily due to the fact that telitacicept and disitamab vedotin became commercially available following the conditional marketing approval from the NMPA in March 2021 and June 2021 respectively, and were included in the NRDL at the end of 2021, resulting in a growth of sales volume and a significant increase in sales force and thus a rise in personnel costs, market development costs, academic promotion costs, etc.

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 RMB219.8 million in 2021 to RMB272.5 million in 2022, primarily due to an increase in employee expenses and depreciation of phase IV antibody building 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 RMB711.0 million in 2021 to RMB982.1 million in 2022. The following table sets forth the components of our research and development expenses for the years indicated.

	Year ended 31 December			
	2022		2021	
	<i>RMB'000</i>	<i>%</i>	<i>RMB'000</i>	<i>%</i>
Employee benefits expenses	321,728	32.8	218,288	30.7
Raw material expenses	163,448	16.6	144,533	20.3
Clinical trial expenses	235,283	24.0	121,250	17.1
Testing expenses	86,031	8.8	57,982	8.2
Depreciation and amortisation expenses	99,271	10.1	84,259	11.9
Utilities	19,594	2.0	17,681	2.5
Others	56,725	5.7	66,980	9.3
Total	<u>982,080</u>	<u>100.0</u>	<u>710,973</u>	<u>100.0</u>

- (i) Employee benefits expenses increased by RMB103.4 million, mainly due to an increase in the number of research and development employees and an increase in staff salary levels and share-base payment expense;
- (ii) Raw material expenses increased by RMB18.9 million, mainly due to the continuous development of drug candidates;
- (iii) Clinical trial expenses increased by RMB114.0 million, mainly due to the continuous clinical development of drug candidates;
- (iv) Testing expenses increased by RMB28.0 million, mainly due to the continuous development of drug candidates;

- (v) Depreciation and amortisation expenses increased by RMB15.0 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 RMB8.2 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 RMB0.3 million for the year ended December 31, 2021 and the net impairment loss on financial assets of RMB11.1 million for the year ended December 31, 2022. The rise in provision of impairment losses is primarily due to the fact that telitaccept and disitamab vedotin became commercially available following the conditional marketing approval from the NMPA in March 2021 and June 2021 respectively, and were included in the NRDL at the end of 2021, resulting in an increase in sales volume and trade receivables from product sales.

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 charity organisations and the donation expenditure of telitaccept and disitamab vedotin. Our other expenses fell from RMB67.0 million in 2021 to RMB16.0 million in 2022, mainly due to a decrease of RMB25.5 million in exchange losses and a total decline of RMB27.1 million in others, such as donation expenditure of telitaccept and disitamab vedotin.

Finance Costs

The Group's finance costs mainly consist of interest on lease liabilities. Our financial costs increased from RMB5.3 million in 2021 to RMB6.8 million in 2022.

Income Tax Expenses

For the years ended 31 December 2021 and 2022, the Group's income tax expenses were nil.

Profit/(loss) for the Year

Based on the factors described above, the Group recorded a profit of RMB276.3 million in 2021 and a loss of RMB998.8 million in 2022.

Liquidity and Financial Resources

Our primary use of cash is to fund research and development expenses. As of December 31, 2022, our net cash used in operating activities was RMB1,263.7 million. Our cash and cash equivalents rose from RMB1,756.8 million as of December 31, 2021 to RMB2,069.2 million as of December 31, 2022, primarily due to an increase in the proceeds raised from A Share Offering.

Loans and Gearing Ratio

As of December 31, 2022, the Group's interest-bearing bank and other borrowings were nil.

The gearing ratio is calculated using the Group's total liabilities divided by its total assets. As of December 31, 2022, the Group's gearing ratio was 17.3% (December 31, 2021: 17.1%).

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 year ended December 31, 2022.

Capital Commitments

As of the years ended December 31, 2021 and 2022, the Group had capital commitments contracted for but not yet provided of RMB523.4 million and RMB467.0 million respectively, primarily in connection with (i) contracts entered into with contractors for the construction of our new manufacturing facilities; and (ii) contracts entered into with suppliers for the purchase of equipment.

Contingent Liabilities

As at December 31, 2022, the Group did not have any contingent liabilities.

Foreign Exchange Exposure

Our financial statements are expressed in RMB, but certain of our cash and cash equivalents and time deposits and other assets 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, 2022, the Group had a total of 3,332 employees. The total remuneration cost for 2022 was RMB810.7 million, as compared to RMB459.2 million for 2021, primarily due to an increase in the number of employees, 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 purchased, sold or redeemed any of the Company's listed securities during the year ended December 31, 2022.

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 for the year ended December 31, 2022.

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, 2022. 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 auditors the accounting principles and policies adopted by the Group and the consolidated financial statements for the year ended December 31, 2022. 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 Group for the year ended December 31, 2022 has been reviewed and agreed by the Group's auditor, Ernst & Young, to the amounts set out in the Group'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, 2022.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS*Year ended 31 December 2022*

	<i>Notes</i>	2022 RMB'000	2021 <i>RMB'000</i>
REVENUE		767,775	1,423,902
Cost of sales	4	<u>(269,939)</u>	<u>(67,163)</u>
Gross profit		497,836	1,356,739
Other income and gains		232,499	185,970
Selling and distribution expenses		(440,697)	(262,967)
Administrative expenses		(272,542)	(219,840)
Research and development costs		(982,080)	(710,973)
Impairment losses on financial assets, net		(11,128)	(342)
Other expenses		(15,962)	(67,006)
Finance costs		<u>(6,757)</u>	<u>(5,323)</u>
(LOSS)/PROFIT BEFORE TAX		(998,830)	276,258
Income tax expense	5	<u>—</u>	<u>—</u>
(LOSS)/PROFIT FOR THE YEAR		<u>(998,830)</u>	<u>276,258</u>
Attributable to:			
Owners of the parent		<u>(998,830)</u>	<u>276,258</u>
(LOSS)/EARNINGS per share ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted (RMB)	6	<u>(1.88)</u>	<u>0.57</u>

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

Year ended 31 December 2022

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
(LOSS)/PROFIT FOR THE YEAR	(998,830)	276,258
OTHER COMPREHENSIVE INCOME		
Other comprehensive income that may be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	<u>3,519</u>	<u>5,846</u>
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	(1,799)	(840)
Income tax effect	<u>270</u>	<u>417</u>
OTHER COMPREHENSIVE INCOME FOR THE YEAR, NET OF TAX	1,990	5,423
TOTAL COMPREHENSIVE INCOME FOR THE YEAR	(996,840)	281,681
Attributable to:		
Owners of the parent	<u>(996,840)</u>	<u>281,681</u>

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

31 December 2022

	<i>Notes</i>	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
NON-CURRENT ASSETS			
Property, plant and equipment		2,406,750	1,577,687
Right-of-use assets		204,778	148,856
Other intangible assets		17,461	13,143
Investments in an associate		1,500	–
Equity investments designated at fair value through other comprehensive income		79,693	12,067
Pledged deposits		616	564
Other non-current assets		98,255	106,939
Total non-current assets		2,809,053	1,859,256
CURRENT ASSETS			
Inventories		522,673	280,314
Trade and bills receivables	8	281,187	7,050
Prepayments, other receivables and other assets		220,952	177,091
Pledged deposits		118,146	78,677
Cash and cash equivalents		2,069,180	1,756,821
Total current assets		3,212,138	2,299,953
CURRENT LIABILITIES			
Trade and bills payables	9	221,692	159,259
Other payables and accruals		585,840	393,130
Lease liabilities		60,154	52,454
Deferred income		15,348	4,442
Other current liabilities		9,267	7,117
Total current liabilities		892,301	616,402
NET CURRENT ASSETS		2,319,837	1,683,551
TOTAL ASSETS LESS CURRENT LIABILITIES		5,128,890	3,542,807

	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
NON-CURRENT LIABILITIES		
Lease liabilities	104,881	50,324
Deferred tax liabilities	40	310
Deferred income	43,669	45,751
	<hr/>	<hr/>
Total non-current liabilities	148,590	96,385
	<hr/>	<hr/>
Net assets	4,980,300	3,446,422
	<hr/> <hr/>	<hr/> <hr/>
EQUITY		
Equity attributable to owners of the parent		
Share capital	544,263	489,837
Treasury shares	(463,028)	(449,170)
Reserves	4,899,065	3,405,755
	<hr/>	<hr/>
Total equity	4,980,300	3,446,422
	<hr/> <hr/>	<hr/> <hr/>

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”)14,000,000	100%	–	Research and development
RemeGen Australia Pty Ltd	South Australia 3 March 2021	100 ordinary shares	–	100%	Research and development and business development
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
Shanghai Rongchang Biotechnology Co. Ltd. (上海榮昌生物科技有限公司)*	Shanghai, PRC 7 May 2022	RMB500,000,000.00	100%	–	Research and development

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

2.1 BASIS OF PREPARATION

These financial statements have been prepared in accordance with International Financial Reporting Standards (“IFRSs”), which comprise all standards and interpretations approved by the International Accounting Standards Board (“IASB”) and the disclosure requirements of the Hong Kong Companies Ordinance.

These financial statements 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 the commercialization stage. A conditional marketing application of the telitacicept developed by the Group was submitted to the National Medical Products Administration (“NMPA”) on 24 October 2019, and was officially approved by the NMPA on 9 March 2021; a conditional marketing application of the disitamab vedotin was submitted to the NMPA on 17 August 2020, and was officially approved by the NMPA on 8 June 2021; other drug candidates are in different preclinical and clinical studies development stage. During the reporting period, the Group initial listing and over-allotment of its shares on the Stock Exchange. As at 31 December 2022, the unused cash of the Group were RMB2,069,180,000, and the Group had current assets exceeded its current liabilities by RMB2,319,837,000. The management of the Group believes that the funds provided or available from the above activities can support the normal operation, research and development and production activities of the Group for at least the next 12 months. Therefore, the Group has prepared these financial statements on a going concern basis.

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 2022. A subsidiary is an entity (including a structured entity), directly or indirectly, controlled by the Company. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee (i.e., existing rights that give the Group the current ability to direct the relevant activities of the investee).

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

- (a) the contractual arrangement with the other vote holders of the investee;
- (b) rights arising from other contractual arrangements; and
- (c) the Group’s voting rights and potential voting rights.

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

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

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

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

2.2 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

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

Amendments to IFRS 3	<i>Reference to the Conceptual Framework</i>
Amendments to IAS 16	<i>Property, Plant and Equipment: Proceeds before Intended Use</i>
Amendments to IAS 37	<i>Onerous Contracts — Cost of Fulfilling a Contract</i>
<i>Annual Improvements to IFRSs 2018-2020</i>	Amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41

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

- (a) Amendments to IFRS 3 replace a reference to the previous *Framework for the Preparation and Presentation of Financial Statements* with a reference to the *Conceptual Framework for Financial Reporting* (the "Conceptual Framework") issued in June 2018 without significantly changing its requirements. The amendments also add to IFRS 3 an exception to its recognition principle for an entity to refer to the Conceptual Framework to determine what constitutes an asset or a liability. The exception specifies that, for liabilities and contingent liabilities that would be within the scope of IAS 37 or I(IFRIC)-Int 21 if they were incurred separately rather than assumed in a business combination, an entity applying IFRS 3 should refer to IAS 37 or I(IFRIC)-Int 21 respectively instead of the Conceptual Framework. Furthermore, the amendments clarify that contingent assets do not qualify for recognition at the acquisition date. The Group has applied the amendments prospectively to business combinations that occurred on or after 1 January 2022. As there were no contingent assets, liabilities and contingent liabilities within the scope of the amendments arising in the business combination that occurred during the year, the amendments did not have any impact on the financial position and performance of the Group.

- (b) Amendments to IAS 16 prohibit an entity from deducting from the cost of an item of property, plant and equipment any proceeds from selling items produced while bringing that asset to the location and condition necessary for it to be capable of operating in the manner intended by management. Instead, an entity recognises the proceeds from selling any such items, and the cost of those items as determined by IAS 2 *Inventories*, in profit or loss. The Group has applied the amendments retrospectively to items of property, plant and equipment made available for use on or after 1 January 2021. Since there was no sale of items produced prior to the property, plant and equipment being available for use, the amendments did not have any impact on the financial position or performance of the Group.
- (c) Amendments to IAS 37 clarify that for the purpose of assessing whether a contract is onerous under IAS 37, the cost of fulfilling the contract comprises the costs that relate directly to the contract. Costs that relate directly to a contract include both the incremental costs of fulfilling that contract (e.g., direct labour and materials) and an allocation of other costs that relate directly to fulfilling that contract (e.g., an allocation of the depreciation charge for an item of property, plant and equipment used in fulfilling the contract as well as contract management and supervision costs). General and administrative costs do not relate directly to a contract and are excluded unless they are explicitly chargeable to the counterparty under the contract. The Group has applied the amendments prospectively to contracts for which it has not yet fulfilled all its obligations at 1 January 2022 and no onerous contracts were identified. Therefore, the amendments did not have any impact on the financial position or performance of the Group.
- (d) *Annual Improvements to IFRSs 2018-2020* sets out amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41. Details of the amendments that are applicable to the Group are as follows:
- IFRS 9 *Financial Instruments*: clarifies the fees that an entity includes when assessing whether the terms of a new or modified financial liability are substantially different from the terms of the original financial liability. These fees include only those paid or received between the borrower and the lender, including fees paid or received by either the borrower or lender on the other's behalf. The Group has applied the amendment prospectively from 1 January 2022. As there was no modification or exchange of the Group's financial liabilities during the year, the amendment did not have any impact on the financial position or performance of the Group.

2.3 ISSUED BUT NOT YET EFFECTIVE INTERNATIONAL FINANCIAL REPORTING STANDARDS

The Group has not applied the following new and revised IFRSs, that have been issued but are not yet effective, in these financial statements.

Amendments to IFRS 10 and IAS 28 (2011)	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture</i> ³
Amendments to IFRS 16	<i>Lease Liability in a Sale and Leaseback</i> ²
IFRS 17	<i>Insurance Contracts</i> ¹
Amendments to IFRS 17	<i>Insurance Contracts</i> ^{1,5}
Amendment to IFRS 17	<i>Initial Application of IFRS 17 and IFRS 9 — Comparative Information</i> ⁶
Amendments to IAS 1	<i>Classification of Liabilities as Current or Non-current (the “2020 Amendments”)</i> ^{2,4}
Amendments to IAS 1	<i>Non-current Liabilities with Covenants (the “2022 Amendments”)</i> ²
Amendments to IAS 1 and IFRS Practice Statement 2	<i>Disclosure of Accounting Policies</i> ¹
Amendments to IAS 8	<i>Definition of Accounting Estimates</i> ¹
Amendments to IAS 12	<i>Deferred Tax related to Assets and Liabilities arising from a Single Transaction</i> ¹

¹ Effective for annual periods beginning on or after 1 January 2023

² Effective for annual periods beginning on or after 1 January 2024

³ No mandatory effective date yet determined but available for adoption

⁴ As a consequence of the 2022 Amendments, the effective date of the 2020 Amendments was deferred to annual periods beginning on or after 1 January 2024. In addition, as a consequence of the 2020 Amendments and 2022 Amendments, International Interpretation 5 *Presentation of Financial Statements — Classification by the Borrower of a Term Loan that Contains a Repayment on Demand Clause* was revised in October 2020 to align the corresponding wording with no change in conclusion

⁵ As a consequence of the amendments to IFRS 17 issued in October 2020, IFRS 4 was amended to extend the temporary exemption that permits insurers to apply IAS 39 rather than IFRS 9 for annual periods beginning before 1 January 2023

⁶ An entity that chooses to apply the transition option relating to the classification overlay set out in this amendment shall apply it on initial application of IFRS 17

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

Amendments to IFRS 10 and IAS 28 (2011) address an inconsistency between the requirements in IFRS 10 and in IAS 28 (2011) 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 between an investor and its associate or joint venture 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 (2011) was removed by the IICPA in January 2016 and a new mandatory effective date will be determined after the completion of a broader review of accounting for associates and joint ventures. 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 Group's financial statements.

Amendments to IAS 1 *Classification of Liabilities as Current or Non-current* clarify the requirements for classifying liabilities as current or non-current, in particular the determination over whether an entity has a right to defer settlement of the liabilities for at least 12 months after the reporting period. Classification of a liability is unaffected by the likelihood that the entity will exercise its right to defer settlement of the liability. The amendments also clarify the situations that are considered a settlement of a liability. In 2022, the HKICPA issued 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. In addition, the 2022 Amendments require additional disclosures by an entity that classifies liabilities arising from loan arrangements as non-current when it has a right to defer settlement of those liabilities that are subject to the entity complying with future covenants within 12 months after the reporting period. The amendments are effective for annual periods beginning on or after 1 January 2024 and shall be applied retrospectively. Earlier application is permitted. An entity that applies the 2020 Amendments early is required to apply simultaneously the 2022 Amendments, and vice versa. The Group 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 Group's financial statements.

Amendments to IAS 1 *Disclosure of Accounting Policies* 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 provide non-mandatory guidance on how to apply the concept of materiality to accounting policy disclosures. Amendments to IAS 1 are effective for annual periods beginning on or after 1 January 2023 and earlier application is permitted. Since the guidance provided in the amendments to IFRS Practice Statement 2 is non-mandatory, an effective date for these amendments is not necessary. The Group is currently revisiting the accounting policy disclosures to ensure consistency with the amendments.

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 amendments are effective for annual reporting periods beginning on or after 1 January 2023 and apply to changes in accounting policies and changes in accounting estimates that occur on or after the start of that period. Earlier application is permitted. The amendments are not expected to have any significant impact on the Group's financial statements.

Amendments to IAS 12 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 amendments are effective for annual reporting periods beginning on or after 1 January 2023 and shall be applied to transactions related to leases and decommissioning obligations at the beginning of the earliest comparative period presented, with any cumulative effect recognised as an adjustment to the opening balance of retained profits or other component of equity as appropriate at that date. In addition, the amendments shall be applied prospectively to transactions other than leases and decommissioning obligations. Earlier application is permitted. The amendments are not expected to have any significant impact on the Group's financial statements.

The Group has applied the initial recognition exception and did not recognise a deferred tax asset and a deferred tax liability for temporary differences for transactions related to leases. Upon initial application of these amendments, the Group will not recognise deferred tax for all temporary differences related to leases at the beginning of the earliest comparative period presented as the Group's sufficient taxable profit is not available. Based on a preliminary assessment, the amendments are not expected to have any significant impact on the Group's financial statements.

3. OPERATING SEGMENT INFORMATION

The Group is engaged in biopharmaceutical research, biopharmaceutical service, biopharmaceutical production and sale, which is 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

	2022	2021
	RMB'000	RMB'000
Mainland China	723,388	131,310
USA	44,387	1,292,592
	<u>767,775</u>	<u>1,423,902</u>

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

(b) *Non-current assets*

	2022	2021
	RMB'000	<i>RMB'000</i>
Mainland China	2,660,910	1,781,060
USA	64,865	65,499
Australia	–	66
	<u>2,725,775</u>	<u>1,846,625</u>

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 2022, no revenue derived from a single customer accounted for 10% or more of the Group's total revenue (2021: RMB1,292,592,000 from a single customer accounted for 10% or more of the Group's total revenue).

4. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	2022	2021
	RMB'000	<i>RMB'000</i>
Revenue from contracts with customers	<u>767,775</u>	<u>1,423,902</u>

Revenue from contracts with customers

(a) Disaggregated revenue information

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Types of revenue		
Licence revenue	–	1,290,875
Sales of goods	738,204	131,310
Service income	29,571	1,717
	<hr/>	<hr/>
Total revenue from contracts with customers	767,775	1,423,902
	<hr/> <hr/>	<hr/> <hr/>
Geographical markets		
Mainland China	723,388	131,310
USA	44,387	1,292,592
	<hr/>	<hr/>
Total revenue from contracts with customers	767,775	1,423,902
	<hr/> <hr/>	<hr/> <hr/>
Timing of revenue recognition		
Transferred at a point in time	738,204	1,423,902
Transferred over time	29,571	–
	<hr/>	<hr/>
Total revenue from contracts with customers	767,775	1,423,902
	<hr/> <hr/>	<hr/> <hr/>

(b) Performance obligations

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

Sales of goods

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

Service income

Revenue from service is recognised over time, using an input method to measure progress towards complete satisfaction of the service, because the customer simultaneously receives and consumes the benefits provided by the Group. The input method recognises revenue on the basis of the labour hours expended relative to the total expected labour hours to complete the service.

Licence revenue

The time when the intellectual property licence is delivered is the time when the performance obligation is fulfilled, and the customer obtains the control of the intellectual property licence at this time, can use and benefit from it, and the Group recognises the income for the part of the down payment amount at the time when the control of the intellectual property licence is transferred. Subsequent milestone payments are variable consideration, and their payment depends on future uncertain events and is difficult to estimate reasonably at this stage. The Group will re-estimate the amount of variable consideration that should be included in the transaction price at the end of the reporting period. For the royalties charged, revenue shall be 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. For the royalties paid by the Group to customers, they are used as consideration payable to customers and are written off against income.

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

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Amounts expected to be recognised as revenue:		
Within one year	<u>51</u>	<u>27,146</u>

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

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Other income		
Government grants*	141,221	140,026
Rental income	2,152	2,279
Bank interest income	61,543	43,348
Investment income from financial investments	12,106	–
Sales of materials	2,182	99
Others	–	124
	<u>219,204</u>	<u>185,876</u>
Gains		
Foreign exchange gains, net	13,234	–
Gain on disposal of Property, plant and equipment	15	–
Gain on early termination of leases	–	1
Others	46	93
	<u>13,295</u>	<u>94</u>

- * 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 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 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 Mainland China were subject to preferential tax rates 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 income tax at a rate of 21% and California state income tax at a rate of 8.84%.

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

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

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

	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Current		
Charge for the year	–	–
Deferred	–	–
	<hr/>	<hr/>
Total tax charge for the year	<u>–</u>	<u>–</u>

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:

	2022	2021
	RMB'000	RMB'000
(Loss)/Profit before tax	<u>(998,830)</u>	<u>276,258</u>
Tax at the statutory tax rate	(254,487)	69,064
Lower tax rates enacted by local authority	148,072	3,676
Expenses not deductible for tax	10,180	6,499
Additional deductible allowance for research and development expenses	(194,727)	(154,438)
Effect of deemed sales	4,737	28,411
Income not subject to tax	(2,436)	–
Utilisation of deductible losses for previously unrecognized deferred tax	–	6,414
Deductible temporary difference and tax losses not recognised	<u>288,661</u>	<u>40,374</u>
Tax charge at the Group's effective rate	<u>–</u>	<u>–</u>

The Company has been recognised as High New Tech Enterprises in 2022, the losses for the portion that has not been offset yet, can be offsetting against future taxable profits of the Company in ten years. The Group has tax losses in Mainland China of RMB3,723,031,000 (2021: RMB2,255,897,000) and certain deductible temporary difference of RMB 630,089,000 (2021: RMB525,176,000) as at the end of the year, that will expire in one to ten years for offsetting against future taxable profits of the companies in which the losses arose.

The Group also has tax losses in the USA, Hong Kong and Australia of RMB 260,639,000 (2021: RMB121,439,000) as at the end of the year, that will be carried forward indefinitely for offsetting against future taxable profits of the companies in which the losses arose.

Deferred tax assets have not been recognised in respect of unused tax loss and certain deductible temporary difference as the Group is not probable that future taxable profits against which the losses or deductible temporary differences can be utilised will be available in the relevant tax jurisdictions and entities.

6. (LOSS)/EARNINGS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic (loss)/earnings per share amount is based on the (loss)/earnings for the year attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 54,426,000 (2021:Nil) 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)/earnings per share are based on:

	2022	2021
	RMB'000	RMB'000
(Loss)/Earnings		
(Loss)/Earnings attributable to ordinary equity holders of the parent, used in the basic (loss)/earnings per share calculation:	<u>(998,830)</u>	<u>276,258</u>
Dilutive potential conversion expenses	<u>–</u>	<u>–</u>
(Loss)/ Earnings attributable to ordinary equity holders of the parent Attributable to continuing operations	<u>(998,830)</u>	<u>276,258</u>
	Number of shares	
	2022	2021
Shares		
Weighted average number of ordinary shares in issue during the year used in the basic (loss)/earnings per share calculation	530,120,137	487,443,301
Effect of dilution — weighted average number of ordinary shares:		
Share options	<u>1,034,407</u>	<u>–</u>
	<u>531,154,544</u>	<u>487,443,301</u>

7. DIVIDENDS

No dividend has been declared and paid by the Company during the year (2021:nil).

8. TRADE AND BILLS RECEIVABLES

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Trade receivables	212,664	2,433
Impairment	(10,633)	(121)
	<hr/>	<hr/>
Trade receivables, net	202,031	2,312
Bills receivable	79,156	4,738
	<hr/>	<hr/>
	281,187	7,050
	<hr/> <hr/>	<hr/> <hr/>

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:

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Within 1 year	202,031	2,312
	<hr/> <hr/>	<hr/> <hr/>

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

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
At beginning of year	121	–
Impairment losses, net	10,512	121
	<hr/>	<hr/>
At end of year	10,633	121
	<hr/> <hr/>	<hr/> <hr/>

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:

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Within 3 months	152,195	119,138
3 to 6 months	57,255	39,938
6 months to 1 year	12,242	46
Over 1 year	<u>–</u>	<u>137</u>
	<u>221,692</u>	<u>159,259</u>

The Group's trade and bills payables included RMB35,000 due to the Group's related parties as at 31 December 2022 (31 December 2021: Nil).

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

10. EVENTS AFTER THE REPORTING PERIOD

There is no 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, 2022 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

“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
“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, refers to our core products including telitacicept (RC18), disitamab vedotin (RC48) and RC28
“Director(s)”	the director(s) of the Company
“CDE”	the Center for Drug Evaluation of China’s National Medical Products Administration
“FDA”	The U.S. Food and Drug Administration
“FISH”	fluorescence in situ hybridisation, a type of in situ hybridisation (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)”	overseas listed foreign invested ordinary 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)
“Main Board”	the Main Board of the Stock Exchange
“Model Code”	the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix 10 to the Listing Rules
“NDA”	new drug application
“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
“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 our 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 immune system attacks its own healthy tissues, causing 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
“%”	percent

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

Yantai, the People’s Republic of China
March 29, 2023

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