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)

ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED 31 DECEMBER 2021

The Board is pleased to announce the consolidated results of the Group for the year ended 31 December 2021, together with the comparative figures for the year ended 31 December 2020.

BUSINESS HIGHLIGHTS

Our product pipeline and business operations have made significant progress last year:

- Telitacicept (RC18, brand name: 泰爱®) was granted a conditional marketing approval for the treatment of SLE by the NMPA in China in March 2021, and became commercially available in April 2021; the drug was included in the updated National Reimbursement Drug List (NRDL) for the treatment of SLE in December 2021.

- Disitamab vedotin (RC48, brand name: 爱地希®) (i) was granted a conditional marketing approval for the treatment of HER2-expressing locally advanced or metastatic gastric cancer (including gastroesophageal junction carcinoma) (GC) by the NMPA in China in June 2021, and became commercially available in July 2021; the drug was included in the updated NRDL for this indication in December 2021; and (ii) was granted a conditional marketing approval for the treatment of HER2-expressing locally advanced or metastatic urothelial cancer (UC) by the NMPA in China in December 2021.

- We have now completed the Phase II clinical study of telitacicept in patients with IgA nephropathy in China. In November 2021, the Company has participated in the 2021 annual meeting of the American Society of Nephrology (ASN), and the investigator has made a presentation on this study with positive data readout. In September 2021, the Company officially launched the Phase II clinical trial of IgA nephropathy in the United States, and the enrollment is moving smoothly.

- In August 2021, the Company entered into an exclusive worldwide license agreement with Seagen Inc. Pursuant to the agreement, Seagen Inc. is granted to develop and commercialize disitamab vedotin in countries of the world other than Greater China and all other countries in Asia (excluding Japan and Singapore). Under the agreement, the Company received an upfront payment of USD200 million in October 2021, followed by milestone payments of up to USD2.4 billion thereafter and the royalties amounting to a high single-digit to mid-teens on future cumulative net sales as Seagen Inc. subsequently continues global development and commercialization of disitamab vedotin.

– In December 2021, the Company announced that the IND application for a Phase II clinical study for disitamab vedotin in combination with toripalimab injection (brand name: 拓益®) in the treatment of perioperative muscle-invasive bladder cancer (MIBC) had been formally accepted by the NMPA.

– As of 31 December 2021, the two sales teams we have established for telitacicept and disitamab vedotin consist of 132 and 180 individuals, respectively.

– The Company has top-notch production facilities that meet global GMP standards, including disposable bag bioreactors with a total capacity of 12,000L for large-scale recombinant protein production. We initiated a manufacturing facility expansion project at the Company's headquarters in Yantai in the first quarter of 2020. The capacity of disposable bag bioreactors has been increased from 12,000L to 36,000L by the end of 2021.

After the reporting period, the Company announced in January 2022 that positive results had been achieved from the Phase II clinical study of telitacicept in primary Sjögren's Syndrome (pSS) in China.

The Company also launched a Phase III clinical study of telitacicept in the treatment of SLE in the United States in March 2022, and is currently screening patients to participate in the study.

The application for investigational new drug for the treatment of perioperative muscle-invasivebladder cancer (MIBC) with the combination of the product of the Company, disitamab vedotin and toripalimab injection was approved by the Center for Drug Evaluation (CDE) of the NMPA for clinical trials in February 2022. We expect to start the clinical study within the year.

The Company has further completed the Phase II clinical study of telitacicept to treat myasthenia gravis (MG) in February 2022 in China. We plan to conduct further clinical studies for this indication.

The Company announced in May 2021 that it planned to apply for listing on the Science and Technology Innovation Board of the Shanghai Stock Exchange. On 11 January 2022, the Company's application for the registration of the listing on the Science and Technology Innovation Board of the Shanghai Stock Exchange was approved by the China Securities Regulatory Commission (CSRC). On 14 March 2022, the Company announced that it entered the period of preliminary price consultation for the A share offering.

FINANCIAL HIGHLIGHTS

	Year ended 31 December	
	2021	2020
	(Audited)	(Audited)
	RMB'000	*RMB'000*
Revenue	**1,423,902**	–
Research and development expenses	**710,973**	465,821
Profit/(loss) before tax	**276,258**	(697,821)
Profit/(loss) for the year	**276,258**	(697,821)
Earnings/(loss) per share	**RMB**	RMB
– Basic and diluted	**0.57**	(1.71)

- For the year ended 31 December 2021, the Group's revenue was approximately RMB1,423.9 million and its gross profit was approximately RMB1,356.7 million.

- Bank balances and cash amounted to approximately RMB1,836.1 million as of 31 December 2021.

- The Group incurred total expenses (including selling and distribution expenses, administrative expenses and research and development expenses) of approximately RMB1,193.8 million for the year ended 31 December 2021, of which approximately RMB711.0 million was research and development expenses.

- The research and development expenses increased by approximately RMB245.2 million, or approximately 52.6%, to approximately RMB711.0 million in 2021.

- The profit/(loss) before tax changed from a loss of approximately RMB697.8 million in 2020 to a profit before tax of approximately RMB276.3 million in 2021.

- Profit/(loss) for the year changed from a loss of approximately RMB697.8 million in 2020 to a profit of approximately RMB276.3 million in 2021.

- The adjusted profit/(loss) changed from a loss of approximately RMB681.3 million in 2020 to a profit of approximately RMB295.5 million in 2021.

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

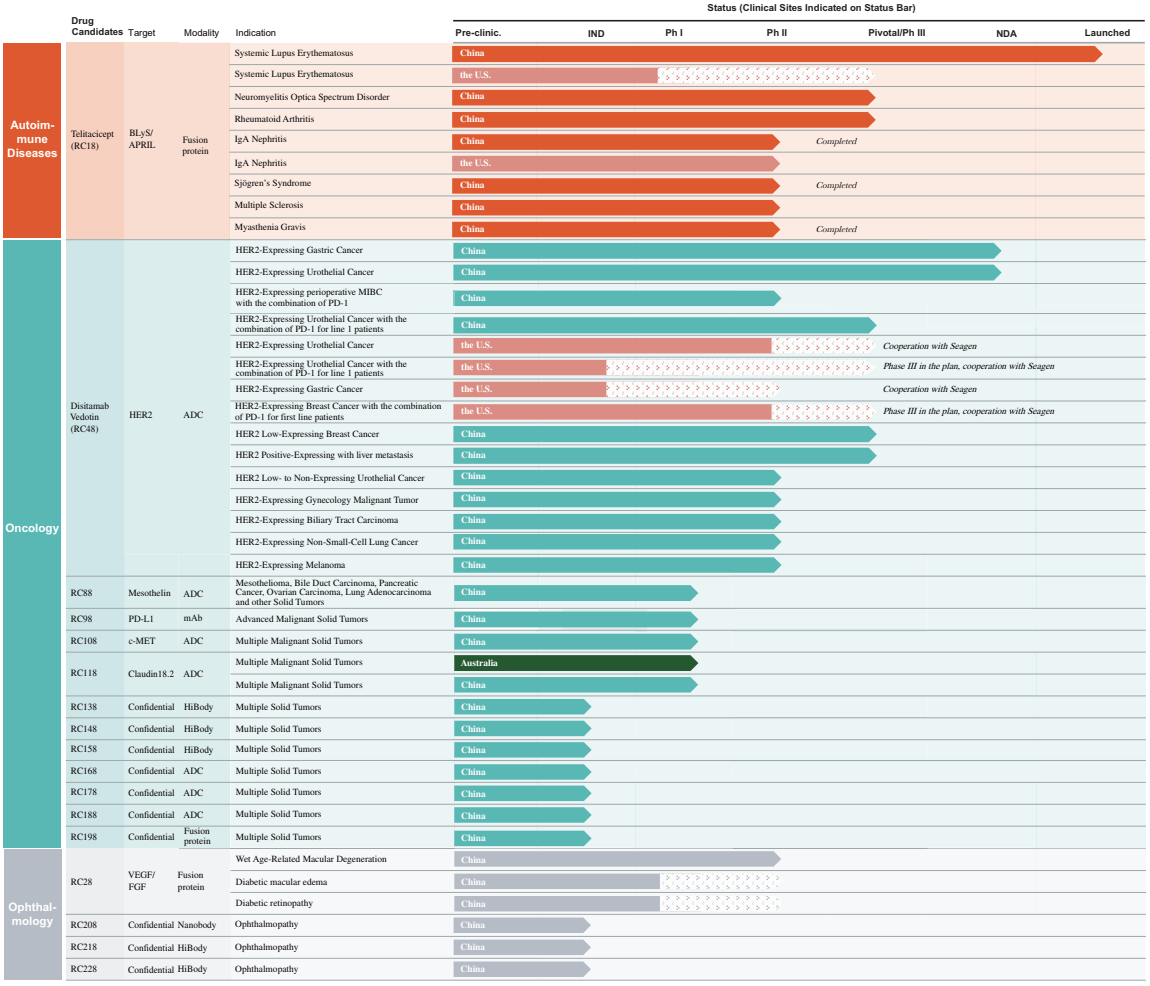
MANAGEMENT DISCUSSION AND ANALYSIS

OVERVIEW

We are a fully-integrated biopharmaceutical company committed to the discovery, development and commercialization of innovative and differentiated biologics for the treatment of autoimmune, oncology and ophthalmic diseases with unmet medical needs in China and globally. Our vision is to become a leading player in the global biopharmaceutical industry. We are one of the few Chinese biotechnology enterprises that have commercialized two products. Since our inception in 2008, we have been dedicated to the research and development of biologics with novel targets, innovative design and breakthrough potential to address global unmet clinical needs. Through more than ten years of efforts, we have built fully-integrated, end-to-end therapeutics development capabilities encompassing all the key biologic drug development functionalities, including discovery, pre-clinical 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 commercialization-stage drugs, telitacicept (RC18) and disitamab vedotin (RC48), are in clinical trials targeting fourteen indications in China and the United States. Our new drug application (NDA) for telitacicept in China for SLE was accepted by the NMPA in November 2019 and we obtained a conditional marketing approval in March 2021. Our NDA for disitamab vedotin (RC48) for the treatment of gastric cancer (GC) in China was granted priority review by the NMPA in August 2020, and was granted a conditional marketing approval in June 2021; its NDA for the treatment of urothelial cancer (UC) was granted priority review by the NMPA in September 2021, and was granted a conditional marketing approval in December 2021. The above two products for the SLE indication and GC indication were included in the updated NRDL in December 2021. In addition, the Company announced in August 2021 that the Company entered into an exclusive worldwide license agreement with Seagen Inc. Pursuant to the agreement, Seagen Inc. is granted to develop and commercialize disitamab vedotin in countries of the world other than Greater China and all other countries in Asia (excluding Japan and Singapore), marking a milestone in the Company's globalization process.

PRODUCT PIPELINE

The following chart illustrates our pipeline and summarizes the development status of our clinical-stage drug candidates and selected IND-enabling stage candidates as of the date of this announcement:



BUSINESS REVIEW

For the year ended 31 December 2021 and up to the date of this announcement, the Group has made the following significant progress:

Telitacicept (RC18)

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

– We are currently evaluating telitacicept in late-stage clinical trials in order to explore its potential to address seven autoimmune diseases, in an attempt to address the significant unmet or underserved medical needs in this therapeutic area.

  o SLE

    ■ *China:* Telitacicept for the treatment of SLE was granted the conditional marketing approval from the NMPA on 9 March 2021 and was included in the updated NRDL in December of the same year. 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 have completed patient enrollment in the Phase III confirmatory clinical trial as of 22 March 2021. The clinical trial is expected to be completed in the second quarter of 2022.

    ■ *United States:* We have launched a Phase III clinical study of telitacicept in the treatment of SLE in the United States in March 2022, and is currently screening patients to participate in the study. Previously in April 2020, the FDA granted fast track designation to telitacicept, which could expedite the review and potential approval process with the FDA.

  o Immunoglobulin A Nephropathy (IgAN)

    ■ *China:* We have completed a randomized, double-blind, placebo-controlled Phase II clinical trial to evaluate the efficacy and safety of telitacicept in patients with IgA nephropathy. Our investigator presented relevant positive clinical data at the "2021 ASN Kidney Week": the reduction of proteinuria level from the treatment groups was statistically higher than the baseline, when compared with the placebo group, the difference was statistically significant. In addition, analysis of several secondary endpoints further identified significant difference between the treatment group and the placebo group.

    ■ *United States:* The FDA approved a Phase II clinical trial of telitacicept in the United States for IgA nephropathy indications in December 2020. We initiated the Phase II clinical trial site for IgA nephropathy in the United States in September 2021, and we had initiated 15 clinical trial sites and enrolled three patients as of 31 December 2021.

  o Sjögren's Syndrome (SS): As of 31 December 2021, we had completed a randomized, double-blind, placebo-controlled Phase II clinical trial in China with positive results. The changes in ESSDAI (EULAR Sjögren's syndrome (SS) disease activity index) scores in the telitacicept treatment group compared with the baseline and the difference between the placebo groups were statistically significant and the clinical treatment reached the endpoints.

  o Neuromyelitis optica spectrum disorder (NMOSD): We are conducting a randomized, double-blind and placebo-controlled Phase III clinical trial to evaluate the efficacy and safety of telitacicept for the treatment of NMOSD in China. We initiated the Phase III clinical trials in September 2017 and enrolled the first patient in January 2018. We have enrolled 125 patients in this trial as of 31 December 2021.

- Rheumatoid arthritis (RA): We are conducting a multi-center, double-blind, placebo-controlled Phase III clinical trial in China. As of 31 December 2021, we have completed patient enrollment and have enrolled 480 patients in this trial. The clinical trial is expected to be completed in the first quarter of 2023.

- Myasthenia gravis (MG): We are conducting a randomized, open-label Phase II clinical trial in China. As of 31 December 2021, we have completed patient enrollment and have enrolled 29 patients in this trial. We have further completed this Phase II study in China in February 2022. Data is expected to be available in the second quarter of 2022.

- Other indications: In addition to the indications described above, we are also evaluating telitacicept for other hard-to-treat autoimmune diseases, namely multiple sclerosis (MS).

– Leveraging our experience in developing telitacicept for SLE globally, we will continue to explore the global path of approval and commercialization for the treatment of other autoimmune diseases. We intend to prioritize indications with high unmet medical needs and sizeable addressable patient population in the global market, such as IgAN and Sjögren's syndrome (SS), or indications for which telitacicept has the potential to be the first biologic therapy.

– **Warning under Rule 18A.08(3) of the Listing Rules:** There is no assurance that the 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)

– 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 tumors. Disitamab vedotin is currently being studied in multiple late-stage clinical trials in China across a variety of solid tumor types. In two Phase II 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 are strategically focused on clinical investigation of disitamab vedotin for 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) and biliary tract cancer (BTC).

– We entered into an exclusive worldwide license agreement with Seagen Inc. ("**Seagen**") in August 2021 to develop and commercialize disitamab vedotin. According to the license agreement, Seagen has been granted an exclusive license to develop and commercialize disitamab vedotin in global regions excluding Asia (Japan and Singapore excluded). We received an upfront payment of USD200 million in October 2021. Under the agreement, we will receive additional milestone payments of up to USD2.4 billion thereafter and the royalties amounting to a high single-digit to mid-teens of future cumulative net sales as Seagen subsequently continues global development and commercialization of disitamab vedotin.

  o GC

    ■ *China:* We have completed our Phase II registrational trial of disitamab vedotin as monotherapy for the treatment of HER2 over-expressing (IHC 2+ or IHC 3+) GC in China in November 2019. Based on the Phase II registrational trial results for the treatment of GC, we submitted our NDA to the NMPA for conditional approval of disitamab vedotin for GC in August 2020, which was accepted by the NMPA and was granted priority review, and received marketing approval in June 2021. In December of the same year, it was included in the updated NRDL.

  o UC

    ■ *China:* We completed a Phase II clinical trial of disitamab vedotin in patients with HER2 over-expressing (IHC 2+ or IHC 3+) UC in China. Based on the positive clinical results of this Phase II clinical trial and after communicating with the NMPA, we initiated a multi-center, single-arm, open-label Phase II registrational clinical trial to evaluate the efficacy of disitamab vedotin as a monotherapy in the treatment of HER2 over-expressing UC in China. In September 2020, we completed the patient enrollment for this trial. In December 2020, we received the Breakthrough Therapy Designation from the NMPA for the treatment of UC. In September 2021, we were granted fast track designation by the NMPA for the treatment of UC. In December 2021, we received marketing approval for this indication. In addition, we are exploring the clinical possibility of disitamab vedotin in combination with PD-1 antibody in the treatment of HER2-expressing UC. In December 2021, the Company announced that the IND application for Phase II clinical study for disitamab vedotin in combination with toripalimab injection (brand name: 拓益®) in the treatment of perioperative muscle-invasive bladder cancer (MIBC) had been accepted officially by the NMPA. The application of this clinical study was granted an implied license for clinical trials by the NMPA in February 2022.

- o BC: On 28 June 2021, the NMPA granted the Company 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. The Company is conducting the Phase III clinical trial in China, and as of 31 December 2021, we had enrolled 18 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 31 December 2021, we had enrolled 148 patients in this trial.

- o NSCLC: We are conducting an open-label Phase Ib trial to evaluate disitamab vedotin as monotherapy for the treatment of HER2 over-expressing (IHC 2+ or IHC 3+) or HER2 mutant NSCLC in China. We have enrolled 37 patients as of 31 December 2021.

- o BTC: We are conducting a multi-center, single-arm and open-label Phase II trial to evaluate disitamab vedotin as monotherapy in the patients with HER2 over-expressing (IHC 2+ or IHC 3+) BTC post to the failure of first-line chemotherapy in China. We have enrolled 24 patients in this trial as of 31 December 2021.

– **Warning under Rule 18A.08(3) of the Listing Rules:** There is no assurance that the 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 (wet AMD), 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 wet AMD patients.

- o wAMD: Currently, we are conducting an open-label, single-arm Phase Ib/IIa dose-expansion trial to evaluate the efficacy and safety of RC28 in the patients with wet AMD. As of 31 December 2021, we have completed patient enrollment and have enrolled 37 patients in this trial.

- o DME: We are currently conducting a multi-center, randomized, active-controlled Phase II clinical trial in China. As of 31 December 2021, we had enrolled 74 patients in this trial.

- o DR: We are currently conducting a multi-center, randomized, active-controlled Phase II clinical trial in China. As of 31 December 2021, we had enrolled 26 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 tumors. It is currently in a Phase I clinical trial in patients with multiple advanced solid tumors, with a particular focus on pancreatic cancer, mesothelioma, bile duct carcinoma, ovarian carcinoma, gastric cancer, triple-negative breast cancer and lung adenocarcinoma. We have enrolled 17 patients in this trial as of 31 December 2021.

– RC98 is an innovative PD-L1 monoclonal antibody we developed for the treatment of solid tumors. 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 tumors, including but not limited to lung cancer and urothelial cancer. We have enrolled 22 patients as of 31 December 2021.

– RC108 is our third ADC product developed in-house that has entered into clinical development stage. It is a c-Met-targeted ADC. c-Met is a receptor tyrosine kinase that, after binding with its 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-characterized oncogene that is associated with poor prognosis in many solid tumor types. We have obtained approval from NMPA and have now started a Phase I clinical trial for c-Met positive advanced solid tumors in China in November 2020. We have enrolled 12 patients as of 31 December 2021.

– RC118 is the Company's fourth ADC drug subject to clinical study, and it targets Claudin 18.2-positive locally advanced unresectable or metastatic malignant solid tumors. It is made by conjugating the recombinant humanized anti-Claudin18.2 monoclonal antibody and the small molecule microtubule inhibitor Monomethyl Auristatin E (MMAE) (a potent microtubule binding agent with its half-maximal inhibitory concentration (IC_{50}) in the sub-nanomolar range, as toxin payloads) with each other via cathepsin-cleavable linkers, and it has optimized drug-to-antibody ratio.

  ■ *Australia:* In July 2021, we obtained the ethical approval from the Australian Human Research Ethics Committee for the Phase I clinical trial of the antibody drug conjugate (ADC) RC118. Currently, we are conducting a Phase I clinical trial in patients with Claudin18.2-positive locally advanced unresectable or metastatic malignant solid tumors in Australia. The clinical study site in Australia was officially launched in November 2021. As of 31 December 2021, 2 patients had been enrolled in this trial, and the test for the first dose group had been completed, with the test for the second dose group being underway.

  ■ *China:* In September 2021, the Phase I clinical trial license for RC118 was obtained from the NMPA. We plan to conduct a Phase I clinical trial in patients with Claudin18.2-positive locally advanced unresectable or metastatic malignant solid tumors in China.

– RC138 is a novel bifunctional antibody, and we are conducting multiple preclinical studies of RC138 monotherapy in advanced solid tumors.

– RC148 is a novel bifunctional antibody, and we are conducting multiple preclinical studies of RC148 monotherapy in advanced solid tumors.

– RC158 is a novel bifunctional antibody, and we are conducting multiple preclinical studies of RC158 monotherapy in advanced solid tumors.

– RC168 is a novel ADC drug, and we are conducting multiple preclinical studies of RC168 monotherapy in advanced solid tumors.

– RC178 is a novel ADC drug, and we are conducting multiple preclinical studies of RC178 monotherapy in advanced solid tumors.

– RC188 is a novel ADC drug, and we are conducting multiple preclinical studies of RC188 monotherapy in advanced solid tumors.

– RC198 is a novel fusion protein, and we are conducting multiple preclinical studies of RC198 monotherapy in advanced solid tumors.

– RC208 is a novel nanobody, and we are conducting multiple preclinical studies of RC208 in the treatment of ophthalmic diseases.

– RC218 is a novel bifunctional antibody, and we are conducting multiple preclinical studies of RC218 in the treatment of ophthalmic diseases.

– RC228 is a novel bifunctional antibody, and we are conducting multiple preclinical studies of RC228 in the treatment of ophthalmic diseases.

– **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, RC208, 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.

Commercialization

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

As of 31 December 2021, the initial sales team for autoimmune diseases has been established and consists of 132 members with rich experience in the commercialization of autoimmune therapeutics.

As the world's first innovative dual-target biological agent for the treatment of SLE, telitacicept was approved for conditional marketing by the NMPA in March 2021 and has been marketed. In 2021, telitacicept generated a revenue of approximately RMB47.3 million, covering 445 hospitals and approximately 2,400 patients in 168 prefecture-level cities in 31 provinces across China. This product was also included in the updated NRDL for the treatment of SLE in December 2021, and we plan to continue to expand this team in 2022.

As of 31 December 2021, the initial sales team for oncology diseases also has been established and consists of 180 members with rich experience in the commercialization of oncology therapeutics. Disitamab vedotin was approved for conditional marketing on 9 June 2021, and was marketed for sales in July 2021. In 2021, disitamab vedotin generated a revenue of RMB84.0 million, covering 374 hospitals and approximately 2,139 patients in 105 prefecture-level cities in 29 provinces across China. This product for the treatment of HER2-expressing locally advanced or metastatic gastric cancer (GC) was also included in the updated NRDL in December 2021, and we plan to continue to expand this team in 2022.

Leveraging the expertise and industry connections of our team, we will 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 to promote the differentiating clinical aspects of our products. Such marketing efforts are expected to commence several months before the expected approval for the commercialization of a drug candidate. In preparation for the sales of telitacicept, for instance, we have identified a number of hospitals, clinics and physicians specialized in the treatment of SLE, and have started to visit the sites and physicians in person for pre-launch training and liaison. In addition, we will utilize 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

The Company announced in January 2022 that positive results had been achieved from the Phase II clinical study of telitacicept in primary Sjögren's Syndrome (pSS) in China. The Company plans to conduct further clinical studies for this indication in the future.

The Company also launched a Phase III clinical study of telitacicept in the treatment of SLE in the United States in March 2022, and currently patients screening has started.

The application for investigational new drug for the treatment of perioperative muscle-invasive bladder cancer (MIBC) with the combination of the product of the Company, disitamab vedotin and toripalimab injection was approved by the Center for Drug Evaluation (CDE) of the NMPA for clinical trials in February 2022. We expect to start the clinical study within the year.

The Company has further completed the Phase II clinical study of telitacicept to treat myasthenia gravis (MG) in February 2022 in China. We plan to conduct further clinical studies for this indication in the future.

The Company announced in May 2021 that it planned to apply for listing on the Science and Technology Innovation Board of the Shanghai Stock Exchange. On 11 January 2022, the Company's application for the registration of the listing on the Science and Technology Innovation Board of the Shanghai Stock Exchange was approved by the CSRC. On 14 March 2022, the Company announced that it entered the period of preliminary price consultation for the A share offering.

THE IMPACT OF COVID-19

The management of the Company expected that clinical trials in and outside mainland China will not be significantly affected by the outbreak of COVID-19. The Directors believe that, based on the information available as of the date of this announcement, the outbreak of COVID-19 would not result in a material disruption to the Group's business operations or a material impact on the financial position or financial performance of the Group. Due to the outbreak of COVID-19, we have taken various measures, including but not limited to reducing face-to-face meetings by means of telephone or video conferences; avoiding unnecessary travels and trips for interviews as well as providing face masks, hand sanitizers and other sanitation supplies.

FUTURE DEVELOPMENT

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

Looking forward to 2022, we will endeavor to commercialize telitacicept and disitamab vedotin and actively expand the market in China. At the same time, we will continue to accelerate the application and clinical trials for the expansion of the indications of these two products. In addition, we will advance the clinical trials of several other autoimmune disease indications of telitacicept as soon as possible. We are currently discussing with CDE regarding the preparation of a pivotal clinical trial protocol for IgA nephropathy and Sjögren's Syndrome.

On the international front, we will step up our efforts for expansion in the international market, especially in the United States and Europe, and quickly advance and initiate clinical studies of our Core Products in the international market. We have started a phase III clinical trial of telitacicept for the treatment of SLE indications and a phase II clinical trial for the treatment of IgAN in the United States in the first quarter of 2022 and the fourth quarter of 2021, respectively. We will spare no effort to push forward the patient enrollment for both trials. With regards to disitamab vedotin, we will continue to work with Seagen to support global clinical trials that are expected to be initiated in 2022.

In addition, we will increase investment in early-stage pipeline products, including RC88, RC98, RC108 and RC118 products in the Phase I trial, and RC138, RC148, RC158, RC168, RC178, RC188 and RC198 products in the IND-enabling stage. At the same time, a number of nanobodies and bispecific antibodies are being developed for the treatment of ophthalmic diseases, including RC208, RC218 and RC228 in the IND-enabling stage.

We will continue to expand our sales team in China, formulate clear and aspiring business strategies, and prepare for commercialization. With our understanding of the Chinese market environment and the rich experience of our sales team personnel, we will formulate stable market access strategies to meet market demand. In addition, we have completed the capacity expansion in 2021, with the production capacity of the manufacturing facilities to increase from 12,000L disposable bag bioreactors to 36,000L.

FINANCIAL REVIEW

Revenue

After obtaining the conditional marketing approvals from the NMPA in March and June 2021 respectively, the Group has commenced the commercialization activities of telitacicept and disitamab vedotin in China. Before that, the Group had not commercialized any products and therefore had not generated any revenue from sales of products.

The Group's revenue for the year ended 31 December 2021 increased to RMB1,423.9 million. The increase was mainly due to (i) RMB131.3 million of product sales revenue recorded during the commercialization of telitacicept and disitamab vedotin in China and (ii) the recognition of the upfront payment received from Seagen for our licensing arrangement of disitamab vedotin.

Other Income and Gains

The Group's other income and gains primarily consist of government grants, rental income, sales of materials, and interest income.

Our other income and gains increased from RMB75.4 million in 2020 to RMB186.0 million in 2021, primarily due to an increase in government grants realised of RMB69.7 million, and an increase in interest income of RMB41.7 million compared with the corresponding period last year.

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 RMB24.2 million in 2020 to RMB263.0 million in 2021, primarily due to the fact that telitacicept for the treatment of SLE obtained the conditional marketing license from the NMPA in March 2021 and became commercially available, and the disitamab vedotin for the treatment of HER2-expressing locally advanced or metastatic gastric cancer (GC) obtained the conditional marketing approval from the NMPA in China in June 2021 and became commercially available in July 2021, for which a sales team was initially established, resulting in increased market development activities and an increase in employee benefits expenses.

Administrative Expenses

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

Our administrative expenses increased from RMB217.6 million in 2020 to RMB219.8 million in 2021, primarily due to (i) an increase in employee benefits expenses of RMB24.1 million, mainly due to an increase in the number of employees, and an increase in their salaries and share-based compensation; (ii) an increase in general office expenses of RMB14.7 million, mainly due to an increase in the number of our administrative employees and office expenses resulting from continuous business development and entertainment expenses resulting from our continuous efforts to develop our business; (iii) an increase in consulting service expenses of RMB11.5 million, mainly due to an increase in corporate business consulting and annual consulting services after the listing of H Shares, and the increase in recruitment fees due to the Company's business development and the increase in new recruits; (iv) an increase in depreciation and amortization expenses of RMB7.4 million, mainly due to the continuous purchase of a large number of office equipment, printers and other office fixed assets with the development and scale expansion of the Group; and (v) an increase in other expenses of RMB6.8 million. Such increase was partially offset by a decrease in listing expenses of RMB62.3 million, which was mainly due to the completion of the listing of H Shares on the Stock Exchange on 9 November 2020.

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 pre-clinical 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 RMB465.8 million in 2020 to RMB711.0 million in 2021. The following table sets forth the components of our research and development expenses for the years indicated.

	Year ended 31 December			
	2021		2020	
	RMB'000	***%***	*RMB'000*	*%*
Employee benefits expenses	**218,288**	**30.7**	122,982	26.4
Raw material expenses	**144,533**	**20.3**	108,787	23.4
Clinical trial expenses	**121,250**	**17.1**	67,570	14.5
Testing expenses	**57,982**	**8.2**	40,300	8.7
Depreciation and amortization expenses	**84,259**	**11.9**	62,977	13.5
Utilities	**17,681**	**2.5**	20,232	4.3
Others	**66,980**	**9.3**	42,973	9.2
Total	**710,973**	**100.0**	465,821	100.0

(i) Employee benefits expenses increased by RMB95.3 million, mainly due to an increase in the number of research and development employees and an increase in staff salary levels;

(ii) Raw material expenses increased by RMB35.7 million, mainly due to the continuous development of drug candidates;

(iii) Clinical trial expenses increased by RMB53.7 million, mainly due to the continuous clinical development of drug candidates;

(iv) Testing expenses increased by RMB17.7 million, mainly due to the continuous development of drug candidates;

(v) Depreciation and amortization expenses increased by RMB21.3 million, mainly due to an increase in depreciation of right-of-use assets as a result of new leases of buildings and an increase in the depreciation of equipment due to new purchases of research and development equipment;

(vi) Utilities decreased by RMB2.6 million;

(vii) Other expenses increased by RMB24.0 million, mainly due to an increase in the amount of external purchases of non-patented technologies, which mainly represented the milestone payments for the joint development of anti-C-MET monoclonal antibody, Claudin18.2-targeted antibody and RC48 antibody-drug conjugate drug.

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 RMB0.05 million for the year ended 31 December 2020 and the net impairment loss on financial assets of RMB0.34 million for the year ended 31 December 2021.

Other Expenses

The Group's other expenses primarily consist of (i) rental related expenses relating to the leases of our facilities to related parties; (ii) expenses incurred for sales of materials; (iii) losses from changes in foreign currency exchange rates; and (iv) other expenses, including our donation to a charity organization and the donation expenditure of telitacicept and disitamab vedotin. Our other expenses increased from RMB36.3 million in 2020 to RMB67.0 million in 2021, mainly due to an increase in donation expenses of RMB38.1 million, a decrease in losses due to changes in foreign currency exchange rates of RMB6.9 million, and a decrease in lease-related expenses of RMB0.5 million as a result of a decrease in leased area.

Finance Costs

The Group's finance costs mainly consist of interest on borrowings from a related party, interest on bank borrowings and interest on lease liabilities. Our financial costs decreased from RMB29.2 million in 2020 to RMB5.3 million in 2021, mainly due to the payment of interests on loans from related parties of RMB23.9 million in the corresponding period last year, which was fully repaid in 2020.

Income Tax Expenses

For the years ended 31 December 2020 and 2021, the Group's income tax expenses were nil.

Profit/(loss) for the Year

Based on the factors described above, the Group recorded a loss for the year of RMB697.8 million in 2020 and a profit for the year of RMB276.3 million in 2021.

Liquidity and Financial Resources

We have incurred net income and net cash flows from operating activities in 2021. Our primary use of cash is to fund research and development expenses. As of 31 December 2021, our net cash generated from operating activities was RMB263.6 million. As of 31 December 2021, we had cash and cash equivalent of RMB1,756.8 million, representing decrease of RMB1,011.7 million from RMB2,768.5 million as of 31 December 2020, primarily due to an increase in research and development expenses and the expenditures on industrialization construction.

Loans and Gearing Ratio

As of 31 December 2021, 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 31 December 2021, the Group's gearing ratio was 17.1% (31 December 2020: 12.7%).

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 31 December 2021.

Capital Commitments

As of 31 December 2021, the Group had capital commitments contracted for but not yet provided of RMB523.4 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 31 December 2021, 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, time deposits, other receivables, trade and other payables 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 31 December 2021, the Group had a total of 2,121 employees. The total remuneration cost for 2021 was RMB459.0 million, as compared to RMB235.5 million for 2020, 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 trainings 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 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 31 December 2021.

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 31 December 2021.

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 31 December 2021. 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 31 December 2021. 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 31 December 2021 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 31 December 2021.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS

Year ended 31 December 2021

	Notes	**2021**	2020
		RMB'000	*RMB'000*
REVENUE	*4*	**1,423,902**	–
Cost of sales		**(67,163)**	–
Gross profit		**1,356,739**	–
Other income and gains		**185,970**	75,400
Selling and distribution expenses		**(262,967)**	(24,180)
Administrative expenses		**(219,840)**	(217,623)
Research and development expenses		**(710,973)**	(465,821)
Impairment losses on financial assets, net		**(342)**	(47)
Other expenses		**(67,006)**	(36,324)
Finance costs		**(5,323)**	(29,226)
PROFIT/(LOSS) BEFORE TAX		**276,258**	(697,821)
Income tax expense	*5*	**–**	–
PROFIT/(LOSS) FOR THE YEAR		**276,258**	(697,821)
Attributable to:			
Owners of the parent		**276,258**	(697,821)
PROFIT/(LOSS) PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted (RMB)	*6*	**0.57**	(1.71)

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

Year ended 31 December 2021

	Notes	**2021**	2020
		RMB'000	*RMB'000*
PROFIT/(LOSS) FOR THE YEAR		**276,258**	(697,821)
OTHER COMPREHENSIVE INCOME/(LOSS)			
Other comprehensive loss that may be reclassified to profit or loss in subsequent periods:			
Exchange differences on translation of foreign operations		**5,846**	(314)
Other comprehensive income 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		**(840)**	1,459
Income tax effect		**417**	(727)
OTHER COMPREHENSIVE INCOME FOR THE YEAR, NET OF TAX		**5,423**	418
TOTAL COMPREHENSIVE PROFIT/(LOSS) FOR THE YEAR		**281,681**	(697,403)
Attributable to:			
Owners of the parent		**281,681**	(697,403)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

31 December 2021

	Notes	**2021**	2020
		RMB'000	*RMB'000*
NON-CURRENT ASSETS			
Property, plant and equipment		**1,577,687**	802,568
Right-of-use assets		**148,856**	137,939
Other intangible assets		**13,143**	5,095
Equity investments designated at fair value through other comprehensive income		**12,067**	12,907
Pledged deposits		**564**	577
Other non-current assets		**106,939**	181,264
Total non-current assets		**1,859,256**	1,140,350
CURRENT ASSETS			
Inventories		**280,314**	66,204
Trade and bills receivables	*8*	**7,050**	–
Prepayments, other receivables and other assets		**177,091**	102,404
Pledged deposits		**78,677**	40,212
Cash and cash equivalents		**1,756,821**	2,768,521
Total current assets		**2,299,953**	2,977,341
CURRENT LIABILITIES			
Trade and bills payables	*9*	**159,259**	62,646
Other payables and accruals		**393,130**	211,320
Interest-bearing bank borrowings		**–**	108,124
Lease liabilities		**52,454**	42,990
Deferred income		**4,442**	6,208
Other current liabilities		**7,117**	–
Total current liabilities		**616,402**	431,288

	Notes	2021 *RMB'000*	2020 *RMB'000*
NET CURRENT ASSETS		**1,683,551**	2,546,053
TOTAL ASSETS LESS CURRENT LIABILITIES		**3,542,807**	3,686,403
NON-CURRENT LIABILITIES			
Lease liabilities		**50,324**	46,578
Deferred tax liabilities		**310**	727
Deferred income		**45,751**	44,477
Total non-current liabilities		**96,385**	91,782
Net assets		**3,446,422**	3,594,621
EQUITY			
Equity attributable to owners of the parent			
Share capital		**489,837**	489,837
Treasury shares		**(449,170)**	–
Reserves		**3,405,755**	3,104,784
Total equity		**3,446,422**	3,594,621

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") 4,000,000	100%	–	Research and development
RemeGen Medical Research (Shanghai) Co., Ltd. (榮昌生物醫藥研究(上海)有限公司)*	Shanghai, PRC 20 May 2020	RMB8,000,000	100%	–	Research and development
RemeGen Australia Pty Ltd	South Australia 3 March 2021	100 ordinary shares	–	100%	Research and development and business development

* 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.

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. As at 31 December 2021, the accumulated unrecovered loss of the Group was RMB343,450,000. 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 met its capital needs for normal operating activities mainly through financing means such as fundraising, shareholder investment and bank borrowings. 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 Group for the year ended 31 December 2021. 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).

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 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16	*Interest Rate Benchmark Reform – Phase 2*
Amendment to IFRS 16	*Covid-19-Related Rent Concessions beyond 30 June 2021* (early adopted)

The nature and the impact of the revised IFRSs are described below:

(a) Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16 address issues not dealt with in the previous amendments which affect financial reporting when an existing interest rate benchmark is replaced with an alternative risk-free rate ("RFR"). The amendments provide a practical expedient to allow the effective interest rate to be updated without adjusting the carrying amount of financial assets and liabilities when accounting for changes in the basis for determining the contractual cash flows of financial assets and liabilities, if the change is a direct consequence of the interest rate benchmark reform and the new basis for determining the contractual cash flows is economically equivalent to the previous basis immediately preceding the change. In addition, the amendments permit changes required by the interest rate benchmark reform to be made to hedge designations and hedge documentation without the hedging relationship being discontinued. Any gains or losses that could arise on transition are dealt with through the normal requirements of IFRS 9 to measure and recognise hedge ineffectiveness. The amendments also provide a temporary relief to entities from having to meet the separately identifiable requirement when an RFR is designated as a risk component. The relief allows an entity, upon designation of the hedge, to assume that the separately identifiable requirement is met, provided the entity reasonably expects the RFR risk component to become separately identifiable within the next 24 months. Furthermore, the amendments require an entity to disclose additional information to enable users of financial statements to understand the effect of interest rate benchmark reform on an entity's financial instruments and risk management strategy.

Since the Group did not have interest-bearing bank borrowings as at 31 December 2021, the amendments did not have any impact on the financial position and performance of the Group.

(b) Amendment to IFRS 16 issued in March 2021 extends the availability of the practical expedient for lessees to elect not to apply lease modification accounting for rent concessions arising as a direct consequence of the covid-19 pandemic by 12 months. Accordingly, the practical expedient applies to rent concessions for which any reduction in lease payments affects only payments originally due on or before 30 June 2022, provided the other conditions for applying the practical expedient are met. The amendment is effective retrospectively for annual periods beginning on or after 1 April 2021 with any cumulative effect of initially applying the amendment recognised as an adjustment to the opening balance of retained profits at the beginning of the current accounting period. Earlier application is permitted.

Since the Group did not receive any rent concessions during the year, the amendment did not have any impact on the financial position and 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 3	*Reference to the Conceptual Framework*[1]
Amendments to IFRS 10 and IAS 28	*Sale or Contribution of Assets between an Investor and its Associate or Joint Venture*[3]
IFRS 17	*Insurance Contracts*[2]
Amendments to IFRS 17	*Insurance Contracts*[2, 4]
Amendments to IAS 1	*Classification of Liabilities as Current or Non-current*[2]
Amendments to IAS 1 and IFRS Practice Statement 2	*Disclosure of Accounting Policies*[2]
Amendments to IAS 8	*Definition of Accounting Estimates*[2]
Amendments to IAS 12	*Deferred Tax related to Assets and Liabilities arising from a Single Transaction*[2]
Amendments to IAS 16	*Property, Plant and Equipment: Proceeds before Intended Use*[1]
Amendments to IAS 37	*Onerous Contracts – Cost of Fulfilling a Contract*[1]
Annual Improvements to IFRS Standards 2018-2020	Amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41[1]
Amendments to IFRS 17	*Initial Application of IFRS 17 and IFRS 9 – Comparative Information*[2]

1 Effective for annual periods beginning on or after 1 January 2022
2 Effective for annual periods beginning on or after 1 January 2023
3 No mandatory effective date yet determined but available for adoption
4 As a consequence of the amendments to IFRS 17 issued in June 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

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

Amendments to IFRS 3 are intended to 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* 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 IFRIC 21 if they were incurred separately rather than assumed in a business combination, an entity applying IFRS 3 should refer to IAS 37 or IFRIC 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 expects to adopt the amendments prospectively from 1 January 2022. Since the amendments apply prospectively to business combinations for which the acquisition date is on or after the date of first application, the Group will not be affected by these amendments on the date of transition.

Amendments to IFRS 10 and IAS 28 address an inconsistency between the requirements in IFRS 10 and in IAS 28 in dealing with the sale or contribution of assets between an investor and its associate or joint venture. The amendments require a full recognition of a gain or loss resulting from a downstream transaction when the sale or contribution of assets 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 was removed 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 IAS 1 *Classification of Liabilities as Current or Non-current* clarify the requirements for classifying liabilities as current or non-current. The amendments specify that if an entity's right to defer settlement of a liability is subject to the entity complying with specified conditions, the entity has a right to defer settlement of the liability at the end of the reporting period if it complies with those conditions at that date. 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. The amendments are effective for annual periods beginning on or after 1 January 2023 and shall be applied retrospectively. Earlier application is permitted. 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 assessing the impact of the amendments on the Group's accounting policy disclosures.

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 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 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.

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, in profit or loss. The amendments are effective for annual periods beginning on or after 1 January 2022 and shall be applied retrospectively only to items of property, plant and equipment made available for use on or after the beginning of the earliest period presented in the financial statements in which the entity first applies the amendments. Earlier application is permitted. The amendments are not expected to have any significant impact on the Group's financial statements.

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 amendments are effective for annual periods beginning on or after 1 January 2022 and shall be applied to contracts for which an entity has not yet fulfilled all its obligations at the beginning of the annual reporting period in which it first applies the amendments. Earlier application is permitted. Any cumulative effect of initially applying the amendments shall be recognised as an adjustment to the opening equity at the date of initial application without restating the comparative information. The amendments are not expected to have any significant impact on the Group's financial statements.

Annual Improvements to IFRS Standards 2018-2020 sets out amendments to IFRS 1, IFRS 9, IAS 41, and Illustrative Examples accompanying IFRS 16. Details of the amendments that are expected to be 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. An entity applies the amendment to financial liabilities that are modified or exchanged on or after the beginning of the annual reporting period in which the entity first applies the amendment. The amendment is effective for annual periods beginning on or after 1 January 2022. Earlier application is permitted. The amendment is not expected to have a significant impact on the Group's financial statements.

- IFRS 16 *Leases*: removes the illustration of payments from the lessor relating to leasehold improvements in Illustrative Example 13 accompanying IFRS 16. This removes potential confusion regarding the treatment of lease incentives when applying IFRS 16.

3. OPERATING SEGMENT INFORMATION

The Group is engaged in biopharmaceutical research, biopharmaceutical service, and 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

	2021	2020
	RMB'000	*RMB'000*
Mainland China	**131,310**	–
USA	**1,292,592**	–
	1,423,902	–

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

(b) Non-current assets

	2021	2020
	RMB'000	*RMB'000*
Mainland China	**1,781,060**	1,122,249
USA	**65,499**	5,194
Australia	**66**	–
	1,846,625	1,127,443

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

Revenue from a customer of the corresponding years contributing over 10% of the total revenue of the Group is as follows:

	2021	2020
	RMB'000	*RMB'000*
Customer A *(note)*	**1,292,592**	–

Note: Revenue from the licensing of intellectual property revenue and service income.

4. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	2021	2020
	RMB'000	*RMB'000*
Revenue from contracts with customers	**1,423,902**	–

Revenue from contracts with customers

(a) Disaggregated revenue information

	2021	2020
	RMB'000	*RMB'000*
Types of revenue		
Licence revenue	**1,290,875**	–
Sales of goods	**131,310**	–
Service income	**1,717**	–
Total revenue from contracts with customers	**1,423,902**	–
Geographical markets		
Mainland China	**131,310**	–
USA	**1,292,592**	–
Total revenue from contracts with customers	**1,423,902**	–
Timing of revenue recognition		
At a point in time	**1,423,902**	–
Total revenue from contracts with customers	**1,423,902**	–

(b) Performance obligations

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

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.

Sales of goods

The performance obligation is satisfied upon delivery of the goods and payment is generally due within 30 days from the delivery.

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

	2021	2020
	RMB'000	*RMB'000*
Amounts expected to be recognised as revenue:		
Within one year	**27,146**	–

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

	2021	2020
	RMB'000	*RMB'000*
Other income		
Government grants*	**140,026**	70,289
Rental income	**2,279**	2,624
Bank interest income	**43,348**	1,655
Investment income from financial investments	**–**	287
Sales of materials	**99**	93
Others	**124**	329
	185,876	75,277
Gains		
Gain on early termination of leases	**1**	5
Others	**93**	118
	94	123

* 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 subsidiary incorporated in the USA is subject to America federal and California state income tax. America federal income tax was provided at the rate of 21% during the year, and California state income tax was provided at the rate of 8.84% during the year on the estimated assessable profits arising in the USA.

The subsidiary incorporated in Hong Kong is subject to Hong Kong profits tax at the rate of 16.5% on any estimated assessable profits arising in Hong Kong during the year. No provision for Hong Kong profits tax has been made as the Group has no assessable profits derived from or earned in Hong Kong during the year.

The subsidiary incorporated in Australia is subject to Australia profits tax at the rate of 25% on any estimated assessable profits arising in Australia during the year. No provision for Australia profits tax has been made as the Group has no assessable profits derived from or earned in Australia during the year.

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

	2021	2020
	RMB'000	*RMB'000*
Current		
Charge for the year	**–**	–
Deferred	**–**	–
Total tax charge for the year	**–**	–

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

The calculation of the basic earnings/(loss) per share amount is based on the earnings/(loss) for the year attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares in issue during the year.

The Group had no potentially dilutive ordinary shares in issue during the years ended 31 December 2021 and 2020.

The calculations of basic and diluted earnings/(loss) per share are based on:

	2021	2020
	RMB'000	*RMB'000*
Earnings/(loss)		
Earnings/(loss) attributable to ordinary equity holders of the parent, used in the basic earnings/(loss) per share calculation:	**276,258**	(697,821)

	Number of shares	
	2021	2020
Shares		
Weighted average number of ordinary shares in issue during the year used in the basic earnings/(loss) per share calculation	**487,443,301**	408,148,548

In May 2020, the Company was converted into a joint stock company and a total of 401,819,202 ordinary shares with par value of RMB1 each were issued and allotted to the respective shareholders of the Company according to the paid-in capital registered under these shareholders on 11 May 2020.

In November 2020, the Company issued its first stock on the Hong Kong Stock Exchange and issued 76,537,000 ordinary shares at HK$52.10 per share. The raised funds were equivalent to RMB3,400,606,000. After deducting the issuance costs, the actual net funds raised were RMB3,284,244,000, including RMB76,537,000 of share capital and RMB3,207,707,000 of share premium.

In December 2020, the Company exercised the over-allotment right and over-allotted 11,480,500 shares at HK$52.10 per share. The raised funds were equivalent to RMB504,406,000. After deducting the issuance expenses, the actual net funds raised were RMB487,302,000, including RMB11,480,500 of share capital and RMB475,821,500 of share premium.

In order to attract and motivate technical talents, encourage and motivate employees who have made beneficial contributions to the Company, and continuously improve the salary incentive system, on 3 February 2021 and 23 March 2021, the Company's board of directors and shareholders' meeting reviewed and approved the First H Share Award and Trust Scheme. According to the scheme, the board of directors of RemeGen may from time to time in its absolute discretion, pay funds to the trustee with funds of the Company for the purchase of a specified number of shares from the open market in accordance with the written instructions of the board of directors. The repurchase funds and purchased shares are held by RC Talent Success Limited ("HoldCo") established by the trustee for the trust. As at 31 December 2021, RemeGen has prepaid HoldCo HK$620 million for the repurchase of H shares. HoldCo purchased 5,066,000 shares in the market at an average price of about HK$106.70 per share, with a total amount of HK$541,204,054.79 (equivalent to RMB449,170,386.87). As at 31 December 2021, the First H Share Award and Trust Scheme has not actually been awarded to the incentive recipients, and 5,066,000 shares are held by HoldCo.

7. DIVIDENDS

No dividend has been declared and paid by the Company during the year (2020: nil).

8. TRADE AND BILLS RECEIVABLES

	2021	2020
	RMB'000	*RMB'000*
Trade receivables	**2,433**	–
Impairment	**(121)**	–
Trade receivables, net	**2,312**	–
Bills receivable	**4,738**	
	7,050	–

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.

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:

	2021	2020
	RMB'000	*RMB'000*
Within 1 year	**2,312**	–

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

	2021	2020
	RMB'000	*RMB'000*
At beginning of year	**–**	–
Impairment losses, net	**121**	–
At end of year	**121**	–

The expected loss rate for the trade receivables generated from the sales of goods which are not past due is assessed to be 0.5%. As at 31 December 2021, all the trade receivables generated from the sale of pharmaceutical products were not past due, and 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:

	2021	2020
	RMB'000	*RMB'000*
Within 3 months	**119,138**	56,498
3 to 6 months	**39,938**	6,113
6 months to 1 year	**46**	14
Over 1 year	**137**	21
	159,259	62,646

There were no trade and bills payables included in the trade and bills payables due to the Group's related parties as at 31 December 2021 (31 December 2020: RMB795,000).

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

10. EVENTS AFTER THE REPORTING PERIOD

On 11 January 2022, the Company's application for the registration of the listing on the Science and Technology Innovation Board was approved by the CSRC. On 14 March 2022, the Company announced that it entered the period of preliminary price consultation for the A share offering.

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 31 December 2021 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

"ADC"	antibody-drug conjugates, a class of biopharmaceutical drug composed of monoclonal antibodies targeted against specific tumor cell surface antigens linked, via chemical linkers, to highly potent anti-tumor small molecule agents
"Audit Committee"	the audit committee of the Board
"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)
"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
"Domestic Share(s)"	ordinary share(s) in the share capital of our Company, with a nominal value of RMB1.00 each, which are subscribed for and paid up in Renminbi and are unlisted Shares which are currently not listed or traded in any stock exchange
"FDA"	The U.S. Food and Drug Administration

"FISH"	fluorescence in situ hybridization, a type of in situ hydridization (ISH) test that detects the genetic material in human cells, including specific genes or portions of genes. In the case of HER2 FISH test, fluorescent labels are used to attach to the hybrid of HER2-genes and the probes and return a score of either positive (+) or negative (-)
"GC"	gastric cancer
"Group", "we", "us" or "our"	the Company and its subsidiaries
"HER2"	human epidermal growth factor receptor 2
"H Shares"	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
"IgA nephropathy"	An autoimmune kidney disease that occurs when immunoglobulin A (IgA) deposits build up in the kidneys, causing localized 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 Domestic Shares, Unlisted Foreign 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)"	the supervisor(s) of the Company
"Unlisted Foreign Shares"	ordinary share(s) issued by our Company with a nominal value of RMB1.00 each and are held by foreign investors and are not listed on any stock exchange
"USA"	the United States of America

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

Yantai, The People's Republic of China
29 March 2022

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 Ms. Yu Shanshan, Mr. Hao Xianjing and Dr. Ma Lan as the independent non-executive directors.

* *For identification purposes only*