Simcere Pharmaceutical Group Limited
先聲藥業集團有限公司

(Incorporated in Hong Kong with limited liability)

(Stock code: 2096)

ANNOUNCEMENT OF ANNUAL RESULTS FOR THE YEAR ENDED DECEMBER 31, 2022

FINANCIAL HIGHLIGHTS

For the year ended December 31, 2022:

- Revenue of the Group was approximately RMB6,319 million, representing an increase of approximately 26.4% as compared to RMB5,000 million of 2021. Of which, revenue from the sales and promotion service of drugs amounted to RMB6,213 million and license income amounted to RMB106 million. The increase in revenue was mainly attributable to the rapid increase in revenue from the innovative pharmaceutical business.
- Revenue from the innovative pharmaceutical business was approximately RMB4,128 million, accounting for 65.3% of the total revenue and representing an increase of approximately 32.3% as compared to RMB3,120 million of 2021.
- Our revenue was mainly derived from the therapeutic areas where our businesses are focused. Of which, revenue from the field of nervous system was approximately RMB2,267 million, accounting for 35.9% of the total revenue and representing an increase of approximately 41.0% as compared to 2021. Revenue from the field of oncology was approximately RMB1,430 million, accounting for 22.6% of the total revenue and representing an increase of approximately 15.5% as compared to 2021. Revenue from the field of autoimmune was approximately RMB1,280 million, accounting for 20.2% of the total revenue and representing an increase of approximately 39.4% as compared to 2021. Revenue from other fields was approximately RMB1,342 million, accounting for 21.3% of the total revenue and representing an increase of approximately 8.6% as compared to 2021.
- Research and development expense was approximately RMB1,728 million, representing an increase of approximately RMB311 million or approximately 21.9% as compared to RMB1,417 million of 2021. The research and development expense to revenue ratio[1] was approximately 27.3% (approximately 28.3% for 2021).
- Profit for the year attributable to equity shareholders of the Company was approximately RMB933 million, representing a decrease of approximately RMB574 million or approximately 38.1% as compared to RMB1,507 million of 2021.
- Basic earnings per share was approximately RMB0.36, representing a decrease of approximately 37.9% as compared to RMB0.58 of 2021.
- Net cash generated from operating activities was approximately RMB1,355 million, while net cash outflow from operating activities for 2021 was approximately RMB202 million.

[1] Research and development expense divided by revenue

The board (the "**Board**") of directors (the "**Directors**") of Simcere Pharmaceutical Group Limited (the "**Company**") is pleased to announce the consolidated financial results of the Company together with its subsidiaries (collectively the "**Group**" or "**We**") for the year ended December 31, 2022 (the "**Reporting Period**"), together with the comparative figures for 2021. The consolidated financial information for the Reporting Period has been reviewed by the audit committee of the Company (the "**Audit Committee**") and audited by the Company's auditor, KPMG.

KEY MILESTONES

As of the date of this announcement, leveraging on clear strategic planning and extraordinary execution skills, the Group has achieved following key milestones and achievements:

COMMERCIALIZATION

Innovative drugs that entered the commercialization stage increased to six. As of the date of this announcement, 2 new innovative drugs were approved for marketing in China, which created new business growth points.

- On July 12, 2022, COSELA® (Trilaciclib Hydrochloride for Injection) was conditionally approved for marketing by National Medical Products Administration of China (the "**NMPA**") for decreasing the incidence of chemotherapy-induced myelosuppression in patients when administered prior to a platinum/etoposide-containing regimen for extensive-stage small cell lung cancer ("**ES-SCLC**").

- On January 28, 2023, XIANNUOXIN® (Simnotrelvir Tablets/Ritonavir Tablets (co-packaged)) was conditionally approved for marketing by the NMPA with urgent review and approval under Special Examination and Approval of Drugs (藥品特別審批程序) for the treatment of adult patients infected with mild-to-moderate Coronavirus Disease 2019 ("**COVID-19**").

For the year ended December 31, 2022, the proportion of the Group's revenue from innovative drugs had increased to 65.3%, hitting a record high as compared to 2021. Revenue from innovative drugs amounted to RMB4,128 million, representing an increase of approximately 32.3% as compared to RMB3,120 million of 2021. The revenue of innovative drugs Sanbexin® and ENWEIDA® has been growing rapidly.

- Sanbexin® (Edaravone and Dexborneol Concentrated Solution for Injection) drove the revenue and sales of nervous system products to record significant year-to-year growth, which further consolidated our leading market position in such area. Sanbexin® has benefited approximately 880,000 patients during the Reporting Period and covers approximately 3,440 medical institutions currently. In January 2023, Sanbexin® was successfully renewed in the National Reimbursement Drug List (the "**NRDL**").

- The revenue contribution achieved by ENWEIDA® (Envafolimab Injection) in the first full year after its launch further verified our commercialization capability. As the first PD-(L)1 antibody drug to be administered by subcutaneous injection in the world and the first domestic PD-L1 antibody drug, ENWEIDA® has benefited approximately 20,000 patients during the Reporting Period by leveraging on its differentiated treatment advantages.

RESEARCH AND DEVELOPMENT

The Group attaches great importance and devotes to the R&D of innovative drugs. Guided by clinical values, the Group focuses on higher efficiency and adheres to differentiation. The innovative drugs R&D pipelines with continuous progress gather momentum for sustainable growth of the Company's development.

- As of the date of this announcement, the Group has nearly 60 product pipelines of innovative drugs and is currently initiating registrational clinical studies for 17 innovative drugs, of which, there are 5 launched products in the stage of expansion of new indications or combined use, 2 drug candidates that are in NDA/pivotal trial stage, 10 drug candidates that are in phase I/II and approximately 40 pre-clinical drug candidates.

- During the Reporting Period, the Group has added 6 PCC molecules and 6 INDs, completed 11 FPIs/FIHs and 7 LPIs, and its clinical projects have enrolled over 2,600 subjects.

We have been promoting the development progress of various innovative drugs in pivotal trial stage. As of the date of this announcement, 3 phase III clinical trials under research had met the primary endpoints and 2 of them had supported successful product launches.

- On February 23, 2022, the phase III clinical trial (TRACES study) of COSELA® (Trilaciclib Hydrochloride for Injection) for the treatment of ES-SCLC patients pertaining to the protection of existing bone marrow met its primary endpoint. The results of such study was disclosed at the World Conference on Lung Cancer ("**WCLC**") in July 2022.

- On December 1, 2022, the phase III clinical study of Sanbexin sublingual tablets for the treatment of Acute Ischemic Stroke ("**AIS**") achieved expected efficacy endpoints. The results showed that Sanbexin sublingual tablets have a good safety profile and can significantly improve the recovery of neurological function and ability to live independently following treatment in AIS patients. The detailed results will be published in medical conferences/academic journals. On December 24, 2022, the Company submitted the pre-NDA application of such drug.

- On January 6, 2023, the phase III clinical study of XIANNUOXIN® for the treatment of adult patients infected with mild-to-moderate COVID-19 met the primary efficacy endpoints. Such study was so far the first phase III registrational clinical study for Chinese patient population infected with the SARS-CoV-2 Omicron variants that has completed the planned number of patient enrollment, and was designed in accordance with international guidance and was the first phase III registrational clinical study worldwide which has met the primary endpoint as time to sustained recovery of 11 symptoms. The detailed results will be published in medical conferences/academic journals.

We establish efficient teams for clinical operation and registration, in order to facilitate the global R&D of product pipelines under research and expedite the achievement of innovation value.

- Speed of various projects' execution set new industry records: COSELA® only spent 708 days from signing contract to obtain interests in China on August 3, 2020 to obtaining conditional approval for marketing by the ES-SCLC indication. The phase III clinical study of Sanbexin sublingual tablets only spent 10 months to complete the enrollment of all 914 patients. XIANNUOXIN® only spent 437 days from signing contracts (pre-clinical candidates) on November 17, 2021 to obtaining conditional approval for marketing.

- Overseas deployment achieved substantial progress: We are initiating or preparing to initiate clinical studies for 3 innovative drug candidates outside China, including Sanbexin sublingual tablets, SIM0235 (TNFR2) and SIM0237 (anti-PD-L1/IL15v bispecific antibody).

BUSINESS DEVELOPMENT

SIM0278, an independently-developed drug candidate, has finished a license-out deal, which achieved zero breakthrough.

- On September 28, 2022, the Group entered into a license-out agreement with Almirall S.A. ("**Almirall**"), an international biopharmaceutical company, to license out SIM0278 (IL-2muFc), which was developed in-house by utilizing the Group's protein engineering platform. Under the agreement, the Group granted Almirall an exclusive right to develop and commercialize SIM0278 outside the Greater China region. The Group received a US$15 million upfront payment and may receive up to US$492 million in development and commercial milestone payments contingent on successful milestone achievements in several indications, with an important part as sales milestones, as well as up to low double-digit tiered royalties based upon future overseas sales.

We achieved a number of strategic cooperations, so as to enlarge our product pipelines and the coverage of disease areas.

- On March 18, 2022, the Group entered into a cooperation agreement with Lynk Pharmaceuticals Co., Ltd., pursuant to which, the Group obtained the exclusive commercial promotion right of highly selective JAK1 inhibitor for rheumatoid arthritis and ankylosing spondylitis indications in China.

- On April 20, 2022, the Group reached strategic cooperation with Nanjiang Neurodawn Pharmaceutical Co., Ltd. (南京寧丹新藥技術有限公司) ("**Neurodawn**") in respect of the overseas interests of Sanbexin sublingual tablets, and the Group intended to initiate clinical studies and commercialization of Sanbexin sublingual tablets outside China.

- On November 15, 2022, the Group entered an exclusive license agreement with Idorsia Pharmaceuticals Ltd. ("**Idorsia**") for the insomnia drug Daridorexant, a dual orexin receptor antagonist. Under the agreement, the Group was granted an exclusive right to develop and commercialize Daridorexant in the Greater China region. Daridorexant has been approved by the U.S. FDA and the Medicines and Healthcare products Regulatory Agency (MHRA) in Great Britain for marketing in the United States and European Union previously.

- During the Reporting Period, we entered into an agreement with HeMo Bioengineering Limited in respect of the commercialization of neuro-intervention products like Afentta® aspiration catheters, which further strengthened the business layout of the neuroscience sector.

MANUFACTURING

The Group improves our production capability and efficiency continuously, so as to adapt to the expanding businesses and strengthen our market competitiveness.

- Application for manufacturing COSELA® in China was progressing well: On January 13, 2023, the supplementary application was submitted, so as to transfer the commercial production to domestic manufacturing facilities as soon as possible.

- As of the date of this announcement, projects under construction, including new manufacturing facilities of Jiangsu Xiansheng Biology Medical Co., Ltd. (江蘇先盛生物醫藥有限公司) (a pharmaceutical ingredient base) and Shandong Simcere Biopharmaceutical Co., Ltd. (山東先聲生物製藥有限公司) are progressing well.

MANAGEMENT DISCUSSION AND ANALYSIS

INDUSTRY REVIEW

In 2022, China's pharmaceutical industry entered a "critical period". Under the policy level, various policies that stimulate innovation and accelerate approval were implemented, while it continuously deepened reforms with the focus on people's health needs: (1) various guiding principles led enterprises to develop with the focus on clinical values and patients' demands; (2) regulatory authorities greatly accelerated reviews and approvals, and more clinical urgently-needed innovative drugs were quickly brought to patients by way of prioritized, special and conditional approvals; (3) the reduction in price of medical insurance drugs has slowed down due to dynamic adjustments, and the policies have inclined towards innovative drugs with higher clinical demands; and (4) real-world studies in medical pilot zones helped innovative drugs enter Chinese market expeditiously. From the industry perspective, under the dual impacts of capital market recession and the outbreak of the pandemic, enterprises were forced to evaluate risks and return more rationally and put emphasis on differentiation, as well as to avoid popular targets and the cluster of tracks, thereby rebalanced the industry development. Certain local pharmaceutical enterprises accelerated the deployment of overseas markets and those globally competitive new drugs began to show their ability of out-licensing and overseas development. Enterprises with R&D layouts more focusing on clinical values, established commercialization teams and virtuous cycles of input-output of innovative drugs are expected to access broader opportunities in the new development cycle.

COMPANY REVIEW

The Company is an innovation and R&D-driven pharmaceutical company with capabilities in R&D, production and professional marketing. The Group primarily focuses on the therapeutic areas of oncology, nervous system, autoimmune and anti-infection, with forward-looking layout of disease areas that have significant clinical needs in the future, aiming to achieve the corporate mission of "providing today's patients with medicines of the future".

In these four major areas, the Group has 6 innovative drugs approved for marketing and sale (including 1 imported innovative drug)[1]. As of December 31, 2022, the Group has more than 10 products recommended in guidelines and pathways issued by over 100 government authorities or prestigious professional associations, and has over 40 products included in the NRDL.

The Group pays high attention to the establishment of innovative drug R&D capability, and has established R&D innovation centers in Shanghai, Nanjing, Beijing and Boston respectively as well as a State Key Laboratory of Neurology and Oncology Drug Development. The Group's R&D system has achieved functions covering the whole process of drug discovery, preclinical development, clinical trial and registration, and owns leading platforms of protein engineering, BsAb/TCE, PAb/NKCE and AI-aided drug discovery. As of the date of this announcement, the Group had a R&D team of approximately 1,100 employees in total with approximately 150 doctors and 520 masters.

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[1] Bristol Myers Squibb (BMS) and the Group have mutually decided to terminate the licensing and supply agreement for Orencia® in China.

The Group has a nationwide marketing network and leading commercialization capability, and will continuously strengthen our professional marketing capability, so as to enhance coverage and access to medicines. As of December 31, 2022, the Group's sales team had a total of approximately 5,000 employees divided into four business units (neuroscience, oncology, autoimmune & comprehensive and retail grossroots) and other support departments across 31 provinces, municipalities and autonomous regions, covering over 2,700 Class III hospitals, approximately 17,000 other hospitals and medical institutions as well as more than 200 large-scale national or regional chain pharmacies in China.

The Group has established manufacturing infrastructures and quality management systems in line with international standards and has continuously improved its manufacturing capabilities of pharmaceuticals. The 5 production facilities that have been put into use all meet the requirements of Chinese GMP, and part of the production lines have received EU GMP certification or the FDA inspection.

Driven by our in-house R&D efforts and synergistic innovation, the Group has established strategic cooperation partnerships with many innovative companies and research institutes, exploring multiple collaborative modes such as cooperative R&D and achievement transfer and continuously developing products that patients urgently need and have significant market potential. We established the Scientific Advisory Board (SAB) comprising over 10 world-renowned scientists in the areas of oncology, nervous system and autoimmune etc., so as to bring their professional capabilities and experiences to provide scientific advice for our early drug discovery and clinical development. Meanwhile, the Group has planned and implemented the "Simcere Project X", aiming to attract global leaders of life science to explore and create unprecedented treatments.

BUSINESS PROSPECTS

Leveraging on the ongoing development of late-stage pipelines and mature commercialization capability, we predict that 2023 will still be a year of newly-launched products having continuous harvests and also a key year for the further exploration of internationalized development. We will insist on executing the following management objectives:

- Strengthening commercialization capability, so as to boost differentiated innovative drugs (Sanbexin®, ENWEIDA® and COSELA®) to achieve high growth continuously. We will explore the registration and marketing of our products in overseas markets (including countries under the "Belt and Road Initiative"). We emphasize the multi-channel development of drug types outside hospitals and advance the establishment of digital marketing capability. Our products will cover more medical institutions and benefit more patients, so as to enhance the accessibility of marketed products continuously.

- We will continue to increase investment in R&D and expedite the execution of our projects under research. We will facilitate independent development candidates with the potential of FIC/BIC to enter clinical trial or POC study (such as TNFR2, SERD and PRMT5). We will accelerate the development of late-stage products (such as Sanbexin sublingual tablets and Suvemcitug) and the researches on new indications and combination of marketed products (such as COSELA® and new indications of Sanbexin®). We will enhance overseas clinical studies as well.

- We will adhere to synergistic innovation and accelerate business development cooperation. We will pay attention to late-stage products with huge clinical demands and carry out efficient searching of assessments and transactions. We will actively explore licensing opportunities of the overseas interests of pipelines at the early stage. We will deepen and initiate the synergistic and innovative cooperation with the Chinese and global leading research institutes and promote communications and cooperations with internal and external parties, thereby achieving excellent alliance management.

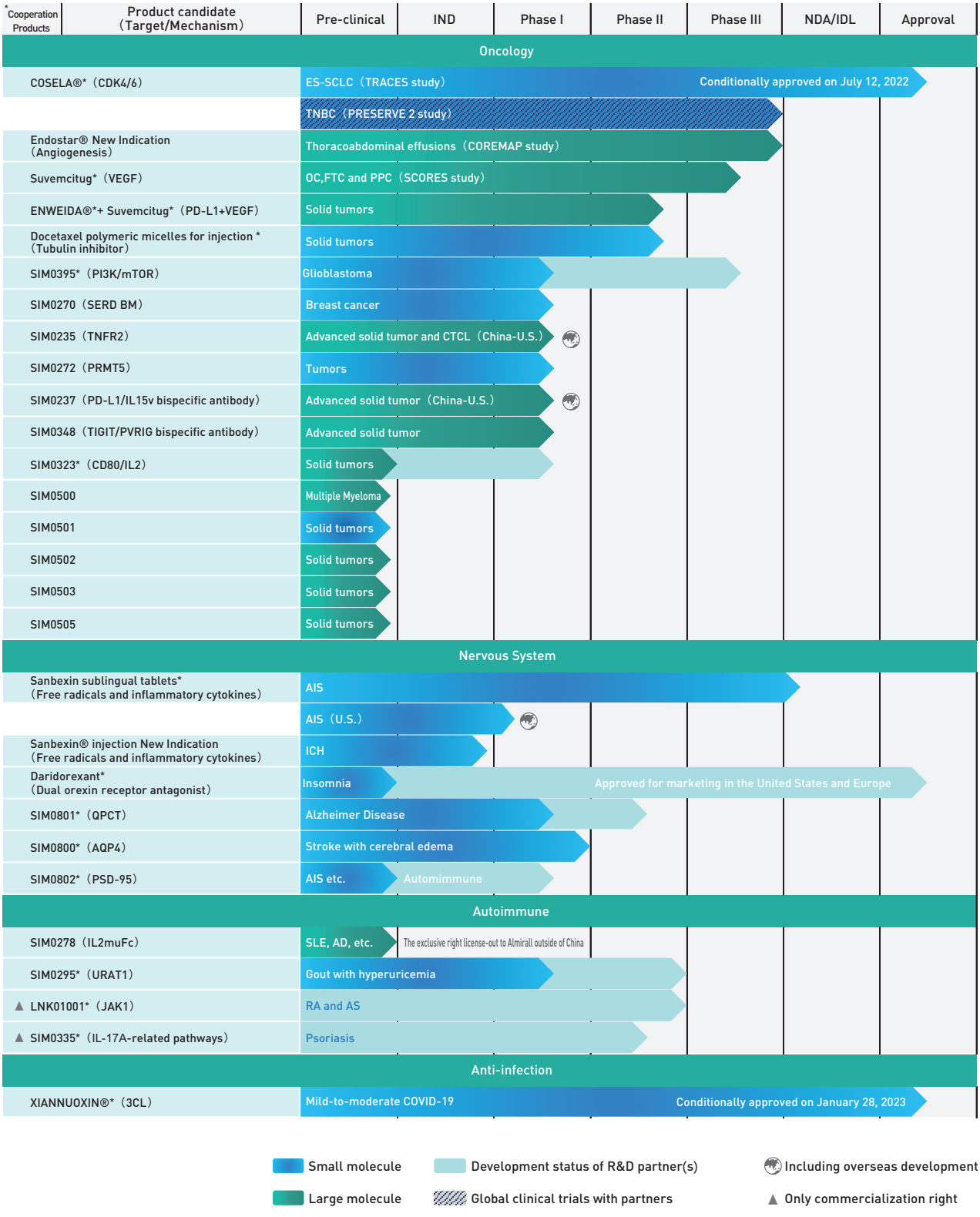
- We will produce more safe, efficacious and high quality pharmaceutical products for patients and accelerate the change of XIANNUOXIN® from conditional approval to full approval so as to help speed up the recovery of social and economic life affected by the pandemic.

- We will improve our organizational capability and continue to increase the talent density. We will achieve clear strategies, focused on management and accurate resources in the level of disease areas, and we will explore more efficient and more constructive innovative development paths.

SUMMARY OF PRODUCT PIPELINES

As of the date of this announcement, the Group has nearly 60 product pipelines of innovative drugs and is currently initiating registrational clinical studies for 17 innovative drugs, of which, there are 5 launched products (new indications/combined development, etc), 2 drug candidates that are in NDA/pivotal trial stage, 10 drug candidates that are in phase I/II and approximately 40 pre-clinical drug candidates. The forms of innovative drugs under development contain monoclonal antibodies, bispecific antibodies, multi-specific antibodies, fusion proteins, ADC and small molecule drugs. The extensive pipeline reserves have huge clinical and commercialization potential, which are expected to help more patients.

The table below summarizes the therapeutic targets, therapeutic areas, rights and development of our principal innovative drugs as of the date of this announcement.


*Cooperation Products
Product candidate (Target/Mechanism)
Pre-clinical
IND
Phase I
Phase II
Phase III
NDA/IDL
Approval
Oncology
COSELA®* (CDK4/6)
ES-SCLC (TRACES study)
Conditionally approved on July 12, 2022
TNBC (PRESERVE 2 study)
Endostar® New Indication (Angiogenesis)
Thoracoabdominal effusions (COREMAP study)
Suvemcitug* (VEGF)
OC,FTC and PPC (SCORES study)
ENWEIDA®*+ Suvemcitug* (PD-L1+VEGF)
Solid tumors
Docetaxel polymeric micelles for injection * (Tubulin inhibitor)
Solid tumors
SIM0395* (PI3K/mTOR)
Glioblastoma
SIM0270 (SERD BM)
Breast cancer
SIM0235 (TNFR2)
Advanced solid tumor and CTCL (China-U.S.)
SIM0272 (PRMT5)
Tumors
SIM0237 (PD-L1/IL15v bispecific antibody)
Advanced solid tumor (China-U.S.)
SIM0348 (TIGIT/PVRIG bispecific antibody)
Advanced solid tumor
SIM0323* (CD80/IL2)
Solid tumors
SIM0500
Multiple Myeloma
SIM0501
Solid tumors
SIM0502
Solid tumors
SIM0503
Solid tumors
SIM0505
Solid tumors
Nervous System
Sanbexin sublingual tablets* (Free radicals and inflammatory cytokines)
AIS
AIS (U.S.)
Sanbexin® injection New Indication (Free radicals and inflammatory cytokines)
ICH
Daridorexant* (Dual orexin receptor antagonist)
Insomnia
Approved for marketing in the United States and Europe
SIM0801* (QPCT)
Alzheimer Disease
SIM0800* (AQP4)
Stroke with cerebral edema
SIM0802* (PSD-95)
AIS etc.
Automimmune
Autoimmune
SIM0278 (IL2muFc)
SLE, AD, etc.
The exclusive right license-out to Almirall outside of China
SIM0295* (URAT1)
Gout with hyperuricemia
▲ LNK01001* (JAK1)
RA and AS
▲ SIM0335* (IL-17A-related pathways)
Psoriasis
Anti-infection
XIANNUOXIN®* (3CL)
Mild-to-moderate COVID-19
Conditionally approved on January 28, 2023
Small molecule
Large molecule
Development status of R&D partner(s)
Global clinical trials with partners
Including overseas development
▲ Only commercialization right

COMMERCIALIZATION STAGE INNOVATIVE PRODUCTS

As of the date of this announcement, we have successfully expanded our commercialized portfolio into six innovative products spanning over multiple therapeutic areas, including nervous system, oncology, autoimmune and anti-infection, which have significant market potentials and synergistic effects. In 2022, revenue from the innovative pharmaceutical business was approximately RMB4,128 million, accounting for 65.3% of the total revenue and representing an increase of approximately 32.3% as compared to RMB3,120 million of 2021. Benefiting from the rapid increase in revenue from the innovative pharmaceutical business, during the Reporting Period, revenue of the Group was approximately RMB6,319 million, representing an increase of approximately 26.4% as compared to RMB5,000 million of 2021. Leveraging on the advantage of products' clinical efficacy as well as the professional and efficient commercialization team, we are confident of the stable growth of revenue from products. In the future, the Group will remain dedicated to market innovative drugs with higher efficacy continuously, so as to fulfill the unmet demands of patients.

Nervous System Products

Sanbexin® (Edaravone and Dexborneol Concentrated Solution for Injection)

Sanbexin® is a category I innovative drug developed by the Group with proprietary intellectual property right used to treat Acute Ischemic Stroke (AIS). Sanbexin® was approved for marketing in China in July 2020 and has been included in the NRDL since December 2020. The results of phase III pivotal clinical TASTE study of Sanbexin®, which are published in STROKE, an international authoritative medicine journal, indicated that, Sanbexin® can significantly increase the proportion of patients with a mRS score of 0-1 after 90 days of treatment of patients, i.e. reduce the proportion of patients disabled by AIS. Sanbexin® was recommended by the Specialists' Consensus on the Clinical Assessment and Treatment of Acute Cerebral Infarction Ischemic Penumbra in China (《急性腦梗死缺血半暗帶臨床評估和治療中國專家共識》) and the Guidelines on Establishment of Stroke Prevention and Treatment System (《腦卒中防治體系建設指導規範》) and other guidelines and consensuses, and multiple relevant studies were presented at the European Stroke Organization Conference (ESOC), the scientific meeting of the American Heart Association (AHA) Hypertension Council and the World Congress of Neurology (WCN).

- The TASTE II study, led by Beijing Tiantan Hospital of the Capital Medical University with the participation of approximately 100 research centers in China, was progressing well. Such study aimed at evaluating the efficacy and safety of Sanbexin® combined with reperfusion in the treatment of AIS patients. On March 21, 2022, such study completed the First-Patient-In ("**FPI**"). As of the date of this announcement, the enrollment of more than 1,300 AIS patients within 24 hours of onset and undergone early endovascular recanalization therapy was completed.

- In May 2022, Sanbexin® was recommended by the 2022 Guidelines on Establishment of Stroke Prevention and Treatment System (《腦卒中防治體系建設指導規範(2022版)》) (Level IIa recommendation, level A evidence). The recommended contents are: Edaravone and dexborneol block the cerebral ischemia cascade through multiple targets such as free radical scavenging, inflammation resistance, glutamate excitotoxicity resistance and mitochondria protection. It can significantly improve the functional outcomes of patients with Ischemic Stroke, and is safe for clinical use, providing a new and more effective clinical treatment for AIS.

- In May 2022, a research result published at the 8th European Stroke Organization Conference (ESOC) indicated that whether thrombolysis treatment is received or not, Sanbexin® significantly lowers the inflammatory factor level of AIS patients and improves nervous functions, for which the improvement made by the treatment group of Sanbexin® combined with thrombolytic drugs is the most distinct.

- Sanbexin® has benefited approximately 880,000 patients during the Reporting Period and covers approximately 3,440 medical institutions currently. In January 2023, Sanbexin® was successfully renewed in the NRDL.

- On February 8, 2023, the Group's application of IND for treatment of hemorrhagic stroke by Sanbexin® was accepted by CDE and it was expected to initiate the clinical trial of such indication in 2023.

Oncology Products

Endostar® (Recombinant Human Endostatin Injection)

Endostar® is the first anti-angiogenic targeted drug in China and the only endostatin approved for sale worldwide. Endostar® has been included in the NRDL since 2017 and is recommended as a first-line treatment for patients with advanced non-small-cell lung cancer ("**NSCLC**") by a number of oncology clinical practice guidelines issued by the National Health Commission of the PRC ("**NHC**"), Chinese Medical Association (中華醫學會) and Chinese Society of Clinical Oncology ("**CSCO**"). Also, it is recommended by various guidelines in relation to nasopharyngeal carcinoma, melanoma, esophageal carcinoma and osteosarcoma. At present, the Group is actively exploring the expansion of new indications of this product in thoracoabdominal effusions.

- On July 28, 2022, COREMAP study, a randomized, controlled and double-blinded multi-center phase III clinical trial of intracavitary injection with Endostar® in combination with Cisplatin versus Placebo in combination with Cisplatin for the treatment of malignant thoracoabdominal effusions, completed the FPI, which was led by Shanghai East Hospital and participated by more than 70 research centers across China. As of the date of this announcement, the COREMAP study has enrolled 328 patients.

- In June 2022, the American Society of Clinical Oncology (ASCO) published 3 important research results about Endostar® at its 58th annual meeting in the form of online abstracts and posters, including three days intravenous infusion of Endostar® in combination with PD-1 monoclonal antibody and chemotherapy for the first-line treatment of EGFR/ALK-negative advanced non-squamous NSCLC, Endostar® in combination with whole brain radiotherapy for the treatment of NSCLC brain metastasis patients, and Endostar® in combination with radiotherapy for the treatment of low-risk locally advanced nasopharyngeal carcinoma.

- On August 6, 2022, a multi-center retrospective study of Endostar® in combination with Camrelizumab and chemotherapy for the treatment of advanced NSCLC was presented at the 2022 WCLC meeting.

- In November 2022, 2 study results of Endostar® were announced at the annual meeting of CSCO, and the data were mainly about advanced NSCLC.

- In December 2022, Endostar® was recommended by the 2022 Guidelines on Radiotherapy of Esophageal Cancer (《中國食管癌放射治療指南(2022年版)》) again (Level II recommendation, Class 2B evidence).

- In December 2022, as recommended by the "Guidelines for the Clinical Application of New Anti-tumor Drugs (2022 edition)" (《新型抗腫瘤藥物臨床應用指導原則(2022年版)》) issued by the National Health Commission of the PRC, except administration by sequential intravenous infusions for 14 days, the clinical practice of Endostar can also apply 210mg continuous intravenous infusion for 72 hours or 120 hours.

ENWEIDA® (Envafolimab Injection)

ENWEIDA® is a single domain antibody against recombinant humanized PD-L1 and a protein fused with Fc, which was conditionally approved to marketing in China by the NMPA on November 25, 2021. ENWEIDA® is the world's first PD-(L)1 antibody to be administered by subcutaneous injection approved for marketing. Its unique method of injection differentiates itself from other PD-(L)1 products currently on the market, with the differentiation advantages of short administration time and good safety. On March 30, 2020, the Group entered into a tripartite cooperation agreement in relation to Envafolimab with 3D (Beijing) Medicines Inc. and Jiangsu Alphamab Biopharmaceuticals Co., Ltd.. The above-mentioned agreement provides the Group with the exclusive right to promote Envafolimab for all oncology indications and the right of first refusal of external licensing or assignment in mainland China.

- In April 2022, ENWEIDA® was firstly included in three CSCO important guidelines: CSCO Diagnosis and Treatment Guidelines for Gastric Cancer 2022 (《CSCO胃癌診療指南2022版》) (Level I recommendation, Class 2A evidence); CSCO Diagnosis and Treatment Guidelines for Colorectal Cancer 2022 (《CSCO結直腸癌診療指南2022版》) (Level II recommendation, Class 2A evidence); CSCO Immune Checkpoints Guidelines for Clinical Use of Inhibitors (《CSCO免疫檢查點抑制劑臨床應用指南2022版》) (Level I recommendation, Class 2A evidence) for recommendation.

- In October and November 2022, ENWEIDA® was newly included in three CSCO guidelines for gynecologic tumor: CSCO Diagnosis and Treatment Guidelines for Endometrial Carcinoma 2022 (《CSCO子宮內膜癌診療指南2022版》) (Level II recommendation); CSCO Diagnosis and Treatment Guidelines for Cervical Cancer 2022 (《CSCO宮頸癌診療指南2022版》) (Level II recommendation); CSCO Diagnosis and Treatment Guidelines for Ovarian Cancer 2022 (Level III recommendation, Class 2B evidence).

- In November 2022, four study results of ENWEIDA® were announced at the annual meeting of the Chinese Society of Clinical Oncology (CSCO), which involved ES-SCLC, microsatellite stable (MSS) colorectal cancer (CRC), NSCLC, renal cell carcinoma (RCC), gastric cancer, esophageal cancer and other tumors.

- In December 2022, ENWEIDA® was included in the China Esophagus Cancer Radiotherapy Guidelines 2022 (《中國食管癌放射治療指南(2022年版)》). The Guidelines mentioned that, phase II/III clinical studies of various PD-1/PD-L1 antibodies (including Envafolimab) plus concurrent chemoradiotherapy for locally advanced inoperable esophageal squamous cell carcinoma are ongoing, which initially demonstrated the efficacy and safety of radiotherapy in combination with immunotherapy.

- On March 9, 2022, the multiple-cohort and multicenter phase II clinical trial led by the Group on the efficacy and safety of Suvemcitug in combination with Envafolimab with or without chemotherapy for the treatment of patients with advanced solid tumors completed the planned enrollment targets and enrolled 86 subjects in total.

Under the guidance of 7 authoritative guidelines and clinical evidence-based evidences, ENWEIDA® is expected to benefit more patients. In the future, Envafolimab will make progress in the treatment of more tumor types and may be recommended by the treatment guidelines of more tumor types (including liver cancer), so as to benefit more patients with tumors.

COSELA® (Trilaciclib Hydrochloride for Injection)

COSELA® is an effective, selective and reversiblecycl in-dependent kinases 4 and 6 (CDK4/6) inhibitor. COSELA® is the world's first-in-class comprehensive myeloprotection innovative drug that can de-administered prior to a chemotherapy and transiently retard hematopoietic stem cells and progenitor cells in G1 phase of cell cycle, thereby protect bone marrow cells from damage caused by cytotoxic chemotherapy. In August 2020, the Group entered into the exclusive license agreement with G1 Therapeutics, Inc. ("**G1 Therapeutics**") to develop and commercialize Trilaciclib Hydrochloride for Injection in the Greater China region. On February 13, 2021, the product was approved for sale by the U.S. FDA. Currently, the product has been recommended by the related key guidelines of National Comprehensive Cancer Network Guidelines ("**NCCN**"), CSCO and other organizations.

- On February 23, 2022, it was announced that COSELA® had reached the primary endpoint for the randomized, double-blind, placebo-controlled and multi-center phase III clinical trial (TRACES study) evaluating the safety, efficacy, and pharmacokinetics of Trilaciclib Hydrochloride for Injection in ES-SCLC patients who are receiving carboplatin in combination with etoposide or topotecan treatment.

- On July 12, 2022, COSELA® was conditionally approved for marketing by the NMPA with an indication label of decreasing the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen for ES-SCLC. This approval for the marketing of COSELA® is based on the data of the safety introduction stage of the TRACES study, the data of the real-world study (Trila-CN-RWS-001 study) in the International Medical Tourism Pilot Zone, Boao Hope City, Hainan Free Trade Port, China, and the previous overseas clinical trial data from G1 Therapeutics.

- In July 2022, the main results of the phase III TRACES study were presented at the WCLC on December 29, 2021: compared with placebo, COSELA® administered before chemotherapy in Chinese patients resulted in a significant decrease in the duration of severe neutropenia in Cycle 1 (0 day vs 2 days; P=0.0003). In addition, COSELA® also significantly decreased the occurrence of severe neutropenia (SN, 7.3% vs 45.2%, P<0.0001), febrile neutropenia (FN, 2.4% vs 16.7%, P=0.0267) and grade 3/4 hematologic toxicity (53.7% vs 88.1%, P=0.0005). In terms of safety, among the patients using COSELA®, all other treatment emergent adverse events (TEAE) were lower than those of the placebo control except for a slight increase in hypertriglyceridemia and γ-glutamyl transferase. Compared with placebo, there are fewer grade ≥3 adverse events using COSELA® (61.0% vs 88.1%), primarily due to the lower incidence of hematological grade ≥3 adverse events (53.7% vs 88.1%).

In addition to the ES-SCLC indications above, COSELA® was also investigated in two phase III clinical trials for metastatic colorectal cancer ("**mCRC**") and triple-negative breast cancer ("**TNBC**"). The Group was responsible for the planning of these two MRCTs in China.

- An international multi-center phase III clinical trial of COSELA® for mCRC with FOLFOXIRI/ bevacizumab (PRESERVE1 Study): In March 2022, as part of the global clinical study, 10 research centers in China completed enrollment of all 53 Chinese patients. On February 13, 2023, G1 Therapeutics announced that the PRESERVE1 study met its primary endpoint in that COSELA® significantly decreased the occurrence of severe neutropenia. However, the ORR showed the placebo group showed a more pronounced outcome and thus G1 Therapeutics decided to stop such study.

- An international multi-center phase III clinical trial of COSELA® for TNBC with gemcitabine and carboplatin (PRESERVE2 study). On January 7, 2022, the Group completed the FPI for this trial in China. On August 2, 2022, the clinical trial completed an enrollment of 38 cases in total in China.

Autoimmune Products

Iremod® (Iguratimod Tablets)

Iremod® is the category 1.1 new drug independently developed by the Group, and also the first Iguratimod pharmaceutical product approved for marketing in the world. Iremod® has been included in the National Medical Insurance Catalogue (B-List) since 2017. The indication is the active rheumatoid arthritis. Since it launched in 2012, Iremod® has benefited over 1 million patients (persons) in China. Iremod® is recommended as the primary therapy drug for the treatment of active rheumatoid arthritis by a number of clinicalpractice guidelines and pathways issued by the NHC, Chinese Medical Association, Asia Pacific League of Associations for Rheumatology and Labor and Welfare of Japan.

- On January 20, 2022, the phase II clinical trial of Iremod® in the treatment of active Primary Sjögren's Syndrome enrolled all 144 subjects.

- In January 2022, the Rheumatoid Arthritis Diagnosis and Treatment Standards (《類風濕關節炎診療規範》) officially released recommended iguratimod among the conventional synthetic disease modifying antirheumatic drugs (csDMARDs).

- In June 2022, two important studies on Iremod® were selected for the posters of the annual meeting of the European League Against Rheumatism (EULAR). One exploratory study on the mechanism of treating rheumatoid arthritisrelated interstitial lung disease shows that: The results from randomly dividing the mouse pulmonary fibrosis model into control group and treatment group with different concentrations, indicate that iguratimod could improve pulmonary fibrosis by inhibiting the initiation of EMT process and NLRP3 inflammasome activation, as well as reducing ROS production, which provides new insights for further application of iguratimod in interstitial pulmonary fibrosis. Another claims-based algorithms retrospective real-world study to evaluate the cost-effectiveness of iguratimod among patients with rheumatoid arthritis shows that: This proves that iguratimod combined with methotrexate for the treatment of rheumatoid arthritis patients is a strategy with both curative effect and economic cost.

- In December 2022, during the annual meeting of Asia-Pacific League of Associations for Rheumatology (APLAR), a real-world evidence of Iremod® treating lupus nephritis (LN) was published. The evidence showed that Iremod® was expected to be a new treatment option for LN patients.

Anti-infection Products

XIANNUOXIN® (Simnotrelvir Tablets/Ritonavir Tablets (co-packaged))

XIANNUOXIN® is the first domestic 3CL small molecule anti-SARS-CoV-2 innovative drug with independent intellectual rights in China, of which, Simnotrelvir targets 3CL protease which is essential for SARS-CoV-2 virus replication, and its combination with low-dose Ritonavir helps to slow down the metabolism or breakdown of Simnotrelvir in body in order to improve the antiviral effect.

To fight against the COVID-19 pandemic and help more patients, with the professional guidance and support of regulatory authorities, the Group spared no efforts in the development and supply upholding of XIANNUOXIN®. It took only 437 days for XIANNUOXIN® from signing contracts (pre-clinical candidates) on November 17, 2021 to obtaining conditional approval for marketing by the NMPA on January 28, 2023. The Group immediately started the production process after being approved and completed all process rapidly, and it took 12 days to complete the production and launch. To guarantee timely medication of COVID-19 patients, especially people are at risk of disease progression, within the "golden 72 hours", we have dedicated resources and teams to help localities to ensure the supply of medical materials, so as to accelerate the admission into hospitals and strive to enhance product accessibility. The major milestones and clinical data of XIANNUOXIN® are listed below:

Pre-clinical stage:

- On November 17, 2021, the Group entered into a technology transfer contract with the Shanghai Institute of Materia Medica of Chinese Academy of Sciences and Wuhan Institute of Virology, pursuant to which, the Group obtained development, production and commercialization rights on an exclusive basis of Simnotrelvir worldwide.

- Preclinical animal trial indicated that Simnotrelvir showed potent, broad-spectrum anti-SARS-CoV-2 activity with no genotoxicity observed.

Clinical stage:

- On March 28, 2022, XIANNUOXIN® obtained the Clinical Trial Approval for drugs issued by the NMPA for the initiation of series clinical trials regarding the treatment of mild-to-moderate COVID-19 infection.

- Phase I clinical trial: On April 10, 2022, the FPI for the phase I clinical trial for safety, tolerability and pharmacokinetics of XIANNUOXIN® among health adult subjects after single/multiple dose administrations was completed at Shandong Provincial Qianfoshan Hospital. On June 1, 2022, such study completed the enrollment of all patients and in-hospital observation.

- Phase Ib clinical trial: On July 23, 2022, the phase Ib clinical trial for adults with COVID-19 infection completed the medication of all patients in the Third People's Hospital of Shenzhen, and follow-up observation of all patients was completed. The results of the clinical trial showed that XIANNUOXIN® has shown positive effects on viral load, negative turning time and elimination of COVID-19-related symptoms.

- Phase II/III clinical trial: On August 19, 2022, the phase III clinical trial XIANNUOXIN® enrolled the first patient in Sanya Central Hospital (Hainan Third People's Hospital). On December 16, 2022, enrollment of all 1,208 patients was completed. Such study has established a total of 43 clinical research centers in 20 provinces, municipalities and autonomous regions in China. Such study is so far the first phase III registrational clinical study for Chinese patient population infected with the SARS-CoV-2 Omicron variants that has completed the planned number of patient enrollment. Such study was designed in accordance with international guidance and was the first phase III registrational clinical study worldwide which has met the primary endpoint as time to sustained recovery of 11 symptoms.

The results of phase II/III clinical trial showed that XIANNUOXIN® was effective in accelerating recovery from symptoms and shortening the duration of disease compared to placebo: a significant reduction of the time to first occurrence of sustained recovery of 11 target COVID-19 symptoms by approximately 1.5 days, with a significant reduction of approximately 2.4 days for the subgroup population with at least one high risk factor for progression to severe COVID-19, while the data suggest superior efficacy of XIANNUOXIN® with early use. XIANNUOXIN® also demonstrates significant antiviral effects: viral load reduced rapidly and significantly after dosing; viral load reduced up to over 96% (treatment difference in change from baseline 1.43 log10 copies/mL) compared to placebo on day 5 after dosing; and nucleic acid conversion time shortened by approximately 2.2 days. Safety data show that XIANNUOXIN® is safe and well tolerated for Chinese patients infected with mild-to-moderate COVID-19. Detailed data of such study are expected to be released in academic journals or conferences in the future.

NDA/PIVOTAL TRIAL STAGE DRUG CANDIDATES

Sanbexin sublingual tablets

Sanbexin sublingual tablets are solid formulations absorbed by the sublingual mucous membrane containing edaravone and dexborneol, which can disintegrate quickly under the tongue and absorb into the blood through the sublingual venous plexus, inhibit inflammations and prevent free radicals, thus minimizing neuronal damage caused by AIS. Such unique dosage form is expected to increase the flexibility of stroke treatment and improve medication compliance. In the future, sequential therapy consisting of Sanbexin sublingual tablets and Sanbexin® (Edaravone and Dexborneol Concentrated Solution for Injection) which has been launched by the Company is expected to enable patients to receive a complete treatment. In addition, administration of sublingual tablets is less dependent on medical facility conditions or compliance of patients, which makes it more suitable for research on new indications such as other nervous system diseases.

- On April 20, 2022, the Group reached further strategic cooperation with Neurodawn in respect of the overseas interests of Sanbexin sublingual tablets. The Group will commence the clinical studies and commercialization of Sanbexin sublingual tablets outside China. Currently, the phase I clinical study of Sanbexin sublingual tablets in the United States is in the preparation stage.

- On May 4, 2022, the phase III clinical trial of Sanbexin sublingual tablets for the treatment of AIS has completed the LPI which only took ten months to complete the enrollment of all 914 patients in advance, and all treatments and visits of patients were completed in August 2022. This multi-center, randomized, double-blind, parallel and placebo-controlled phase III study was led by Peking University Third Hospital with participation of approximately 40 research centers nationwide, which enrolled patients aged 18–80 with AIS within 48 hours of onset. The primary endpoint of the trial was the proportion of participants with an mRS score of 0~1 on the 90th day after treatment, i.e. proportion of patients who regained independent living function. At the same time, other efficacy and safety indicators were evaluated and biomarkers for stroke were explored.

- On December 1, 2022, the above phase III clinical trial has completed Database Lock (DBL) and statistical analyses. The data showed that, compared with placebo, Sanbexin sublingual tablets have significantly improved the recovery of neurological function and ability to live independently following treatment in AIS patients, achieving expected efficacy endpoints with a good safety profile. The detailed results are expected to be published in academic journals or conferences. The success of such study has demonstrated the clinical values of Sanbexin sublingual tablets in the treatment of AIS, which is expected to bring new treatment options for AIS patients.

- On December 24, 2022, the Group has submitted the Pre-NDA of Sanbexin sublingual tablets and is currently expediting the declaration of its NDA.

Suvemcitug

Suvemcitug is a new-generation recombinant humanized anti-vascular endothelial growth factor (anti-VEGF) monoclonal antibody. In its pre-clinical studies, Suvemcitug has shown higher anti-tumor efficacy than bevacizumab at the same dose in multiple cancer models. In the phase Ib clinical trial conducted in China for the treatment of ovarian cancer, preliminary results showed a favorable safety profile and efficacy signals.

- On June 11, 2021, the FPI for the phase III clinical trial of Suvemcitug in combination with chemotherapy compared with placebo in combination with chemotherapy in patients with recurrent epithelial ovarian cancer, fallopian tube cancer and primary peritoneal cancer who failed to be treated with platinum chemotherapy regimen (SCORES Study) was completed. As of the date of this announcement, SCORES Study enrolled over 350 subjects in 53 centers in China, and the enrollment of all patients is expected to complete in the first half of 2023.

- On June 8, 2022, the Group completed the enrollment for safety run-in period for a multiple-cohorts and multi-center phase II clinical trial to evaluate the safety and efficacy of Suvemcitug in combination with Envafolimab with or without chemotherapy in patients with advanced solid tumors. As of the date of this announcement, the intended enrollment has been achieved and enrolled 86 subjects in total.

PHASE I/II STAGE DRUG CANDIDATES

SIM0395 (Paxalisib)

SIM0395 is a BBB-penetrant inhibitor of the PI3K/mTOR pathway. A phase II clinical study showed that Paxalisib has shown highly encouraging signals of clinical efficacy among glioblastoma patients with unmethylated MGMT promoter status. Paxalisib was awarded the GBM orphan drug certification by FDA in 2018 and the fast track certification by FDA, the rare childhood disease and orphan drug certification of diffuse intrinsic pontine glioma (DIPG) in 2020. In March 2021, the Group entered into an exclusive licensing agreement with Kazia to introduce the development and commercialization rights of SIM0395 for all indications in the Greater China region. At present, the partner Kazia is in the international multi-center pivotal phase III clinical trial for glioblastoma (GBM AGILE Study).

Docetaxel polymeric micelles for injection

Docetaxel polymeric micelles for injection uses solubilizing carrier of docetaxel with the polyethylene glycol monomethyl ether-polylactic acid block copolymer (mPEG-PDLLA), an amphiphilic biocompatible biodegradable material, to reduce the allergy and hematotoxicity of docetaxel injection, and facilitate clinical application. In September 2020, the Group reached a global cooperation with Suzhou Hightechbio Biotechnology Co., Ltd. on this product.

- On March 31, 2022, the FPI for the open, multiple-cohorts and multi-center phased II clinical trial on the dosing of Docetaxel Polymeric Micellar for Injection was completed at Tianjin Medical University Cancer Institute and Hospital. As of the date of this announcement, approximately 30 patients were enrolled.

SIM0270 (SERD)

SIM0270 is the second-generation oral selective estrogen receptor degrading agent (SERD) with blood-brain barrier-penetrating properties independently developed by the Group. The efficacy of SIM0270 in the in vivo model is significantly better than an intramuscular SERD drug already on the market, and is equivalent to the efficacy of the leading compound in the clinical trial stage. It reflects a brain-to-blood ratio significantly better than competing compounds and also shows a tumor- inhibiting drug therapy far superior to fulvestrant on the brain orthotropic model of breast cancer. It is expected to be used for the treatment of breast cancer with brain metastases.

- On December 27, 2021, SIM0270 obtained the Clinical Trial Approval issued by the NMPA, which is intended for the clinical trial of ER+/HER2-breast cancer.

- On May 18, 2022, the phase Ia monotherapy clinical trial of SIM0270 completed the FPI in Tianjin Medical University Cancer Institute & Hospital, and is currently undergoing the study of dose escalation stage for monotherapy.

- On February 3, 2023, the treatment of estrogen receptor positive breast cancer using SIM0270 in combination with piperacil or ivimox has obtained the Clinical Trial Approval issued by the NMPA, and it is planned to begin the enrollment of combined dose group in the second half of 2023.

SIM0235 (TNFR2)

SIM0235 is a tumor-immune target human immunoglobulin G1 (IgG1) humanized anti-tumor necrosis factor receptor type 2 (TNFR2) monoclonal antibody independently developed by the Group. The preclinical pharmacodynamics model shows significant single-agent efficacy and the potential and superior safety in combination with PD-1. SIM0235 can specifically recognize TNFR2 expressed on the cell surface and kill immunosuppressive cells such as regulatory T cells (Treg) and myeloid derived suppressor cells (MDSC) with high expression of TNFR2 through Fc end functions including antibody dependent cell-mediated cytotoxicity (ADCC) and antibody dependent cell-mediated phagocytosis (ADCP). At the same time, it can also block the activation of endogenous tumor necrosis factor (TNF) on TNFR2, inhibit the immunosuppressive function mediated by TNFR2 and the proliferation of related TNFR2+ immunosuppressive cells Treg and MDSC, enhance the body's killing immune response to tumor and play an anti-tumor role. In addition, SIM0235 can specifically recognize TNFR2 expressed on the surface of tumor cells and directly kill tumor cells with high expression of TNFR2 through the effector function mediated by Fc end of antibody.

- On December 6, 2021, SIM0235 obtained the Clinical Trial Approval issued by the NMPA, which is designed to be used for clinical trials of relapsed or refractory advanced solid tumors and cutaneous T-cell lymphoma (CTCL) in China.

- On January 29, 2022, FDA approved the clinical application of the drug, which is designed to be used for clinical trials of advanced solid tumors and CTCL, and achieved the first patient enrollment in the United States on October 31, 2022.

- On March 16, 2022, the FPI for phase I clinical trial of SIM0235 in China was completed at Sun Yat-sen University Cancer Center. This is the first-in-human dosing of SIM0235 and is the first time that a drug candidate for this target has been used in Chinese subjects. The phase I clinical trial will evaluate the safety, pharmacokinetics, pharmacodynamic characteristics and anti-tumor efficacy of SIM0235.

- On March 13, 2023, the Group reached a clinical development cooperation agreement with MSD to explore the possibility of using SIM0235 in combination with KEYTRUDAR (Pembrolizumab), a PD-1 antibody drug in the above phase I trial.

SIM0272 (PRMT5)

SIM0272 is a PRMT5 inhibitor independently developed by the Group with high PRMT5 inhibitory activity and high selectivity. PRMT5 is overexpressed in many cancers, including lung, breast, gastric, colorectal, ovarian, leukaemia and lymphoma, and is associated with progression and poor prognosis in most cancers. Preclinical pharmacokinetic studies revealed that SIM0272 tended to distribute within the tumor with an intratumoral drug concentration to plasma drug ratio of approximately 10 times that of other in study PRMT5 inhibitors and exhibits proliferation inhibitory activity against a variety of hematologic and solid tumor cells in vitro, with the potential to substantially reduce plasma exposure and target related hematologic toxic side effects while inhibiting tumors.

- On March 21, 2022, SIM0272 obtained the Clinical Trial Approval for drugs issued by the NMPA, which is designed for conducting clinical trials for advanced malignant tumors.

- In April 2022, SIM0272 preclinical key information was presented as an oral report at the American Association for Cancer Research (AACR).

- On June 27, 2022, the FPI for the multi-institutional phase I clinical trial which evaluated safety, tolerability, efficacy and pharmacokinetics of SIM0272 in patients with advanced malignant tumors was completed at Shandong Provincial Oncology Hospital.

SIM0237 (PD-L1/IL15v bispecific antibody)

SIM0237 is an anti-PD-L1 monoclonal antibody fused with IL-15/IL-15Rα sushi protein and developed in-house by utilizing the Group's protein engineering platform. It can block the PD-1/PD-L1 immunosuppressive pathway via binding to PD-L1 and activate the immune system through its IL-15 part, thus playing a synergistic role of relieving immunosuppression and boosting the immune system to exhibit antitumor effect. Preclinical studies showed that SIM0237 is more effective than PD-L1 or IL-15 mono treatment in mouse tumor models, suggesting a high potential for clinical development.

- On October 27, 2022, the U.S. Food and Drug Administration has approved the investigational new drugs (IND) application of SIM0237. On December 23, 2022, SIM0237 has obtained the Clinical Trial Approval issued by the NMPA. Pursuant to which, the MRCT clinical trial of SIM0237 is being conducted in the U.S. and China, which is intended to treat advanced solid tumors.

- On March 8, 2023, a phase 1 first-in-human, open-label and multi-center study for the assessment of safety, tolerability, pharmacokinetics and preliminary anti-tumor activity among adult subjects of SIM0237 advanced solid tumors completed the FPI in Hunan Cancer Hospital.

SIM0348 (humanized TIGIT/PVRIG bispecific antibody)

SIM0348 is an IgG1-based humanized TIGIT/PVRIG bispecific antibody developed in-house by utilizing the Group's protein engineering platform. It can specifically bind two novel immune checkpoint proteins, human TIGIT and PVRIG at the same time, aiming to block the interaction between CD155/TIGIT and CD112/PVRIG, and improve the anti-tumor activity of immune cells. SIM0348 has Fc-mediated effector function and can kill immunosuppressive Treg cells with high expression of TIGIT and dual expression of TIGIT and PVRIG, while better mediating the activation and killing effect of NK cells and further enhancing the tumor-killing ability of dual antibodies.

- On December 28, 2022, SIM0348 injection obtained the Clinical Trial Approval issued by the NMPA of China, which is intended to be used in clinical trials for the treatment of advanced solid tumors.

SIM0801 (QPCT)

SIM0801 is an oral small molecule inhibitor targeting glutamine acyl cyclase (QPCT)[2]. By inhibiting QPCT to prevent the formation of toxic N3pE starch protein, SIM0801 can play a role in the early stage of disease, which may prevent neuronal damage. In June 2021, the Group established a strategic regional licensing partnership with Vivoryon Therapeutics N.V. ("**Vivoryon**") for the development and commercialization of SIM0801 and other drugs in the Greater China region. In December 2021, the FDA granted "Fast Track" accreditation to the candidate drug.

- On February 24, 2022, SIM0801 obtained the Clinical Trial Approval issued by the NMPA, which is intended for the treatment of MCI or mild dementia caused by Alzheimer's disease (AD) and the support for the phase I and phase II clinical trial in China.

SIM0800 (AQP4)

SIM0800 is an Aquaporin-4 (AQP4) inhibitor[3] developed based on the Aquaporin water channel theory which has been awarded the Nobel Prize. It is intended for the treatment of acute severe ischaemic stroke complicated by cerebral oedema, as a first-in-class small molecule drug with a novel mechanism of action for brain oedema therapy. The Group entered into a license agreement with Aeromics, Inc. in October 2019, pursuant to which, the Group obtained a proprietary and sublicensable license for its self-funded research, development, production and commercialization of SIM0800 in the Greater China region.

- On February 25, 2023, the phase I clinical trial of SIM0800 completed the LPI.

SIM0335 (IL-17A related pathways)

SIM0335 is a drug candidate developed by BCY Pharm Co., Ltd. ("**BCY**") that controls fatty acid metabolism and works on IL-17A-related pathways. SIM0335 is a topical ointment with 3-Ocyclohexanecarbony1-11-keto-β-boswellic acid (CKBA) being the active ingredient. Phase I clinical results showed that the systematic exposure was low and the systematic safety risk was expected to be small.

- On May 27, 2022, the FPI for the phase IIa clinical trial of SIM0335 for the treatment of plaque psoriasis was completed at Wuxi Second People's Hospital. The trial is designed to evaluate the safety, efficacy and pharmacokinetics of SIM0335 for mild-to-moderate plaque psoriasis. On January 12, 2023, such study completed the enrollment of all patients.

- On March 2, 2023, Guangdong Taienkang Pharmaceutical Co., Ltd. acquired 50% equity interests in BCY and BCY was no longer a subsidiary of the Group[4].

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[2] SIM0801: original code was SIM0408.

[3] SIM0800: original code was SIM0307.

[4] The Group retains the production and commercialization right of SIM0335 in psoriasis indication in Mainland China, Hong Kong and Macau.

SELECTED PRE-CLINICAL STAGE DRUG CANDIDATES

We have approximately 40 candidates in the pre-clinical stage and our in-house pipelines focus on differentiated targets with FIC and BIC potential, which provide strong and diversified product pipelines for the long-term sustainable growth of the Company.

SIM0278 (IL2 mu Fc)

SIM0278 is an interleukin 2 mutant fusion protein (IL-2 mu Fc) that activates regulatory T cells developed in-house by utilizing the Group's protein engineering platform. This IND ready subcutaneous injection will potentially be developed to treat various autoimmune diseases. SIM0278 exhibits improved PK profile and selective activation of Treg cells with no activation of effector T cells or NK cells to restore immune balance which has been demonstrated in multiple preclinical disease models.

- On September 28, 2022, the Group has entered into a licensing agreement with Almirall, an international biopharmaceutical company. Under the agreement, the Group granted Almirall an exclusive right to develop and commercialize SIM0278 outside the Greater China region, the Group received a US$15 million upfront payment and may receive up to US$492 million in development and commercial milestone payments contingent on successful milestone achievements in several indications, with an important part as sales milestones, as well as up to low double-digit tiered royalties based upon future overseas sales. The Group will retain all rights to the product in the Greater China region.

Daridorexant

Daridorexant is a insomnia drug that the Group cooperates with Idorsia. Daridorexant is a dual orexin receptor antagonist, which blocks the binding of the wake-promoting neuropeptides orexins (orexin A and orexin B). Rather than inducing sleep through broad inhibition of brain activity, Daridorexant blocks only the activation of orexin receptors. Consequently, Daridorexant decreases the wake drive, allowing sleep to occur, without altering the proportion of sleep stages. Phase III data has been reported in The Lancet Neurology: the pivotal studies demonstrated that Daridorexant significantly improved sleep onset, sleep maintenance and selfreported total sleep time at months one and three compared to placebo. In all treatment groups the proportions of sleep stages were preserved, in contrast to findings reported with benzodiazepine receptor agonists. Daridorexant is able to improve both nighttime sleep and daytime function in adults with chronic insomnia disorder.

- In January 2022, Daridorexant was approved by the U.S. Food and Drug Administration (FDA) and subsequently made commercially available in May 2022. In April 2022, marketing authorization of Daridorexant was granted by the European Commission and subsequently by the Medicines and Healthcare products Regulatory Agency (MHRA) in Great Britain via the European Commission Decision Reliance Procedure (ECDRP).

- On November 15, 2022, the Group entered into an exclusive licensing agreement with Idorsia, and be granted an exclusive right to develop and commercialize Daridorexant in the Greater China region.

- On December 25, 2022, the Group has submitted the Pre-IND of the product in China.

SIM0323 (CD80/IL2)

SIM0323 is the first-in-class CD80/IL-2 bifunctional fusion protein developed by the Group and GI Innovation, Inc. The preclinical pharmacodynamic model shows significant single-drug efficacy and the potential for combined use with other anticancer drugs, such as PD-1 inhibitors and chemotherapeutics. In 2021, the partner was approved for clinical trials by the Korean Ministry of Food and Drug Safety and the U.S. FDA to carry out phase I/II clinical trials of the drug.

SIM0419 (PSD-95)

SIM0419 is a dimer peptide candidate drug (AVLX-144) that the Group cooperates with Avilex, a Danish biotechnology company, and is intended to be used for the treatment of a variety of neurological diseases such as AIS and Subarachnoid Hemorrhage (SAH). The action target is PSD-95. PSD-95 can induce the production of neuroexcitotoxic substances and damage neurons by forming a complex with N-methyl-D-aspartate (NMDA) receptor and neuronal nitric oxide synthase (nNOS), one of the subtypes of glutamate receptor. SIM0419, as a dimer inhibitor of PSD-95, can simultaneously bind to two PDZ domains in PSD-95 and block the interaction between PSD-95, NMDA and nNOS. Its molecular structure has been optimized to have higher affinity, higher stability and stronger neuroprotective activity.

GENERIC PHARMACEUTICALS

For the year ended December 31, 2022, the Group obtained approvals for 3 new generic pharmaceuticals, including edoxaban tosilate tablet (15mg, 30mg and 60 mg), ibrutinib capsules (140mg) and tenofovir alafenamide fumarate tablet (25mg). Meanwhile, it obtained 2 consistency evaluation applications regarding Biapenem for injection (0.3g) and amoxicillin and clavulanate potassium for suspension (0.15625g).

INTELLECTUAL PROPERTY RIGHTS

Meanwhile, the Group attaches great importance to the protection of intellectual property rights. For the year ended December 31, 2022, the Group had 245 new patent applications (including domestic and overseas unpublished patent applications): 238 invention patent applications, 1 utility model patent application and 6 appearance design patent applications. As of December 31, 2022, the Group has accumulatively obtained 221 invention patents, 82 utility model patents and 24 appearance design patents.

IMPACT OF COVID-19

Since the beginning of December 2022, the government issued certain new precautions against COVID-19, which cancelled regional lockdown, quarantine requirements and inter-regional travelling restrictions successively. Although the relaxation of COVID-19-related pandemic control measures led to the resumption of numerous offline business operation across China, the infection rate of Chinese population has been surging therewith.

Under such circumstances, in order to fight against the COVID-19 pandemic and help more patients in need, the Group made swift decisions and invested in R&D, and closely cooperated and worked together with relevant research institutes and clinical centers situated throughout China, which contributed to the successful development of XIANNUOXIN® (Simnotrelvir Tablets/Ritonavir Tablets (co-packaged)), the first 3CL anti-COVID-19 oral small molecule innovative drug with proprietary intellectual property right in China. Such drug was launched to the market promptly after being approved to marketing and successively supplied to various medical organizations. The outbreak of pandemic at the end of the year has caused slight impacts to the promotion of the Group's certain research projects and product admission in the short term. However, the situation has quickly returned to normal within one month and has not caused significant impacts to our business operation and financial condition. The Group's adequacy of capital liquidity and working capital can also meet the Company's operational needs and capital commitments.

The Group will still pay close attention to the development of the COVID-19 (including the subsequent outbreak caused by the new variant of the COVID-19, if any), and devote resources to guarantee the supply of XIANNUOXIN® in regions, so as to strive for timely and effective treatment of COVID-19 patients, especially patients at high risk of disease progression. For other products under research, we will follow the applicable regulatory guidelines on clinical trials during the COVID-19, strive to reduce delays and interruptions, and take relevant measures to minimize the pandemic's impact.

PROFIT FOR THE YEAR ATTRIBUTABLE TO EQUITY SHAREHOLDERS OF THE COMPANY

The Group recorded a profit for the year attributable to equity shareholders of the Company of approximately RMB933 million for 2022, representing a decrease of approximately RMB574 million or approximately 38.1% from RMB1,507 million for 2021. Such decrease in profit for the year attributable to equity shareholders of the Company was mainly attributable to the following investment portfolio and one-off gain items: (1) the net realized and unrealized gains (before tax) on financial assets at fair value through profit or loss for 2022 decreased by approximately RMB270 million as compared to that for 2021 due to the fair value change of the investment portfolio held by the Group for 2022; and (2) the impact of one-off gain, including (a) a gain (before tax) from the conversion into fair value measurement of certain investments in associates of the Company of approximately RMB314 million recorded for 2021 due to the loss of significant influence on such associates of the Company during 2021, and (b) a gain (before tax) from the disposal of the Group's entire equity interest in Simgene Group Limited of approximately RMB399 million recorded for 2021.

LIQUIDITY AND FINANCIAL RESOURCES

The Group maintained a sound financial position. For the year ended December 31, 2022, net cash generated from operating activities was approximately RMB1,355 million, while net cash outflow from operating activities for the year ended December 31, 2021 was approximately RMB202 million. Such change was mainly attributable to the increase in revenue and changes in the operating expenses in 2022. As at December 31, 2022, the Group had cash and cash equivalents of approximately RMB1,658 million (as at December 31, 2021: approximately RMB973 million) and time deposits of approximately RMB975 million (as at December 31, 2021: approximately RMB1,620 million). As at December 31, 2022, the Group had a balance of bank loans of approximately RMB1,292 million (as at December 31, 2021: approximately RMB1,530 million), all of which would mature within one year. As of December 31, 2022, approximately RMB1,193 million of the Group's bank loan balance bore interest at fixed rates, and the effective interest rate range for these loans was 1.0% to 2.73% per annum. As at December 31, 2022, the gearing ratio of the Group (total liabilities divided by total assets) was approximately 33.7% (as at December 31, 2021: approximately 36.4%).

Currently, the Group follows a set of funding and treasury policies to manage its capital resources and prevent risks involved. The Group expects to fund its working capital and other capital requirements from a combination of various sources, including but not limited to external financing at reasonable market rates. In order to better control and minimize the cost of funds, the Group's treasury activities are centralized.

The assets and liabilities of the Group were denominated in RMB, EUR, USD, GBP and HKD. During the Reporting Period, the Group did not employ financial derivatives or enter into foreign derivative contracts to hedge against foreign exchange risk. However, the Group manages the foreign exchange risks by closely monitoring the net exposure of foreign exchange risk to minimize the impact of foreign exchange fluctuations.

PLEDGE OF GROUP'S ASSETS

As at December 31, 2022, the Group pledged bills receivable of approximately RMB115 million for issuance of bank acceptance bills and pledged bank deposits of approximately RMB0.56 million for issuance of letter of guarantee.

CONTINGENT LIABILITIES

In June 2022, a subsidiary of the Group received a notice that it was being sued by a customer in respect of a supply arrangement of raw materials with an indemnity claim of approximately RMB200 million. This claim was on its early stage. Based on the legal advice and available evidences, the Directors do not believe it probable that the court will find against them. No provision has therefore been made in respect of this claim.

Save as disclosed above, as at December 31, 2022, the Group had no other contingent liabilities.

SIGNIFICANT INVESTMENTS HELD

As of December 31, 2022, the Company has a significant investment, with a value of 5% or more of the Company's total assets, in 3D Medicines Inc. ("**3D Medicines**").

3D Medicines (Stock Code: 1244) is a bio-pharmaceutical company listed on the Main Board of the Stock Exchange with a focus on the research and development of oncology therapies for cancer patients, especially those who require long-term care. As of December 31, 2022, the total investment amount of the Company in 3D Medicines amounted to USD40.0 million and the Company held 23,047,468 shares of 3D Medicines, representing 9.02% of the total issued share capital of 3D Medicines. As of December 31, 2022, the fair value of the Company's interests in 3D Medicines amounted to approximately RMB875 million, representing approximately 8.1% of the total assets of the Company as of December 31, 2022.

For the year ended December 31, 2022, the unrealised gain recognised on the Company's investment in 3D Medicines amounted to approximately RMB394 million. The Company has not received any dividend from such investment. According to the annual results announcement for the year ended December 31, 2022 published by 3D Medicines on March 30, 2023, for the year ended December 31, 2022, it recorded revenue of approximately RMB567.39 million and total comprehensive loss for the year of approximately RMB1,052.03 million.

The Board is of the opinion that the Company's investment in 3D Medicines has enhanced the Group's further exploration and development in oncology area, and created synergies with the Group's existing oncology drug promotion business.

Save as disclosed above, during the Reporting Period, the Group did not have any other significant investments.

FUTURE PLANS FOR MATERIAL INVESTMENTS AND CAPITAL ASSETS

Save as disclosed in "Use of Proceeds from the Listing" in this announcement, as at December 31, 2022, the Group did not have any other future plans for material investments and capital assets.

MATERIAL ACQUISITIONS AND DISPOSALS

For the year ended December 31, 2022, the Group had no material acquisition or disposal of subsidiaries, associates and joint venture.

EMPLOYEES AND REMUNERATION POLICY

As at December 31, 2022, the Group had a total of 7,832 full-time employees. The Group attached great importance to the recruitment, training and retention of outstanding employees, maintained a high standard in selecting and recruiting talents worldwide, and offered competitive compensation packages. The remuneration of employees mainly included basic salary, performance-based bonus and long- term incentives. Remuneration of the full time Directors and senior management who worked full time for the Company shall be determined by the Remuneration and Appraisal Committee under the Board with reference to the principal duties of relevant managerial positions, the results of performance assessment, as well as the remuneration level in the market. For the year ended December 31, 2022, staff costs (including emoluments, social insurance and other benefits of the Directors) amounted to approximately RMB2,137 million. The Group established Simcere Institute, providing employees with training on a regular basis, including orientation programs and technical training for new employees, professional and management training for middle and senior management, and health and safety training across all staff. In addition, the Group has also adopted a restricted share unit scheme on May 20, 2021, with an aim to (1) incentivise the existing and incoming directors, senior management and employees for their contribution to the Group; and (2) attract, motivate and retain skilled and experienced personnel to strive for the future development and expansion of the Group by providing them with the opportunity to own equity interests in the Company.

DEFINED CONTRIBUTION RETIREMENT PLAN

The Group only operates defined contribution pension plans. Employees of the Group's PRC subsidiaries are required to participate in a defined contribution retirement plan administered and operated by the local municipal government. The Group's PRC subsidiaries contribute funds which are calculated on certain percentages of the average employee salary as agreed by the local municipal government to the plan to fund the retirement benefits of the employees.

No forfeited contribution (by the Group on behalf of its employees who leave the scheme prior to vesting fully in such contributions) is available to be utilized by the Group to reduce the contributions payable in the future years or to reduce the Group's existing level of contributions to the defined contribution retirement plan.

FINAL DIVIDENDS

On March 31, 2023, the Board declared the payment of final dividend of RMB0.16 per Share for the year ended December 31, 2022 to shareholders whose names are on the register of members of the Company on Monday, June 26, 2023. Based on the total number of Shares in issue as of December 31, 2022, the total final dividend to be paid by the Company amounts to approximately RMB425,660,000. The proposed final dividend will be subject to the approval by the shareholders of the Company at the annual general meeting of the Company (the "**AGM**") to be held on Thursday, June 15, 2023 and is expected to be distributed to shareholders on or before Wednesday, July 12, 2023.

USE OF PROCEEDS FROM THE LISTING

The net proceeds from the initial public offering of the shares of the Company in October 2020 and allotment and issuance of shares of the Company pursuant to the partial exercise of the over-allotment option in November 2020 (the "**Net Proceeds**"), amounted to approximately HK$3,513 million in aggregate. The proposed use of the net proceeds was disclosed in the prospectus of the Company dated October 13, 2020 (the "**Prospectus**"). The following table sets out the utilization of the Net Proceeds as of the December 31, 2022 and the expected timeline for utilization:

Purpose	Percentage of the total amount	Amount of Net Proceeds received (HK$ in million)	Amount of Net Proceeds utilized during the year ended December 31, 2022 (HK$ in million)	Amount of Net Proceeds utilized as of December 31, 2022 (HK$ in million)	Amount of Net Proceeds unutilized as of December 31, 2022 (HK$ in million)	Expected timeline for utilization
Continued research and development of the Group's selected product candidates in its strategically focused therapeutic areas	60%	2,107.85	701.51	1,196.91	910.94	The actual Net Proceeds are expected to be fully utilized by 2027.
Reinforcement of the Group's sales and marketing capabilities	10%	351.31	67.30	351.31	–	The actual Net Proceeds have been fully utilized in 2022.
Investment in companies in the pharmaceutical or biotechnology sector	10%	351.31	236.64	351.31	–	The actual Net Proceeds have been fully utilized in 2022.
Repayment of certain of the Group's outstanding bank loans	10%	351.31	–	351.31	–	The actual Net Proceeds have been fully utilized in 2020.
Working capital and other general corporate purposes	10%	351.31	–	351.31	–	The actual Net Proceeds have been fully utilized in 2021.
Total	**100%**	**3,513.09**	**1,005.45**	**2,602.15**	**910.94**	

For more details, please refer to the section headed "Future Plans and Use of Proceeds — Use of Proceeds" of the Prospectus. On April 15, 2021, the Board resolved to reallocate the net proceeds amounted to approximately HK$325.62 million for the selected cell therapy product candidates, including CD19 CART-cell therapy (Indication 1), CD19 CART-cell therapy (Indication 2), BCMA CART-cell therapy and SIM0325, to the selected oncology product candidates that are currently under development, including COSELA® (SCLC, metastatic CRC and TNBC), SIM0395 and Docetaxel Polymeric Micellar for Injection. On August 31, 2022, the Board resolved to reallocate part of the unutilized Net Proceeds amounted to approximately HK$530 million which originally proposed to be used in selected innovative oncology product candidate at pre-clinical stages (including SIM-200, SIM-203-1, SIM-203-2, SIM-203-3 and SIM-236) to continuous R&D of Sanbexin sublingual tablets, Sanbexin® (Edaravone and Dexborneol Concentrated Solution for Injection), XIANNUOXIN® and SIM0278. For details, please refer to the announcements of the Company dated April 15, 2021 and August 31, 2022 in relation to the change in use of proceeds (the "**Announcements**"). As of December 31, 2022, the Net Proceeds utilized was approximately HK$2,602.15 million and the Net Proceeds unutilized was approximately HK$910.94 million. The Company intends to apply the unutilized Net Proceeds as of December 31, 2022 in the manner and proportion set out in the Prospectus and the Announcements.

OTHER INFORMATION

PURCHASE, SALE OR REDEMPTION OF THE COMPANY'S LISTED SECURITIES

Neither the Company nor any of its subsidiaries had purchased, sold or redeemed any of the Company's listed securities for the year ended December 31, 2022.

IMPORTANT EVENTS AFTER THE REPORTING PERIOD

As of the date of this announcement, no important events occurred after the Reporting Period which had a material impact on the Group.

COMPLIANCE WITH THE CORPORATE GOVERNANCE CODE

The Group is committed to maintaining and promoting stringent corporate governance. The principles of the Group's corporate governance are to promote effective internal control measures, uphold a high standard of ethics, transparency, responsibility and integrity in all aspects of business operation, so as to ensure that its business and operation are conducted in accordance with applicable laws and regulations, enhance the transparency of the Board and strengthen the accountability to all shareholders. The Group's corporate governance practices are based on the principles and code provisions prescribed in the Corporate Governance Code (the "**CG Code**") as set out in Appendix 14 to the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "**Listing Rules**").

Save as disclosed in this announcement, the Group has complied with the code provisions contained in the CG Code for the year ended December 31, 2022.

Under Code Provision C.2.1 of Part 2 of the CG Code, the roles of chairman and chief executive officer should be separate and should not be performed by the same individual. As of December 31, 2022, the roles of Chairman and Chief Executive Officer of the Company were not separated and Mr. REN Jinsheng ("**Mr. REN**") currently performs these two roles. Mr. REN is the founder of the Group, the Chairman of the Board and the Chief Executive Officer of the Company. He has been primarily responsible for developing overall corporate business strategies and business operation of the Group and making significant business and operational decisions of the Group. The Directors jointly consider that vesting the roles of both the Chairman of the Board and the Chief Executive Officer of the Company in Mr. REN is beneficial to the business prospects of the Group by ensuring consistent leadership to the Group as well as prompt and effective decision making and implementation, given that: (1) any decision to be made by the Board requires approval by at least a majority of Directors; (2) Mr. REN and other Directors are aware of and undertake to fulfill their fiduciary duties as Directors, which require, among other things, that he acts for the benefit and in the best interests of the Company and will make decisions for the Company accordingly; (3) the balance of power and authority is ensured by the operations of the Board, which consists of four executive Directors (including Mr. REN) and four independent non-executive Directors, and has a fairly strong independence element; and (4) the overall strategic and other key business, financial, and operational policies of the Company are made collectively after thorough discussion at both Board and senior management levels. The Directors jointly believe that this structure will not impair the balance of power and authority between the Board and the management of the Company.

COMPLIANCE WITH THE MODEL CODE FOR SECURITIES TRANSACTIONS BY DIRECTORS

The Group has adopted the Model Code for Securities Transactions by Directors of Listed Issuers (the "**Model Code**") as set out in Appendix 10 to the Listing Rules as the Company's code of conduct regarding the Directors' securities transactions. Having made specific enquiry of all the Directors of the Company, all the Directors confirmed that they have strictly complied with the Model Code for the year ended December 31, 2022.

AUDIT COMMITTEE AND REVIEW OF FINANCIAL INFORMATION

The Group established the Audit Committee with written terms of reference in compliance with the CG Code. The Audit Committee consists of three members as of the date of this announcement, all of which are independent non-executive Directors, namely Mr. WANG Xinhua, Mr. SONG Ruilin and Mr. WANG Jianguo. The chairperson of the Audit Committee is Mr. WANG Xinhua. Mr. WANG Xinhua possesses the appropriate professional qualifications and accounting and related financial management expertise. The main duties of the Audit Committee are to review and supervise the financial reporting process and internal control system of our Group, oversee the audit process, review and oversee the existing and potential risks of the Group and perform other duties and responsibilities as assigned by the Board.

The Audit Committee has reviewed the financial reporting processes of the Group and the annual results and consolidated financial statements of the Group for the the year ended December 31, 2022, and is of the opinion that these statements have complied with the applicable accounting standards, the Listing Rules and legal requirements, and that adequate disclosure has been made.

SCOPE OF WORK OF KPMG

The financial figures in respect of the Group's consolidated statement of profit or loss, consolidated statement of profit or loss and other comprehensive income, consolidated statement of financial position and the related notes thereto for the year ended December 31, 2022 as set out in the preliminary announcement have been agreed by the Group's auditor, KPMG, Certified Public Accountants, to the amounts set out in the Group's consolidated financial statements for the year. The work performed by KPMG in this respect did not constitute an assurance engagement and consequently no opinion or assurance conclusion has been expressed by KPMG on the preliminary announcement.

ANNUAL GENERAL MEETING

The AGM will be held on Thursday, June 15, 2023. A notice convening the AGM will be published and dispatched to the shareholders of the Company in the manner required by the Listing Rules in due course.

CLOSURE OF REGISTER OF MEMBERS

For the purpose of ascertaining the members' eligibility to attend and vote at the AGM, the Group's register of members will be closed from Monday, June 12, 2023 to Thursday, June 15, 2023 (both days inclusive), during which no transfer of share will be registered. The record date will be Thursday, June 15, 2023. In order to be eligible to attend and vote at the AGM, unregistered holders of shares of the Group shall ensure that all transfer documents accompanied by the relevant share certificates must be lodged with the Group's share registrar in Hong Kong, Computershare Hong Kong Investor Services Limited, at Shops 1712-1716, 17th Floor, Hopewell Centre, 183 Queen's Road East, Wan Chai, Hong Kong for registration not later than 4:30 p.m. on Friday, June 9, 2023.

In order to determine the entitlement of shareholders to the proposed final dividend, the register of members of the Group will be closed from Wednesday, June 21, 2023 to Monday, June 26, 2023 (both days inclusive), during which no transfer of shares will be registered. The record date will be Monday, June 26, 2023. All transfer documents together with the relevant share certificates must be lodged with the Group's share registrar in Hong Kong, Computershare Hong Kong Investor Services Limited, at Shops 1712-1716, 17th Floor, Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong for registration not later than 4:30 p.m. on Tuesday, June 20, 2023.

PUBLICATION OF THE ANNUAL RESULTS AND ANNUAL REPORT

The annual results announcement is published on the website of the Stock Exchange (www.hkexnews.hk) as well as the website of the Group (www.simcere.com). The Group's 2022 annual report will be dispatched to shareholders according to their requirements and will be published on the aforementioned websites in due course.

APPRECIATION

The Board would like to express its gratitude to all shareholders for their understanding, support and trust, with which all employees of the Group, guided by patient needs, will continue to work diligently as one in the long run.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS

For the year ended December 31, 2022

	Note	**2022**	2021
		RMB'000	*RMB'000*
Revenue	*3*	**6,319,096**	4,999,718
Cost of sales		**(1,322,246)**	(1,079,983)
Gross profit		**4,996,850**	3,919,735
Other income	*4(a)*	**172,260**	149,510
Other net gain	*4(b)*	**254,264**	1,215,210
Research and development costs		**(1,728,269)**	(1,416,721)
Selling and distribution expenses		**(2,402,371)**	(2,036,705)
Administrative and other operating expenses		**(444,201)**	(366,657)
Reversal/(recognition) of impairment loss on trade and other receivables		**13,972**	(15,828)
Profit from operations		**862,505**	1,448,544
Finance income	*5(a)*	**59,867**	68,287
Finance costs	*5(a)*	**(34,408)**	(70,848)
Net finance income/(costs)		**25,459**	(2,561)
Share of profits/(losses) of associates		**115**	(43,916)
Share of profits/(losses) of a joint venture		**75**	(270)

	Note	**2022**	2021
		RMB'000	*RMB'000*
Profit before taxation	*5*	**888,154**	1,401,797
Income tax	*6*	**40,478**	97,124
Profit for the year		**928,632**	1,498,921
Attributable to:			
Equity shareholders of the Company		**932,768**	1,507,096
Non-controlling interest		**(4,136)**	(8,175)
Profit for the year		**928,632**	1,498,921
Earnings per share	*8*		
Basic (RMB)		**0.36**	0.58
Diluted (RMB)		**0.36**	0.58

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the year ended December 31, 2022

	Note	**2022**	2021
		RMB'000	*RMB'000*
Profit for the year		**928,632**	1,498,921
Other comprehensive income for the year (after tax adjustments)	*7*		
Items that will not be reclassified to profit or loss:			
Financial assets at fair value through other comprehensive income (FVOCI) – net movement in fair value reserves (non-recycling), net of tax		**(156,346)**	16,372
Exchange difference on translation of financial statements		**176,813**	(59,356)
Other comprehensive income for the year		**20,467**	(42,984)
Total comprehensive income for the year		**949,099**	1,455,937
Attributable to:			
Equity shareholders of the Company		**953,235**	1,464,112
Non-controlling interest		**(4,136)**	(8,175)
Total comprehensive income for the year		**949,099**	1,455,937

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As at December 31, 2022

	Note	**December 31, 2022**	December 31, 2021
		RMB'000	*RMB'000*
Non-current assets			
Property, plant and equipment		**2,135,781**	1,931,212
Intangible assets		**379,896**	59,691
Goodwill		**172,788**	172,788
Interest in an associate		**4,978**	4,863
Interest in a joint venture		**4,477**	4,402
Prepayments, deposits and other receivables		**97,470**	76,564
Financial assets at fair value through other comprehensive income		**137,774**	291,727
Financial assets at fair value through profit or loss		**2,056,700**	1,940,375
Time deposits	*10(c)*	**10,752**	410,000
Deferred tax assets		**326,713**	289,972
		5,327,329	5,181,594
Current assets			
Inventories		**302,373**	235,157
Trade and bills receivables	*9*	**2,337,443**	2,398,767
Prepayments, deposits and other receivables		**165,698**	140,034
Taxation recoverable		**6,506**	16,789
Pledged deposits	*10(b)*	**560**	1,580
Restricted deposits	*10(b)*	**19,378**	4,005
Time deposits	*10(c)*	**964,226**	1,210,078
Cash and cash equivalents	*10(a)*	**1,657,600**	973,139
		5,453,784	4,979,549

	Note	**December 31, 2022**	December 31, 2021
		RMB'000	*RMB'000*
Current liabilities			
Bank loans	*11*	**1,292,067**	1,530,085
Lease liabilities		**58,756**	31,558
Trade and bills payables	*12*	**334,444**	323,951
Other payables and accruals	*13*	**1,267,899**	1,162,014
Taxation payable		**10,562**	16,155
		2,963,728	3,063,763
Net current assets		**2,490,056**	1,915,786
Total assets less current liabilities		**7,817,385**	7,097,380
Non-current liabilities			
Lease liabilities		**155,921**	74,239
Deferred income		**403,350**	417,613
Deferred tax liabilities		**115,291**	142,771
		674,562	634,623
NET ASSETS		**7,142,823**	6,462,757
CAPITAL AND RESERVES			
Share capital		**3,081,131**	3,002,871
Reserves		**4,045,630**	3,434,126
Total equity attributable to equity shareholders of the Company		**7,126,761**	6,436,997
Non-controlling interest		**16,062**	25,760
TOTAL EQUITY		**7,142,823**	6,462,757

NOTES TO THE FINANCIAL STATEMENTS

For the year ended December 31, 2022

1 GENERAL INFORMATION AND BASIS OF PREPARATION OF THE FINANCIAL STATEMENTS

Simcere Pharmaceutical Group Limited (the "**Company**") was incorporated in Hong Kong on November 30, 2015 as a limited liability company with its registered office at 43/F, AIA Tower, 183 Electric Road, North Point, Hong Kong. The Company's shares were listed on the Main Board of the Stock Exchange of Hong Kong Limited on October 27, 2020. The Company is an investment holding company. The Company and its subsidiaries (together, "**the Group**") are principally engaged in the research and development, manufacturing and sales of pharmaceutical products as well as rendering promotion service of pharmaceutical products that are not manufactured by the Group.

These financial statements have been prepared in accordance with all applicable Hong Kong Financial Reporting Standards ("**HKFRSs**") which collective term includes all applicable individual Hong Kong Financial Reporting Standards, Hong Kong Accounting Standards ("**HKAS**") and Interpretations issued by the Hong Kong Institute of Certified Public Accountants ("**HKICPA**"), accounting principles generally accepted in Hong Kong and the requirements of the Hong Kong Companies Ordinance. These financial statements also comply with the applicable disclosure provisions of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited.

The financial information relating to the financial year ended December 31, 2022 and 2021 that is included in this preliminary annual results announcement does not constitute the Company's statutory annual consolidated financial statements for those years year but is derived from those financial statements. Further information relating to these statutory financial statements required to be disclosed in accordance with section 436 of the Companies Ordinance is as follows:

The Company has delivered the financial statements for the year ended December 31, 2021 to the Registrar of Companies as required by section 662(3) of, and Part 3 of Schedule 6 to, the Companies Ordinance and will deliver the financial statements for the year ended December 31, 2022 in due course.

The Company's auditor has reported on the consolidated financial statements of the Group for both years. The auditor's reports were unqualified; did not include a reference to any matters to which the auditor drew attention by way of emphasis without qualifying its reports; and did not contain a statement under sections 406(2), 407(2) or (3) of the Companies Ordinance.

2 CHANGES IN ACCOUNTING POLICIES

The HKICPA has issued the following amendments to HKFRSs that are first effective for the current accounting period of the Group:

- Amendments to HKAS 16, *Property, plant and equipment: Proceeds before intended use*
- Amendments to HKAS 37, *Provisions, contingent liabilities and contingent assets: Onerous contracts — cost of fulfilling a contract*

None of these developments have had a material effect on how the Group's results and financial position for the current or prior periods have been prepared or presented. The Group has not applied any new standard or interpretation that is not yet effective for the current accounting period.

3 REVENUE AND SEGMENT REPORTING

(a) Revenue

(i) Disaggregation of revenue

Disaggregation of revenue from contracts with customers by business lines is as follows:

	2022	2021
	RMB'000	*RMB'000*
Revenue from contracts with customers within the scope of HKFRS 15		
Sales of pharmaceutical products	**5,612,064**	4,592,371
Promotion service income	**601,487**	407,347
License income	**105,545**	–
	6,319,096	4,999,718

The Group's revenue from contracts with customers was recognized at point in time for the year ended December 31, 2022.

The Group's customer base is diversified and nil (2021: nil) customers with whom transactions have exceeded 10% of the Group's revenues for the year ended December 31, 2022.

(ii) Revenue expected to be recognized in the future arising from contracts with customers in existence at the reporting date

The Group has applied the practical expedient in paragraph 121 of HKFRS 15 to its sales contracts for goods such that information about revenue expected to be recognized in the future is not disclosed in respect of revenue that the Group will be entitled to when it satisfies the remaining performance obligations under the contracts for sales of goods that had an expected duration of one year or less.

(b) Segment reporting

Operating segments are identified on the basis of internal reports that the Group's most senior executive management reviews regularly in allocating resources to segments and in assessing their performances.

The Group's most senior executive management makes resources allocation decisions based on internal management functions and assess the Group's business performance as one integrated business instead of by separate business lines or geographical regions. Accordingly, the Group has only one operating segment and therefore, no segment information is presented.

HKFRS 8, Operating Segments, requires identification and disclosure of information about an entity's geographical areas, regardless of the entity's organization (i.e. even if the entity has a single reportable segment). The Group operates within one geographical location because primarily all of its revenue was generated in the PRC and primarily all of its non-current operating assets and capital expenditure were located/incurred in the PRC. Accordingly, no geographical information is presented.

4 OTHER INCOME AND OTHER NET GAIN

(a) Other income

	2022	2021
	RMB'000	*RMB'000*
Government grants *(Note)*	**125,172**	96,214
Rental income	**17,738**	17,350
Property management income	**11,573**	9,519
Consulting and technology service income	**6,682**	7,837
Others	**11,095**	18,590
	172,260	149,510

Note:

During the year ended December 31, 2022, the Group received unconditional government grants of RMB80,130,000 (2021: RMB57,687,000) as rewards of the Group's contribution to technology innovation and regional economic development.

During the year ended December 31, 2022, the Group received conditional government grants of RMB1,927,000 (2021: RMB nil) as subsidies for construction and equipment and recognized such grants of RMB33,894,000 (2021: RMB32,477,000) in the consolidated statements of profit or loss when related conditions were satisfied. During the year ended December 31, 2022, the Group received conditional government grants of RMB32,942,000 (2021: RMB8,189,000) as encouragement of technology research and development and recognized such type of grants of RMB11,148,000 (2021: RMB6,050,000) in the consolidated statements of profit when related conditions were satisfied.

(b) Other net gain

	2022	2021
	RMB'000	*RMB'000*
Net foreign exchange (loss)/gain	**(57,215)**	116,009
Net (loss)/gain on disposal of property, plant and equipment	**(10,571)**	2,685
Net realized loss on trading securities	**–**	(119)
Net realized and unrealized gains on financial assets at fair value through profit or loss	**113,112**	382,849
Indemnity from contract termination	**208,938**	–
Net gain arising from fair value remeasurement of interest in former associates	**–**	314,456
Net gain on disposal of interest in subsidiaries	**–**	399,330
	254,264	1,215,210

5 PROFIT BEFORE TAXATION

Profit before taxation is arrived at after charging/(crediting):

(a) Net finance (income)/costs

	2022	2021
	RMB'000	*RMB'000*
Interest income from bank deposits	**(59,867)**	(68,287)
Finance income	**(59,867)**	(68,287)
Interest expenses on bank loans	**27,654**	63,864
Interest expenses on lease liabilities	**6,754**	6,984
Finance costs	**34,408**	70,848
Net finance (income)/costs	**(25,459)**	2,561

(b) Staff costs

	2022	2021
	RMB'000	*RMB'000*
Salaries, wages and other benefits	**1,903,727**	1,498,480
Contributions to defined contribution retirement plans	**95,265**	69,769
Equity settled share-based payment expenses	**138,290**	62,392
	2,137,282	1,630,641

(c) Other items

	2022	2021
	RMB'000	*RMB'000*
Cost of inventories recognized as expenses *(Note i)*	**879,438**	763,015
Depreciation charge		
– owned property, plant and equipment	**208,317**	189,120
– right-of-use assets	**59,626**	45,270
Amortization of intangible assets	**14,985**	17,417
Research and development costs *(Note ii)*	**1,728,269**	1,416,721
(Reversal)/recognition of impairment loss on trade and other receivables	**(13,972)**	15,828
Auditors' remuneration		
– audit services	**4,000**	4,000
– non-audit services	**294**	241

Notes:

(i) Cost of inventories recognized as expenses includes amounts relating to staff costs, depreciation and amortization expenses, which are also included in the respective total amounts disclosed separately above or in Note 5(b) for each of these types of expenses.

(ii) Research and development costs include amounts relating to staff costs, depreciation and amortization expenses, which are also included in the respective total amounts disclosed separately above or in Note 5(b) for each of these types of expenses.

6 INCOME TAX IN THE CONSOLIDATED STATEMENTS OF PROFIT OR LOSS

Taxation in the consolidated statements of profit or loss represents:

	2022	2021
	RMB'000	*RMB'000*
Current tax		
PRC Corporate Income Tax		
Provision for the year	**11,262**	17,858
(Over)/under-provision in respect of prior years	**(13,677)**	4,791
	(2,415)	22,649
Overseas Corporate Income Tax		
Provision for the year	**9**	7,294
Deferred tax		
Origination and reversal of temporary differences	**(38,072)**	(127,067)
Total income tax	**(40,478)**	(97,124)

Income tax for the PRC operations is charged at the statutory rate of 25% of the assessable profits under tax rules and regulations in the PRC. Certain PRC subsidiaries are subject to a preferential income tax of 15% under the relevant tax rules and regulations.

Taxation in other jurisdiction is calculated at the rates prevailing in the relevant jurisdictions.

7 OTHER COMPREHENSIVE INCOME

Tax effects relating to each component of other comprehensive income

	Exchange differences on translation of financial statements	Financial assets at fair value through other comprehensive income – net movement in fair value reserves (non-recycling)	Total
	RMB'000	*RMB'000*	*RMB'000*
For the year ended December 31, 2021			
Before-tax amount	(59,356)	19,212	(40,144)
Tax expense	–	(2,840)	(2,840)
Net-of-tax amount	(59,356)	16,372	(42,984)
For the year ended December 31, 2022			
Before-tax amount	176,813	(183,953)	(7,140)
Tax expense	–	27,607	27,607
Net-of-tax amount	176,813	(156,346)	20,467

8 EARNINGS PER SHARE

(a) Basic earnings per share

The calculation of basic earnings per share is based on the profit attributable to equity shareholders of the Company of RMB932,768,000 (2021: RMB1,507,096,000) and the weighted average of 2,611,171,592 ordinary shares (2021: 2,608,641,618) in issue during the year, calculated as follows:

Weighted average number of ordinary shares

	2022	2021
Issued ordinary shares at January 1	**2,628,290,618**	2,608,641,618
Effect of ordinary shares issued	**17,704,132**	5,844,000
Effect of unvested shares under 2021 RSU Scheme	**(34,823,158)**	(5,844,000)
Weighted average number of ordinary shares at December 31	**2,611,171,592**	2,608,641,618

(b) Diluted earnings per share

The calculation of diluted earnings per share is based on the profit attributable to equity shareholders of the Company of RMB932,768,000 (2021: RMB1,507,096,000) and the weighted average of ordinary shares of 2,620,375,892 (2021: 2,611,357,884 shares), calculated as follows:

Weighted average number of ordinary shares (diluted)

	2022	2021
Weighted average number of ordinary shares at 31 December	**2,611,171,592**	2,608,641,618
Effect of contingently issuable shares under 2021 RSU Scheme	**9,204,300**	2,716,266
Weighted average number of ordinary shares (diluted) at 31 December	**2,620,375,892**	2,611,357,884

9 TRADE AND BILLS RECEIVABLES

	2022	2021
	RMB'000	*RMB'000*
Trade receivables	**1,871,314**	2,017,320
Bills receivable	**490,804**	419,635
	2,362,118	2,436,955
Less: loss allowance	**(24,675)**	(38,188)
	2,337,443	2,398,767

All of the trade and bills receivables are expected to be recovered within one year.

As at December 31, 2022, bills receivable of RMB115,465,000 were pledged for issuance of bills payable (2021: RMB80,786,000).

Aging analysis

As of the end of the reporting period, the aging analysis of trade and bills receivables, based on the invoice date and net of loss allowance, is as follows:

	2022	2021
	RMB'000	*RMB'000*
Within 3 months	**1,818,648**	1,561,742
Over 3 months but within 12 months	**518,145**	831,220
Over 12 months	**650**	5,805
	2,337,443	2,398,767

Trade and bills receivables are due within 30 - 90 days from the date of billing.

10 CASH AND CASH EQUIVALENTS, PLEDGED DEPOSITS, RESTRICTED DEPOSITS, AND TIME DEPOSITS

(a) Cash and cash equivalents comprise:

	2022	2021
	RMB'000	*RMB'000*
Cash at bank	**1,657,600**	973,139

As at December 31, 2022, cash and cash equivalents situated in Mainland China amounted to RMB1,495,666,000 (2021: RMB571,340,000). Remittance of funds out of Mainland China is subject to relevant rules and regulations of foreign exchange control.

(b) Pledged deposits and restricted deposits comprise:

	2022	2021
	RMB'000	*RMB'000*
Pledged deposits for		
– issuance of letter of guarantee	**560**	1,580

	2022	2021
	RMB'000	*RMB'000*
Restricted deposits for		
– research and development projects	**13,435**	4,005
– 2021 RSU Scheme	**5,943**	–
	19,378	4,005

(c) Time deposits comprise:

	2022	2021
	RMB'000	*RMB'000*
Current portion	**964,226**	1,210,078
Non-current portion	**10,752**	410,000
	974,978	1,620,078

11 BANK LOANS

The maturity profile for the interest-bearing bank loans of the Group at the end of each reporting period is as follows:

	2022	2021
	RMB'000	*RMB'000*
Short-term bank loans	**1,183,700**	991,571
Current portion of long-term bank loans	**108,367**	538,514
Within 1 year or on demand	**1,292,067**	1,530,085

The bank loans were secured as follows:

	2022	2021
	RMB'000	*RMB'000*
Bank loans		
– Secured	**–**	1,134,596
– Unsecured	**1,292,067**	395,489
	1,292,067	1,530,085

12 TRADE AND BILLS PAYABLES

	2022	2021
	RMB'000	*RMB'000*
Trade payables	**226,159**	256,131
Bills payable	**108,285**	67,820
	334,444	323,951

As of the end of the reporting period, the aging analysis of trade and bills payables, based on the invoice date, is as follows:

	2022	2021
	RMB'000	*RMB'000*
Within 3 months	**239,712**	252,556
3 to 12 months	**93,289**	70,567
Over 12 months	**1,443**	828
	334,444	323,951

All of the trade and bills payables are expected to be settled within one year or repayable on demand.

13 OTHER PAYABLES AND ACCRUALS

	2022	2021
	RMB'000	*RMB'000*
Accrued expenses *(Note i)*	**583,739**	546,992
Contract liabilities *(Note ii)*	**63,338**	26,140
Payable for employee reimbursements	**28,884**	105,691
Payables for staff related costs	**335,384**	279,064
Payables for purchase of property, plant and equipment	**21,877**	35,334
Other tax payables	**133,859**	76,667
Payables for research and development	**41,695**	23,757
Others	**59,123**	68,369
	1,267,899	1,162,014

All of the other payables and accruals are expected to be settled within one year or repayable on demand.

Notes:

(i) Accrued expenses primarily comprise marketing and promotion expenses, research and development costs and other expenses.

(ii) Contract liabilities represent customers' advances received for goods that have not yet been transferred to the customers.

14 DIVIDENDS

(i) Dividend payable to equity shareholders of the Company attribute to the year:

	2022	2021
	RMB'000	*RMB'000*
Dividends proposed after the end of the reporting period of RMB 0.16 per ordinary share (2021: RMB0.15 per ordinary share)	**425,660**	394,244
Less: Dividends for unvested shares under 2021 RSU scheme	**(6,761)**	(2,948)
	418,899	391,296

The final dividend proposed after the end of the reporting period has not been recognized as a liability at the end of the reporting period.

(ii) Dividends payable to equity shareholders of the Company attributable to the previous financial years, declared and approved during the year:

	2022	2021
	RMB'000	*RMB'000*
Dividends in respect of previous financial years approved and paid during the year, of RMB0.15 per share (2021: RMB0.15 per share)	**391,296**	391,296

By order of the Board
Simcere Pharmaceutical Group Limited
Mr. REN Jinsheng
Chairman and Chief Executive Officer

Hong Kong, March 31, 2023

As at the date of this announcement, the Board comprises Mr. REN Jinsheng as the Chairman and executive Director, Mr. TANG Renhong, Mr. WAN Yushan and Ms. WANG Xi as the executive Directors; and Mr. SONG Ruilin, Mr. WANG Jianguo, Mr. WANG Xinhua and Mr. SUNG Ka Woon as the independent non-executive Directors.