# 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 INTERIM RESULTS FOR THE SIX MONTHS ENDED JUNE 30, 2021

## BUSINESS HIGHLIGHTS

We are rapidly transforming into an innovative company, and revenue from innovative pharmaceuticals is becoming the main source of revenue for the Group. For the six months ended June 30, 2021, sales revenue from innovative pharmaceuticals was approximately RMB1.22 billion, which increased significantly by approximately 56.8% as compared to the revenue from innovative pharmaceuticals for the same period of last year. The revenue from innovative pharmaceuticals contributed 57.6% of the total revenue for the same period to set a historic high (the proportions for 2018, 2019 and 2020 were 25.5%, 32.9% and 45.1%, respectively). Such achievements were mainly attributable to the rapid sales revenue growth of Sanbexin®, our core innovative pharmaceutical launched in July 2020.

We continue to increase investment in innovation to further enrich our product pipeline. The Group currently has nearly 60 innovative pharmaceutical projects in its R&D pipeline with 11 innovative pharmaceutical products in the stage of clinical study. For the six months ended June 30, 2021, 5 pivotal registrational trials and phase III clinical trials and 1 phase I clinical trial were newly added, 7 Clinical Trial Approvals were received and the first patient in for 7 trials were completed. As at the date of this announcement, there were 6 pivotal registrational trials and phase III clinical trials, 2 phase II clinical trials and 5 phase I clinical trials in progress.

We adhere to the dual-drive strategy of independent R&D and R&D cooperation. In March and June 2021, we reached strategic cooperation with Kazia Therapeutics and Vivoryon Therapeutics, respectively, striving to make the research and development results in the global life sciences field benefit more patients as soon as possible.

## FINANCIAL HIGHLIGHTS

For the six months ended June 30, 2021, the Group recorded the following unaudited financial results:

- Revenue of approximately RMB2,120 million, representing an increase of approximately 10.1% as compared with that for the same period of last year;
- Research and development costs of approximately RMB627 million, representing an increase of approximately 38.0% as compared with that for the same period of last year, which accounted for approximately 29.6% of the revenue;
- Profit for the period of approximately RMB555 million, representing an increase of approximately 200.2% as compared with that for the same period of last year;
- Basic earnings per share of approximately RMB0.21, representing an increase of approximately 162.5% as compared with that for the same period of last year.

The board of directors (the "**Board**" or the "**Directors**") of Simcere Pharmaceutical Group Limited (the "**Company**") is pleased to announce the unaudited condensed consolidated financial results of the Company together with its subsidiaries (collectively the "**Group**") for the six months ended June 30, 2021 (the "**Reporting Period**" or the "**Period**"), together with the comparative figures for the corresponding period in 2020. The unaudited condensed consolidated financial information for the Reporting Period have been reviewed by the audit committee of the Company (the "**Audit Committee**").

## COMPANY OVERVIEW

Simcere Pharmaceutical Group Limited, now rapidly transitioning to an innovation and R&D-driven pharmaceutical company, has R&D, production and professional marketing capabilities.

The Group focuses on three therapeutic areas, oncology, central nervous system diseases and autoimmune diseases. In these three areas, the Group has four innovative pharmaceuticals approved for sale (including an imported innovative pharmaceutical).

Attaching great importance to innovative pharmaceutical R&D, we devote ourselves to research and increase the R&D investment year on year. We have three innovative drug R&D centers located in Shanghai, Nanjing in the People's Republic of China ("**PRC**" or "**China**") and Boston in the United States of America ("**U.S.**" or "**United States**"), and was approved by the Ministry of Science and Technology of the PRC to build the National Key Laboratory of Translational Medicine and Innovative Pharmaceuticals. The Group currently has a R&D team of approximately 900 staff and nearly 60 innovative product candidates in its R&D pipeline.

We have leading commercial capabilities with nationwide sales and distribution network. As innovative pharmaceuticals continue to be approved for sale, the Group constantly enhanced training and improved the professional academic promotion capabilities of its marketing team, so as to ensure the speed and efficiency of commercial promotion and increase product coverage. As at June 30, 2021, the Group had a total of approximately 4,000 salespersons.

We establish world-class manufacturing infrastructures and quality control standards, and have continuously improved our manufacturing capabilities of pharmaceuticals. The Group currently has five PRC GMP certified production facilities for the manufacturing of our pharmaceutical products, and we have received EU GMP certification or passed the U.S. FDA inspection for some of our production workshops.

Driven by our in-house R&D efforts and R&D collaborations, we continuously develop products that patients urgently need and have significant market potential, striving to achieve the corporate mission of "providing today's patients with medicines of the future".

## MAJOR PRODUCTS

| | |
|---|---|
| Oncology Products | Endostar® (recombinant human endostatin injection)<br>Jepaso® (nedaplatin for injection)<br>Sinofuan® (5-fluorouracil implants) |
| Central Nervous System Products | Sanbexin® (edaravone and dexborneol concentrated solution for injection)<br>Bicun® (edaravone injection) |
| Autoimmune Products | Iremod® (iguratimod tablets)<br>Orencia® (abatacept injection)<br>Yingtaiqing® (diclofenac sodium sustained release capsules/gel) |
| Other Products | Newanti® (biapenem for injection)<br>ZAILIN® (amoxicillin granules/dispersible tablets/capsules)<br>Softan® (rosuvastatin calcium tablets) |

## MANAGEMENT DISCUSSION AND ANALYSIS

### Industry Review

After the new round of medical and healthcare system reform, China's innovative pharmaceutical industry ushered in an accelerated all-round development. Since the beginning of this year, the epidemic has been contained effectively; the drug evaluation and approval has been expedited; the volume-based procurement of generic pharmaceuticals has become a regular mechanism; the inclusion of innovative pharmaceuticals into the catalog of medicines covered by the national medical insurance after negotiations had been materialized within a much shorter timeframe. All these improvements have boosted the confidence of the industry about innovation investment. China's innovative pharmaceutical enterprises have drawn the attention of an increasing number of investors in the first half of the year. We believe that only by advancing the transition to innovation-driven development with firm determination, making deployment with forward thinking and unique insight, building a R&D organization full of vitality and cultivating a prominent commercialization ability, we can strengthen our core competence amid the complicated and changeable competition situation in the future.

### Key Milestones

During the six months ended June 30, 2021, the Group made a series of advances in respect of our product candidates and business operations, including the following key milestones and achievements:

On January 18, 2021, the innovative pharmaceutical Trilaciclib obtained the Clinical Trial Approval issued by the Center for Drug Evaluation ("**CDE**") of National Medical Products Administration, PRC (the "**NMPA**"), which is designed for preventing chemotherapy-induced myelosuppression of patients with small-cell lung cancer. On April 9, 2021 and June 10, 2021, the pharmaceutical product obtained another two phase III Clinical Trial Approvals issued by the NMPA respectively for two indications: metastatic colorectal cancer and triple negative breast cancer.

On February 9, 2021, Sevacizumab obtained the Clinical Trial Approval issued by the NMPA for treatment of malignant solid tumors, and the first patient in for the phase III clinical trial for ovarian cancer was completed on June 11.

On February 16, 2021, data from the result of phase III TASTE Trial relating to Sanbexin® (edaravone and dexborneol concentrated solution for injection), a category I innovative drug developed by the Group, was published in *STROKE*, a leading international authoritative medicine journal. The trial included a total of approximately 1,200 acute ischemic stroke patients and was completed at 48 clinical centers in China.

On March 18, 2021, the NMPA issued the Clinical Trial Approval for new indications of Endostar® (recombinant human endostatin injection). Pursuant to the approval, the Group plans to conduct a randomized, controlled and double-blinded multi-centre phase III clinical study of intracavitary injection with Endostar® in combination with Cisplatin versus Placebo in combination with Cisplatin for the treatment of malignant thoracoabdominal effusions.

On March 29, 2021, the Group entered into an exclusive license agreement with Kazia Therapeutics, to introduce the right to develop and commercialize SIM0395 (Paxalisib) for all indications in Greater China. SIM0395 is a PI3K/mTOR pathway inhibitor that can penetrate the blood-brain barrier and currently is in the global phase II/III clinical trial for treatment of glioblastoma (GBM).

On April 12, 2021, SIM0307, an innovative drug pipeline product, obtained the Clinical Trial Approval issued by the NMPA. SIM0307 is an Aquaporin-4 (AQP4) inhibitor 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.

On June 17, 2021, the Group obtained the Clinical Trial Approval issued by the NMPA for lenvatinib mesilate capsules, which was used in a multi-center phase Ib/II clinical study for evaluation on treatment of advanced solid tumors with Envafolimab in combination with Lenvatinib.

On June 29, 2021, the Group entered into a strategic regional licensing partnership under the license agreement to develop and commercialize two medicines targeting the neurotoxic amyloid species N3pE (pGlu – A β ) for treating Alzheimer's disease (AD) in Greater China with Vivoryon Therapeutics, namely Varoglutamstat, an oral small molecule inhibitor targeting glutaminyl peptide cyclotransferase (QPCT) in the global clinical phase IIb, preventing the formation of the toxic amyloid N3pE and PBD-C06, preclinical monoclonal N3pE-antibody.

For the six months ended June 30, 2021, the Group completed the first patient in (FPI) for 7 trials: SIM0201 (January 5, for solid tumor), SIM0295 (January 11, for gout with hyperuricemia), SIM0335 (March 30, for psoriasis), new indication of Iremod® (April 28, for Sjögren's syndrome), Trilaciclib (May 25, for small cell lung cancer), Sevacizumab (June 11, for ovarian cancer) and Sanbexin sublingual tablets (June 28, for acute ischemic stroke).

Following the Reporting Period and up to the disclosure date of this announcement, the Group completed the FPI for another trial, namely new indication of Endostar® (July 28, for thoracoabdominal effusions).

On July 29, 2021, a multiple-cohorts and multi-institutional phase II clinical trial of Sevacizumab in combination with Envafolimab with or without chemotherapy for the treatment of patients with advanced solid tumors obtained the Clinical Trial Approval issued by the NMPA.

For details of each of the above, please refer to the ensuing paragraphs of this announcement and, where appropriate, previous announcements of the Company published on the websites of The Stock Exchange of Hong Kong Limited (the "**Stock Exchange**") and the Company.

**Revenue**

For the six months ended June 30, 2021, the revenue of the Group was approximately RMB2.12 billion. In particular, the revenue from innovative pharmaceuticals is becoming the main source of revenue for the Group, and amounted to approximately RMB1.22 billion, representing a significant increase of approximately 56.8% as compared to the revenue of RMB778 million from innovative pharmaceuticals for the same period of 2020. The revenue from innovative pharmaceuticals contributed 57.6% of the total revenue for the same period to set a historic high (25.5%, 32.9% and 45.1% for 2018, 2019 and 2020, respectively).

Most of the Group's revenue primarily concentrated on the strategically focused therapeutic areas: oncology diseases, central nervous system diseases and autoimmune diseases. The increase of our total revenue during the first half of 2021 was mainly due to the rapid increase in revenue from Sanbexin® (edaravone and dexborneol concentrated solution for injection) launched in July 2020.

***Central Nervous System Products***

Main products in this therapeutic area include Sanbexin® (edaravone and dexborneol concentrated solution for injection), and Bicun® (edaravone injection). For the six months ended June 30, 2021, revenue from the central nervous system product portfolio reached approximately RMB595 million, accounting for approximately 28.1% of the Group's total revenue.

Sanbexin® is a category I innovative drug developed by the Group with proprietary intellectual property right. According to Frost & Sullivan (Beijing) Inc., Shanghai Branch Co. ("**Frost & Sullivan**"), it is the only pharmaceutical for the treatment of stroke which has obtained the approval for sale in the past five years worldwide.

- On February 16, 2021, data from the result of phase III TASTE Trial relating to Sanbexin® was published in *STROKE*, a leading international authoritative medicine journal. The trial included a total of approximately 1,200 acute ischemic stroke patients and was completed at 48 clinical centers in China, with randomized, double-blind, positive controlled, head-to-head comparison with edaravone monotherapy conducted. Data shows that Sanbexin® has the efficacy advantage and is fairly safe.

- On March 1, 2021, the "Drugs Catalogue for the National Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance ("**NRDL**")" was officially implemented. Sanbexin® was included in the NRDL on December 28, 2020.

- As of June 30, 2021, Sanbexin® has been sold to 30 provinces, municipalities and autonomous regions across the country, covering approximately 1,500 medical institutions.

***Oncology Products***

Main products in this therapeutic area include Endostar® (recombinant human endostatin injection), Jepaso® (nedaplatin for injection) and Sinofuan® (5-fluorouracil implants). For the six months ended June 30, 2021, revenue from the oncology product portfolio reached approximately RMB553 million, accounting for approximately 26.1% of the Group's total revenue.

Endostar® (recombinant human endostatin injection) is the first proprietary anti-angiogenic targeted drug in China and the only endostatin approved for sale in China and 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**"). In September 2020, CSCO's Expert Committee on Antineoplastic Safety Management (中國臨床腫瘤學會抗腫瘤藥物安全管理專家委員會) and Expert Committee on Vascular Targeting Therapy (血管靶向治療專家委員會) published the Expert Consensus on the Clinical Application of Recombinant Human Endostatin to Treat Malignant Serous Effusion (《重組人血管內皮抑制素治療惡性漿膜腔積液臨床應用專家共識》) in Chinese Clinical Oncology. Based on the relevant translational research, clinical trial and real world study, the consensus aimed to provide guidance for the reasonable application of Endostar® in the clinical practice to treat malignant serous effusions (including malignant pleural effusions, malignant ascites and malignant pericardial effusions).

- On March 18, 2021, the Group obtained the Clinical Trial Approval issued by the NMPA for the phase III clinical trial of Endostar® on the new indication of malignant thoracoabdominal effusions, that is, a randomized, controlled and double-blinded multi-centre phase III clinical study of intracavitary injection with Endostar® in combination with Cisplatin versus Placebo in combination with Cisplatin for the treatment of malignant thoracoabdominal effusions. The first patient in for the clinical trial was completed on July 28, 2021.

- In June 2021, the American Society of Clinical Oncology (ASCO) published 4 important research results in relation to Endostar® at its 57th annual meeting in the form of online summaries, including the combination with Nivolumab to treat non-small cell lung cancer, the combination with radiotherapy to treat nasopharyngeal carcinoma and the combination with chemotherapy to treat melanoma.

***Autoimmune Products***

Main products in this therapeutic area include Iremod® (iguratimod tablets), Orencia® (abatacept injection) and Yingtaiqing® (diclofenac sodium sustained release capsules/gel). For the six months ended June 30, 2021, revenue from the autoimmune product portfolio reached approximately RMB317 million, accounting for approximately 15.0% of the Group's total revenue.

Iremod® (iguratimod tablets), the first iguratimod pharmaceutical product approved for sale in the world and the only of its kind approved for sale in China, is the only small molecule DMARD that is developed independently and marketed in China in the recent ten years. Iremod® has been included in the NRDL since 2017 and is recommended as the primary therapy drug for the treatment of active rheumatoid arthritis by a number of clinical practice guidelines and pathways issued by the NHC, Chinese Medical Association, Asia Pacific League of Associations for Rheumatology and the Ministry of Health, Labor and Welfare of Japan. Currently, we are actively promoting the indication expansion program on Sjögren's syndrome for this product. In April 2020, Iremod® was adopted in the "Primary Sjögren's Syndrome Diagnosis and Treatment Standards" (《原發性乾燥綜合徵診療規範》) issued by the Division of Rheumatology of the Chinese Medical Doctor Association (中國醫師協會風濕免疫科醫師分會).

- In March 2021, the results of the phase IV prospective real-world study on Iremod® were published online in *The Lancet Regional Health-Western Pacific*, a sub publication of The Lancet.

- On April 28, 2021, the first patient in for the phase II clinical research on the treatment of active primary Sjögren's syndrome with Iremod® was enrolled.

- In June 2021, two important studies on Iremod® were selected for the poster of the annual meeting of the European League Against Rheumatism (EULAR).

***Other Products***

Main products in these therapeutic areas include Newanti® (biapenem for injection), ZAILIN® (amoxicillin granules/dispersible tablets/capsules) and Softan® (rosuvastatin calcium tablets). For the six months ended June 30, 2021, revenue from the said product portfolio reached approximately RMB480 million, accounting for approximately 22.6% of the Group's total revenue.

**Research and Development**

The Group pays high attention to the R&D of innovative pharmaceutical, continues to increase R&D investment year on year. During the six months ended June 30, 2021, R&D investment amounted to approximately RMB627 million, accounting for approximately 29.6% of the revenue (in 2018, 2019 and 2020, the Group's R&D investment accounted for 9.9%, 14.2% and 25.3% respectively), representing an increase of approximately RMB173 million or 38.0% as compared to the same period of 2020.

The Group's R&D strategy continues to focus on the three advantageous therapeutic areas: oncology, central nervous system and autoimmune, and develops products covering both small molecule chemical drugs and large molecule biologics. The Group pays high attention to the building of innovative pharmaceutical R&D ability, and establishes innovative drug R&D centers in Shanghai, Nanjing and Boston, with about 900 R&D fellows (including about 110 doctors and 480 masters) and the clinical study team expanding rapidly to over 200 team members from the scale of 2020. The drug R&D of the Group has realized functions covering the whole process from drug discovery, pharmaceutical test, clinical trial to registration, and a national key laboratory of translational medicine and innovative pharmaceuticals was approved for construction.

The Group currently has nearly 60 innovative pharmaceutical projects in its R&D pipeline with 11 innovative pharmaceutical products in the stage of clinical study. As at June 30, 2021, 6 studies were in the stage of pivotal registrational trials and phase III clinical trials, namely Sanbexin sublingual tablets (for acute ischemic stroke), Trilaciclib (for SCLC, CRC and TNBC), recombinant human endostatin for new indications (for thoracoabdominal effusions) and Sevacizumab (for ovarian cancer), the latter 5 of which were newly added in the first half of 2021; 1 study was in the stage of phase II clinical trials, namely iguratimod tablets for new indications (for Sjögren's syndrome); 5 products were in the stage of phase I clinical trials, namely SIM0201 (for solid tumor), docetaxel polymeric micelles for injection (for solid tumor), SIM0335 (for psoriasis), SIM0295 (for gout with hyperuricemia) and SIM0307 (stroke with cerebral oedema), the latter 1 of which was newly added in the first half of 2021. In addition, on July 29, 2021, the Group recorded a new phase II clinical study for Sevacizumab in combination with Envafolimab (for solid tumor).

| Therapeutic area | Product candidate | Target/mechanism | Intended indication(s) | Internally developing/ developing in collaboration with R&D partner(s) | Status |
|---|---|---|---|---|---|
| Oncology | Trilaciclib | CDK4/6 | SCLC | Collaboration with G1 Therapeutics | Phase III clinical trials; for launch in the U.S. |
| | | | mCRC | | Phase III clinical trials |
| | | | TNBC | | Phase III clinical trials |
| | Recombinant human endostatin (New indication) | Angiogenesis pathway | Thoracoabdominal effusions | Internally developing | Phase III clinical trials |
| | Sevacizumab | VEGF | Ovarian cancer | Collaboration with Apexigen | Phase III clinical trials |
| | Sevacizumab+Envafolimab | VEGF+PD-L1 | Solid tumors | Collaboration with 3D Medicines (Beijing) and Jiangsu Alphamab | Phase II clinical trials |
| | SIM0201 | NTRK/ROS1/ALK | Solid tumors | Internally developing | Phase I clinical trials |
| | Docetaxel polymeric micelles for injection | Tubulin inhibitor | Solid tumors | Collaboration with Hightechbio | Phase I clinical trials |
| | SIM0395 | PI3K/mTOR pathway inhibitor | Glioblastoma | Collaboration with Kazia | pre-IND |
| | SIM0323 | CD80/IL2 | Solid tumors | Collaboration with GI Innovation | pre-IND |
| | SIM0270 | Second-generation oral SERD | Breast cancer | Internally developing | pre-IND |
| | SIM0235 | TNFR2 | Solid tumors | Internally developing | pre-IND |
| | SIM0237 | PD-L1/IL15 | Solid tumors | Internally developing | Pre-clinical |
| Central nervous system | Sanbexin sublingual tablets | Free radicals and inflammatory cytokines | Acute ischemic stroke | Collaboration with Neurondawn Pharmaceutical | Phase III clinical trials |
| | SIM0307 | AQP4 | Stroke with cerebral edema | Collaboration with Aeromics | Phase I clinical trials |
| | SIM0339 | DAPK1 | Ischemic stroke | Collaboration with Primary Peptides | Pre-clinical |
| | SIM0408 | QPCT | Alzheimer's disease | Collaboration with Vivoryon Therapeutics | |
| Autoimmune | Iguratimod tablets (New indication) | Inflammatory cytokines and immunoglobulins | Sjögren's syndrome | Internally developing | Phase II clinical trials |
| | SIM0335 | IL-17A-related pathways | Psoriasis | Internally developing | Phase I clinical trials |
| | SIM0295 | URAT1 | Gout with hyperuricemia | Collaboration with JW Pharmaceutical | Phase I clinical trials |
| | SIM0278 | IL2muFc | Systemic lupus erythematosus | Internally developing | Pre-clinical |

Small molecule chemical drugs

Large molecule biologics

Development status of R&D partner(s)

Worldwide multi-centre clinical trials

**Chart The Group's Major Innovative Pharmaceutical Candidates and Their Development Status as at the Date of This Announcement**

Meanwhile, the Group attaches great importance to the protection of intellectual property rights. For the six months ended June 30, 2021, the Group had 93 new patent applications (including domestic and overseas unpublished patent applications): 81 invention patent applications, 10 utility model patent applications and 2 appearance design patent applications. As at June 30, 2021, the Group has accumulatively obtained 185 invention patents, 70 utility model patents and 19 appearance design patents.

For the six months ended June 30, 2021, the Group obtained approvals for 4 generic pharmaceuticals including Celecoxib capsules, mycophenolate mofetil capsules, nifedipine controlled-release tablets and bendamustine hydrochloride for injection (25mg). Besides, lenvatinib mesilate capsules obtained the approval in July 2021. Meanwhile, it obtained the consistency evaluation application regarding pemetrexed disodium for injection.

**Milestone of Drug Candidates in the NDA Stage**

**Envafolimab** is a recombinant single domain antibody against PD-L1 fused with human Fc. On March 30, 2020, the Group entered into a tripartite cooperation agreement in relation to Envafolimab with 3D Medicines (Beijing) Co., Ltd. (思路迪(北京)醫藥科技有限公司) ("**3D Medicines (Beijing)**") and Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (江蘇康寧傑瑞生物製藥有限公司) ("**Jiangsu Alphamab**"). The abovementioned agreement provides the Group with the exclusive right to promote Envafolimab for all oncology treatment indications in Mainland China. It is expected that the product will be approved for sale in China in the second half of 2021 and potentially become the first subcutaneously injectable anti-PD-L1 domain antibody worldwide.

- On June 17, 2021, the Group obtained the Clinical Trial Approval issued by the NMPA for a multi-center phase Ib/II clinical study for evaluation on treatment of advanced solid tumors with Envafolimab in combination with Lenvatinib. During the clinical study, our partner 3D Medicines (Beijing) led the design and development of the clinical trials.

- On July 29, 2021, the Group obtained the Clinical Trial Approval issued by the NMPA for a multiple-cohorts and multi-institutional phase II clinical study on the efficacy and safety of Sevacizumab (BD0801) in combination with Envafolimab with or without chemotherapy for the treatment of patients with advanced solid tumors.

**Drug Candidates in the Clinical Stage**

**Sanbexin sublingual tablets** are the solid dosage form of edaravone dexborneol compound. Sublingual administration of this compound inhibits inflammation and improves the permeability in the blood-brain barrier, minimizing brain injury or impairment caused by acute ischemic stroke (AIS). Sequential therapy consisting of Sanbexin sublingual tablets and edaravone and dexborneol concentrated solution for injection is designed to enable patients to receive a timely and 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 chronic central nervous system diseases.

- In December 2020, the product was approved by the CDE to conduct the phase III clinical trial directly after the phase I clinical trial. On June 28, 2021, the first patient in for the phase III clinical study for the treatment of AIS with Sanbexin sublingual tablets was completed, and currently more than 100 patients have been successfully enrolled in.

**Trilaciclib** is an effective, selective and reversible cyclin-dependent kinases 4 and 6 (CDK4/6) inhibitor. This first-in-class innovative drug can transiently retard hematopoietic stem cells and progenitor cells in G1 phase of cell cycle, thereby protecting bone marrow cells from damages of cytotoxic chemotherapy. In August 2020, the Group entered into the exclusive license agreement with G1 Therapeutics to develop and commercialize Trilaciclib in Greater China. On February 13, 2021, the product was approved for sale by the U.S. FDA, with the indication being preventive use in small cell lung cancer patients treated with a platinum-containing regimen in combination with etoposide-containing regimen or topotecan-containing regimen, to decrease the incidence of chemotherapy-induced myelosuppression.

- On January 18, 2021, Trilaciclib obtained the Clinical Trial Approval issued by the NMPA, to conduct the phase III clinical trial for small cell lung cancer patients. On May 25, 2021, the first patient in for this trial has been completed.

- On March 23, 2021, Trilaciclib was recommended by the National Comprehensive Cancer Network ("**NCCN**") Guidelines.

- On April 9, 2021 and June 10, 2021, the Group also obtained the Clinical Trial Approval issued by the NMPA for two phase III clinical trials of the product for indications of metastatic colorectal cancer and triple negative breast cancer, which were incorporated into a worldwide international multi-centre clinical trial program.

- On June 2, 2021, the product issued the first prescription in China in Hainan Free Trade Port Boao Hope City, and initiated the real world study.

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

- On February 9, 2021, the NMPA issued the Clinical Trial Approval for the initiation of phase III trials for the treatment of malignant solid tumors with sevacizumab, and the first patient with ovarian cancer was dosed in the phase III clinical trial on June 11.

- On July 29, 2021, the Group obtained the Clinical Trial Approval issued by the NMPA for a multiple-cohorts and multi-institutional phase II clinical trial to evaluate the safety and efficacy of Sevacizumab in combination with Envafolimab with or without chemotherapy in patients with advanced solid tumors.

**SIM0307** is an Aquaporin-4 (AQP4) inhibitor 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 SIM0307 in the Greater China region.

- On April 12, 2021, SIM0307 obtained the Clinical Trial Approval issued by the NMPA and initiated the phase I clinical trial study in China.

**SIM0201** With the Group's in-house R&D efforts, SIM0201 is an effective multi-target tyrosine kinase inhibitor for NTRK, ROS1 or ALK fusion mutation. The pre-clinical animal model showed that SIM0201 can penetrate the blood-brain barrier and has favorable efficacy to metastatic brain tumors. Phase I clinical trial study on SIM0201 is undergoing in China.

- On January 5, 2021, the first patient in for the phase I clinical trial of SIM0201 was completed, with dose finding undergoing.

**Docetaxel polymeric micelles for injection** The polyethylene glycol monomethyl ether-polylactic acid block copolymer (mPEG-PDLLA), an amphiphilic biocompatible biodegradable material, is used as the solubilizing carrier of docetaxel to reduce the allergy and hematotoxicity of docetaxel injection to facilitate clinical application. In September 2020, the Group reached a global cooperation with Suzhou Hightechbio Biotechnology Co., Ltd. on this product. Phase I clinical trial study on docetaxel polymeric micelles for injection is undergoing in China, with dose finding completed.

**SIM0335** With the Group's in-house R&D efforts, SIM0335 is an innovative small molecule drug, a category I drug candidate and the first of its kind in the world that controls fatty acid metabolism and works on IL-17A-related pathways, intended for the treatment of mild to moderate plaque psoriasis through topical administration. Phase I clinical trial study on SIM0335 is undergoing in China.

- On March 30, 2021, the first patient in for the phase I clinical trial of SIM0335 was completed.

**SIM0295** is an effective selective urate transport protein 1 (URAT1) inhibitor that effectively reduce blood serum urate levels by inhibiting the reabsorption of uric acid in renal tubules and increasing uric acid excretion, and can be used in the treatment of gout with hyperuricemia. In the cooperation with JW Pharmaceutical, the Group is responsible for developing and commercializing the product in Mainland China.

- On January 11, 2021, we completed the first patient in for the phase I clinical trial of the product in China. All the enrollment has been completed as of the date of this announcement, with the clinical data summary undergoing.

- In March 2021, the partner JW Pharmaceutical completed the phase IIb clinical trial for the product in South Korea.

**Selected Drug Candidates in the Pre-clinical Stage**

**SIM0395** is a PI3K/mTOR pathway inhibitor that can penetrate the blood-brain barrier and currently the partner Kazia Therapeutics is in the global phase II/III clinical trial for treatment of glioblastoma (GBM).

- On May 21, 2021, the Group submitted the pre-IND application to the CDE and have currently obtained assessment comments from the CDE.

**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 the only SERD-type fulvestrant for intramuscular injection currently on the market in the world, 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 orthotopic model of breast cancer.

- On June 20, 2021, the Group submitted the pre-IND application to the CDE.

**SIM0235** is a tumor-immune target tumor necrosis factor receptor 2 (TNFR2) inhibitor independently developed by the Group. The preclinical pharmacodynamic model shows single-agent efficacy equivalent to PD-L1 and the potential and superior safety in combination with PD-1.

- On June 30, 2021, the Group submitted the pre-IND application to the CDE.

**SIM0323** is the first-in-class CD80/IL-2 bifunctional fusion protein developed by the Group and GI Innovation. The preclinical pharmacodynamic model shows significant single-drug efficacy and the potential for combined use with PD-1 inhibitor.

- On April 21, 2021 and June 10, 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.

- On July 28, 2021, the Group submitted the pre-IND application to the CDE.

## LIQUIDITY AND FINANCIAL RESOURCES

The Group maintained a sound financial position. As at June 30, 2021, we had cash and cash equivalents of approximately RMB1,285 million (as at December 31, 2020: approximately RMB3,270 million), time deposits of approximately RMB1,618 million (as at December 31, 2020: nil). As at June 30, 2021, the Group had a balance of bank loans of RMB1,962 million (as at December 31, 2020: RMB3,068 million), of which RMB1,962 million (as at December 31, 2020: RMB1,793 million) would mature within one year. As at June 30, 2021, approximately RMB1,869 million of the Group's bank loan balance bore interest at fixed rates, and the effective interest rate range for these loans is 0.20% to 4.90%. As at June 30, 2021, the gearing ratio of the Group (total liabilities divided by total assets) was approximately 43.0% (as at December 31, 2020: approximately 51.2%).

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 internal financing and external financing at reasonable market rates. In order to better control and minimize the cost of funds, the Group's treasury activities are centralized and all cash transactions are dealt with the banks with good reputation.

Most assets and liabilities of the Group were denominated in RMB, USD and Euro. Currently, the Group does not employ any financial instruments or enter into any foreign exchange contracts to hedge against foreign exchange risk. However, by closely monitoring the net exposure of foreign exchange risk, the Group managed the foreign exchange risk, thus minimizing the impact of foreign exchange fluctuations.

## PLEDGE OF GROUP'S ASSETS

As at June 30, 2021, approximately RMB209 million land and buildings was secured as guarantees of certain banking credits granted to the Group. Save as disclosed above, as at June 30, 2021, the Company had no other pledged assets.

## CONTINGENT LIABILITIES

As at June 30, 2021, the Group had no material contingent liabilities.

## SIGNIFICANT INVESTMENTS HELD

As at June 30, 2021, the Group did not have any significant investments.

## FUTURE PLANS FOR MATERIAL INVESTMENTS AND CAPITAL ASSETS

Save as disclosed in "Use of Proceeds from the Listing" below in this announcement, as at June 30, 2021, the Group did not have any other plans for material investments and capital assets.

## MATERIAL ACQUISITIONS AND DISPOSALS

During the six months ended June 30, 2021, the Group entered into the Share Purchase Agreement with Excel Good Group Limited ("**EGG**") and Simgene Group Limited ("**Simgene**") on April 15, 2021, pursuant to which the Company agreed to sell 100% of the total issued share capital of Simgene to EGG for a consideration of RMB104.17 million. For details, please refer to the announcement of the Company dated April 15, 2021 in respect of the connected transaction in relation to disposal of subsidiaries. Save as disclosed above, during the six months ended June 30, 2021, the Group has no material acquisition or disposal of subsidiaries, associates and joint venture.

## EMPLOYEES AND REMUNERATION POLICY

As at June 30, 2021, the Group had a total of 6,204 full-time employees. We attached great importance to the recruitment, training and retention of outstanding employees, maintaining a high standard in selecting and recruiting talents worldwide, and offers competitive compensation packages. The remuneration of employees mainly included basic salary, performance-based bonus and long-term incentives. Remuneration of the 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. During the six months ended June 30, 2021, staff costs (including emoluments, social insurance and other benefits of the Directors) amounted to approximately RMB670 million. We 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.

The Group has conditionally approved and adopted a restricted share units scheme on May 20, 2021 to incentivize the existing and incoming directors, senior management and employees for their contribution to the Group, and attracts, motivates and retains 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. For details of the restricted share units scheme, please refer to the announcement of the Company dated May 20, 2021. As at July 16, 2021, 10,937,000 restricted share units had been granted by the Company pursuant to the restricted share units scheme.

## INTERIM DIVIDEND

The Board has resolved not to declare any interim dividend for the six months ended June 30, 2021.

## 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 pursuant to the partial exercise of the over-allotment option in November 2020 (the "**Net Proceeds**") amounted in aggregate to approximately HK$3,513 million. The proposed use of the net proceeds was disclosed in the prospectus of the Company dated October 13, 2020 (the "**Prospectus**"). As at June 30, 2021, the net proceeds utilized was approximately HK$1,281 million and the remaining net proceeds was approximately HK$2,232 million. As at June 30, 2021, the net proceeds utilized by the Group were as follows:

| Purpose | Percentage of the total amount | Net amount of raised funds received (HK$ in million) | Net amount of raised funds unutilized as at June 30, 2021 (HK$ in million) | Net amount of raised funds utilized as at June 30, 2021 (HK$ in million) | Expected timeline for utilization |
|---|---|---|---|---|---|
| Continued research and development of our selected product candidates in our strategically focused therapeutic areas | 60% | 2,107.85 | 1,831.93 | 275.92 | The actual net proceeds are expected to be fully utilized by 2027. |
| Reinforcement of our sales and marketing capabilities | 10% | 351.31 | 157.20 | 194.11 | The actual net proceeds are expected to be fully utilized by 2022. |
| Investment in companies in the pharmaceutical or biotechnology sector | 10% | 351.31 | 242.55 | 108.76 | The actual net proceeds are expected to be fully utilized by 2023. |
| Repayment of certain of our 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 the first half of 2021. |
| **Total** | **100%** | **3,513.09** | **2,231.68** | **1,281.41** | |

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 CAR T-cell therapy (Indication 1), CD19 CAR T-cell therapy (Indication 2), BCMA CAR T-cell therapy and SIM0325, to the selected oncology product candidates that are currently under development, including Trilaciclib (Indication 1, Indication 2 and Indication 3), SIM0395 and Docetaxel Polymeric Micellar for Injection, details of which were disclosed in the Company's announcement of change in use of proceeds dated April 15, 2021. Saved as disclosed therein, the Company intends to apply the unutilised net proceeds as at June 30, 2021 in the manner and proportion set out in the Prospectus.

## 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 during the period from January 1, 2021 to June 30, 2021.

### Change in Directors' Information

Mr. ZHANG Cheng has tendered his resignation as an executive Director and the chief operating officer of the Company to the Board with effect from March 31, 2021 due to his personal career development. For details, please refer to the announcement of the Company dated March 31, 2021.

Save as disclosed above, there is no other change in the Director's information required to be disclosed pursuant to Rule 13.51B of the Listing Rules from the date of the 2020 annual report of the Company to the date of this announcement.

### Important Events After the Reporting Period

As at the date of this announcement, the Group has no important events that are required to be disclosed after the Reporting Period.

### Compliance With the Corporate Governance Code

The Group is committed to maintaining and promoting stringent corporate governance. The principle of the Group's corporate governance is to promote effective internal control measures, uphold a high standard of ethics, transparency, responsibility and integrity in all aspects of business, to ensure that its business and operation are conducted in accordance with applicable laws and regulations, to enhance the transparency of the Board, and to strength 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.

Save as disclosed below, the Group has complied with the code provisions contained in the CG Code during the period from January 1, 2021 to June 30, 2021.

Under code provision A.2.1 of the CG Code, the roles of chairman and chief executive officer should be separated and performed by different individuals. As of June 30, 2021, the roles of Chairman and Chief Executive Officer of the Company were not separated and Mr. REN Jinsheng 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. Directors 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. In addition, Directors believe that this structure will not impair the balance of power and authority between the Board and the management of the Company, given that: (i) any decision to be made by the Board requires approval by at least a majority of Directors; (ii) Mr. REN and the other Directors are aware of and undertake to fulfil 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; (iii) the balance of power and authority is ensured by the operations of the Board, which consists of three executive Directors (including Mr. REN), one non-executive Director and three independent non-executive Directors, and has a fairly strong independence element; and (iv) 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.

**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 Group's code of conduct regarding the Directors' securities transactions. Having made specific enquiry of all the Directors of the Group, all the Directors confirmed that they have strictly complied with the Model Code from January 1, 2021 to June 30, 2021.

**Audit Committee and Review of Financial Information**

The Group established an audit committee with written terms of reference in compliance with the CG Code. The Audit Committee consists of 3 members, all of which are independent non-executive Directors, being 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 unaudited condensed consolidated interim financial statements and interim report of the Group for the six months ended June 30, 2021, 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.

## Independent Review of Auditor

The interim financial report for the six months ended June 30, 2021 is unaudited, but has been reviewed by KPMG, in accordance with Hong Kong Standard on Review Engagements No. 2410 "Review of interim financial information performed by the independent auditor of the entity" issued by the Hong Kong Institute of Certified Public Accountants, whose unmodified review report is included in the interim report to be sent to the Shareholders.

## Publication of the Interim Results Announcement and Interim Report

The interim results announcement and the interim report will be 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 2021 interim report will be dispatched to shareholders and will be published on the aforementioned websites in due course.

## PROSPECTS

As revenue from innovative pharmaceuticals made greater contribution and the R&D pipeline of innovative pharmaceuticals was advanced rapidly during the first half of the year, Simcere has become a pharmaceutical company focused on innovative pharmaceutical business. In the second half of 2021, we will continue to invest in the R&D of innovative pharmaceuticals with a firm determination, enhance the talent density, improve the efficiency of R&D and management, and adhere to the strategy of open innovation and collaborative efforts, so as to provide today's patients with medicines of the future under the guidance of the huge unmet clinical demands.

## CONSOLIDATED STATEMENT OF PROFIT OR LOSS

*For the six months ended June 30, 2021 – unaudited*

| | | Six months ended June 30, | |
|---|---|---|---|
| | | **2021** | 2020 |
| | *Note* | ***RMB'000*** | *RMB'000* |
| **Revenue** | *4* | **2,120,002** | 1,925,413 |
| Cost of sales | | **(456,977)** | (388,130) |
| **Gross profit** | | **1,663,025** | 1,537,283 |
| Other revenue | *5(a)* | **62,670** | 43,072 |
| Other net gain/(loss) | *5(b)* | **490,504** | (6,447) |
| Research and development costs | | **(626,803)** | (454,091) |
| Selling and distribution expenses | | **(830,178)** | (628,502) |
| Administrative and other operating expenses | | **(203,112)** | (193,464) |
| **Profit from operations** | | **556,106** | 297,851 |
| Finance income | *6(a)* | **28,014** | 10,851 |
| Finance costs | *6(a)* | **(47,396)** | (79,576) |
| Net finance costs | | **(19,382)** | (68,725) |
| Share of losses of associates | | **(14,750)** | (4,353) |
| Share of losses of a joint venture | | **(134)** | (40) |
| **Profit before taxation** | *6* | **521,840** | 224,733 |
| Income tax | *7* | **33,055** | (39,898) |
| **Profit for the period** | | **554,895** | 184,835 |
| **Attributable to:** | | | |
| Equity shareholders of the Company | | **557,814** | 185,518 |
| Non-controlling interest | | **(2,919)** | (683) |
| **Profit for the period** | | **554,895** | 184,835 |
| **Earnings per share** | *8* | | |
| Basic and diluted *(RMB)* | | **0.21** | 0.08 |

## CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

*For the six months ended June 30, 2021 – unaudited*

| | Six months ended June 30, | |
|---|---|---|
| | **2021** | 2020 |
| | ***RMB'000*** | *RMB'000* |
| **Profit for the period** | **554,895** | 184,835 |
| **Other comprehensive income for the period (after tax adjustments)** | | |
| *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 | **179,150** | 133,077 |
| *Items that may be reclassified subsequently to profit or loss:* | | |
| Exchange difference on translation of financial statements of entities with functional currencies other than Renminbi ("**RMB**") | **(12,465)** | 3,533 |
| **Other comprehensive income for the period** | **166,685** | 136,610 |
| **Total comprehensive income for the period** | **721,580** | 321,445 |
| **Attributable to:** | | |
| Equity shareholders of the Company | **724,499** | 322,128 |
| Non-controlling interest | **(2,919)** | (683) |
| **Total comprehensive income for the period** | **721,580** | 321,445 |

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

*At June 30, 2021 – unaudited*

| | Note | **June 30, 2021** ***RMB'000*** | December 31, 2020 *RMB'000* |
|---|---|---|---|
| **Non-current assets** | | | |
| Property, plant and equipment | | **1,988,214** | 2,127,879 |
| Intangible assets | | **68,150** | 77,108 |
| Goodwill | | **172,788** | 172,788 |
| Interest in associates | | **255,068** | 211,148 |
| Interest in a joint venture | | **4,538** | 4,672 |
| Prepayments and deposits | | **45,232** | 113,534 |
| Financial assets at fair value through other comprehensive income | | **483,314** | 327,655 |
| Financial assets at fair value through profit or loss | | **1,180,204** | 1,231,701 |
| Time deposits | *10* | **400,000** | – |
| Deferred tax assets | | **212,618** | 210,093 |
| | | **4,810,126** | 4,476,578 |
| **Current assets** | | | |
| Trading securities | | **–** | 3,634 |
| Inventories | | **292,646** | 262,673 |
| Trade and bills receivables | *9* | **1,992,498** | 1,871,012 |
| Prepayments, deposits and other receivables | | **327,149** | 120,557 |
| Taxation recoverable | | **19,725** | 21,335 |
| Pledged deposits | *10* | **–** | 917,377 |
| Restricted deposits | *10* | **1,581** | 3 |
| Time deposits | *10* | **1,218,000** | – |
| Cash and cash equivalents | *10* | **1,284,596** | 3,270,241 |
| | | **5,136,195** | 6,466,832 |
| **Current liabilities** | | | |
| Bank loans | *11* | **1,961,526** | 1,792,940 |
| Lease liabilities | | **37,738** | 38,098 |
| Trade and bills payables | *12* | **195,817** | 242,077 |
| Other payables and accruals | *13* | **1,336,174** | 1,323,343 |
| Taxation payable | | **21,666** | – |
| Provision | | **–** | 100,700 |
| | | **3,552,921** | 3,497,158 |
| **Net current assets** | | **1,583,274** | 2,969,674 |
| **Total assets less current liabilities** | | **6,393,400** | 7,446,252 |

**CONSOLIDATED STATEMENT OF FINANCIAL POSITION (Continued)**
*At June 30, 2021 – unaudited*

| | Note | **June 30, 2021** ***RMB'000*** | December 31, 2020 *RMB'000* |
|---|---|---|---|
| **Non-current liabilities** | | | |
| Bank loans | *11* | **–** | 1,275,550 |
| Lease liabilities | | **123,927** | 193,430 |
| Deferred income | | **430,319** | 447,950 |
| Deferred tax liabilities | | **166,818** | 193,598 |
| | | **721,064** | 2,110,528 |
| **NET ASSETS** | | **5,672,336** | 5,335,724 |
| **CAPITAL AND RESERVES** | | | |
| Share capital | | **3,002,871** | 3,002,871 |
| Reserves | | **2,638,449** | 2,298,918 |
| **Total equity attributable to equity shareholders of the Company** | | **5,641,320** | 5,301,789 |
| **Non-controlling interest** | | **31,016** | 33,935 |
| **TOTAL EQUITY** | | **5,672,336** | 5,335,724 |

## NOTES TO THE FINANCIAL STATEMENTS

*For the six months ended June 30, 2021*

### 1 GENERAL INFORMATION

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.

### 2 BASIS OF PREPARATION

This unaudited interim financial information was extracted from the interim financial report of the Group for the six months ended June 30, 2021.

This interim financial report has been prepared in accordance with the applicable disclosure provisions of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, including compliance with Hong Kong Accounting Standard ("**HKAS**") 34, issued by the Hong Kong Institute of Certified Public Accountants ("**HKICPA**").

The interim financial report has been prepared in accordance with the same accounting policies adopted in the 2020 annual financial statements, except for the accounting policy changes that are expected to be reflected in the 2021 annual financial statements. Details of any changes in accounting policies are set out in Note 3.

The preparation of an interim financial report in conformity with HKAS 34 requires management to make judgements, estimates and assumptions that affect the application of policies and reported amounts of assets and liabilities, income and expenses on a year to date basis. Actual results may differ from these estimates.

This interim financial report contains condensed consolidated financial statements and selected explanatory notes. The notes include an explanation of events and transactions that are significant to an understanding of the changes in financial position and performance of the Group since the 2020 annual financial statements. The condensed consolidated interim financial statements and notes thereon do not include all of the information required for a full set of financial statements prepared in accordance with HKFRSs.

The interim financial report is unaudited, but has been reviewed by KPMG in accordance with Hong Kong Standard on Review Engagements 2410, *Review of interim financial information performed by the independent auditor of the entity*, issued by the HKICPA.

The financial information relating to the financial year ended 31 December 2020 that is included in the interim financial report as comparative information does not constitute the Company's statutory annual consolidated financial statements for that financial year but is derived from those financial statements. Further information relating to these statutory financial statements disclosed in accordance with section 436 of the Hong Kong Companies Ordinance (Cap. 622) is as follows:

The Company has delivered the financial statements for the year ended 31 December 2020 to the Registrar of Companies as required by section 662(3) of, and Part 3 of Schedule 6 to, the Companies Ordinance.

The Company's auditor has reported on those financial statements. The auditor's report was unqualified; did not include a reference to any matters to which the auditor drew attention by way of emphasis without qualifying its report; and did not contain a statement under section 406(2), 407(2) or (3) of the Companies Ordinance.

## 3 CHANGES IN ACCOUNTING POLICIES

The Group has applied the following amendments to HKFRSs issued by the HKICPA to this interim financial report for the current accounting period:

- Amendment to HKFRS 16, *Covid-19-related rent concessions beyond 30 June 2021*
- Amendments to HKFRS 9, HKAS 39, HKFRS 7, HKFRS 4 and HKFRS 16, *Interest rate benchmark reform – phase 2*

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 in this interim financial report. The Group has not applied any new standard or interpretation that is not yet effective for the current accounting period.

## 4 REVENUE AND SEGMENT REPORTING

### (a) Revenue

The principal activities of the Group are 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.

#### *(i) Disaggregation of revenue*

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

| | **Six months ended June 30,** | |
|---|---|---|
| | **2021** | 2020 |
| | ***RMB'000*** | *RMB'000* |
| Sales of pharmaceutical products | **1,945,601** | 1,803,398 |
| Promotion service income | **174,401** | 122,015 |
| | **2,120,002** | 1,925,413 |

The Group's revenue from contracts with customers was recognized at point in time for the six months ended June 30, 2021.

#### *(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.

## 5 OTHER REVENUE AND OTHER NET GAIN/(LOSS)

### (a) Other revenue

| | Six months ended June 30, | |
|---|---|---|
| | **2021** | 2020 |
| | ***RMB'000*** | *RMB'000* |
| Government grants | **38,165** | 32,514 |
| Rental income | **8,341** | 5,497 |
| Property management income | **2,855** | 1,441 |
| Consulting and technology service income | **3,759** | 1,383 |
| Others | **9,550** | 2,237 |
| | **62,670** | 43,072 |

### (b) Other net gain/(loss)

| | Six months ended June 30, | |
|---|---|---|
| | **2021** | 2020 |
| | ***RMB'000*** | *RMB'000* |
| Net foreign exchange gain/(loss) | **30,402** | (19,867) |
| Net gain/(loss) on disposal of property, plant and equipment | **208** | (3,053) |
| Net realized and unrealized loss on trading securities | **(119)** | (102) |
| Net realized and unrealized (loss)/gain on financial assets at fair value through profit or loss | **(42,658)** | 13,261 |
| Net gain on disposal of interest in associates | **103,341** | – |
| Net gain on disposal of interest in subsidiaries | **399,330** | 1,552 |
| Gain arising from business combination | **–** | 1,762 |
| | **490,504** | (6,447) |

## 6 PROFIT BEFORE TAXATION

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

### (a) Net finance costs

| | Six months ended June 30, | |
|---|---|---|
| | **2021** | 2020 |
| | ***RMB'000*** | *RMB'000* |
| Interest income from bank deposits | **(28,014)** | (10,721) |
| Interest income from loans to related parties | **–** | (130) |
| Finance income | **(28,014)** | (10,851) |
| Interest expenses on bank loans | **43,121** | 78,937 |
| Interest expenses on loans from related parties | **–** | 298 |
| Interest expenses on lease liabilities | **4,275** | 5,124 |
| Less: borrowing costs capitalized as construction in progress | **–** | (4,783) |
| Finance costs | **47,396** | 79,576 |
| Net finance costs | **19,382** | 68,725 |

### (b) Other items

| | Six months ended June 30, | |
|---|---|---|
| | **2021** | 2020 |
| | ***RMB'000*** | *RMB'000* |
| Depreciation charge | | |
| – owned property, plant and equipment | **97,834** | 75,421 |
| – right-of-use assets | **24,230** | 22,412 |
| Amortization of intangible assets | **8,958** | 8,152 |
| Provision for impairment loss on trade and other receivables | **39,634** | 7,662 |
| Provision for write-down of inventories | **8,893** | 5,913 |
| Listing expenses | **–** | 13,880 |

## 7 INCOME TAX IN THE CONSOLIDATED STATEMENTS OF PROFIT OR LOSS

Taxation in the consolidated statements of profit or loss represents:

| | Six months ended June 30, | |
|---|---|---|
| | **2021** | 2020 |
| | ***RMB'000*** | *RMB'000* |
| **Current tax** | | |
| *PRC Corporate Income Tax* | | |
| Provision for the period | **22,039** | 29,537 |
| Under/(over) – provision in respect of prior years | **4,791** | (4,138) |
| | **26,830** | 25,399 |
| **Deferred tax** | **(59,885)** | 14,499 |
| **Total income tax** | **(33,055)** | 39,898 |

The provision for PRC income tax is based on the respective corporate income tax rates applicable to the subsidiaries located in the PRC as determined in accordance with the relevant income tax rules and regulations of the PRC.

## 8 EARNINGS PER SHARE

The calculation of basic and diluted earnings per share is based on the profit attributable to equity shareholders of the Company of RMB557,814,000 (six months ended June 30, 2020: RMB185,518,000) and the weighted average of 2,608,641,618 ordinary shares (six months ended June 30, 2020: 2,345,117,618 ordinary shares) in issue during the interim period.

Diluted earnings per share is equal to basic earnings per share as there were no dilutive potential shares outstanding the six months ended June 30, 2021 and 2020.

## 9 TRADE AND BILLS RECEIVABLES

| | **June 30,** | December 31, |
|---|---|---|
| | **2021** | 2020 |
| | ***RMB'000*** | *RMB'000* |
| Trade receivables | **1,761,499** | 1,522,578 |
| Bills receivable | **291,250** | 369,275 |
| | **2,052,749** | 1,891,853 |
| Less: loss allowance | **(60,251)** | (20,841) |
| | **1,992,498** | 1,871,012 |

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

**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:

| | **June 30, 2021** | December 31, 2020 |
|---|---|---|
| | ***RMB'000*** | *RMB'000* |
| Within 3 months | **1,254,090** | 1,553,979 |
| Over 3 months but within 12 months | **728,103** | 315,238 |
| Over 12 months | **10,305** | 1,795 |
| | **1,992,498** | 1,871,012 |

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

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

**(a) Cash and cash equivalents comprise:**

| | **June 30, 2021** | December 31, 2020 |
|---|---|---|
| | ***RMB'000*** | *RMB'000* |
| Cash at bank | **1,284,596** | 3,270,241 |

**(b) Pledged deposits and restricted deposits comprise:**

| | **June 30, 2021** | December 31, 2020 |
|---|---|---|
| | ***RMB'000*** | *RMB'000* |
| Pledged deposits for | | |
| – issuance of bills payable and letters of credit | **–** | 1,777 |
| – banking facilities | **–** | 915,600 |
| | **–** | 917,377 |

| | **June 30, 2021** | December 31, 2020 |
|---|---|---|
| | ***RMB'000*** | *RMB'000* |
| Restricted deposits for | | |
| – research and development projects | **3** | 3 |
| – others | **1,578** | – |
| | **1,581** | 3 |

The pledged deposits will be released upon the settlement of the relevant bills payable and letters of credit by the Group or the termination of relevant banking facilities. The restricted deposits will be used for funding certain research and development projects and other contracts.

**(c) Time deposits:**

| | **June 30, 2021** | December 31, 2020 |
|---|---|---|
| | ***RMB'000*** | *RMB'000* |
| Current portion | **1,218,000** | – |
| Non-current portion | **400,000** | – |
| | **1,618,000** | – |

## 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:

| | **June 30, 2021** | December 31, 2020 |
|---|---|---|
| | ***RMB'000*** | *RMB'000* |
| Short-term bank loans | **1,168,075** | 1,560,740 |
| Current portion of long-term bank loans | **793,451** | 232,200 |
| Within 1 year or on demand | **1,961,526** | 1,792,940 |
| After 1 year but within 2 years | **–** | 1,231,450 |
| After 2 years but within 5 years | **–** | 44,100 |
| More than 5 years | **–** | – |
| | **–** | 1,275,550 |
| | **1,961,526** | 3,068,490 |

The bank loans were secured as follows:

| | **June 30, 2021** | December 31, 2020 |
|---|---|---|
| | ***RMB'000*** | *RMB'000* |
| Bank loans | | |
| – Secured | **1,859,712** | 1,992,450 |
| – Unsecured | **101,814** | 1,076,040 |
| | **1,961,526** | 3,068,490 |

## 12 TRADE AND BILLS PAYABLES

| | **June 30, 2021** | December 31, 2020 |
|---|---|---|
| | ***RMB'000*** | *RMB'000* |
| Trade payables | **80,884** | 115,462 |
| Bills payable | **114,933** | 126,615 |
| | **195,817** | 242,077 |

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

| | **June 30, 2021** | December 31, 2020 |
|---|---|---|
| | ***RMB'000*** | *RMB'000* |
| Within 3 months | **138,049** | 191,610 |
| 3 to 12 months | **53,335** | 48,617 |
| Over 12 months | **4,433** | 1,850 |
| | **195,817** | 242,077 |

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

## 13 OTHER PAYABLES AND ACCRUALS

| | **June 30, 2021** | December 31, 2020 |
|---|---|---|
| | ***RMB'000*** | *RMB'000* |
| Accrued expenses *(Note i)* | **453,631** | 719,708 |
| Contract liabilities *(Note ii)* | **17,704** | 18,762 |
| Payable for employee reimbursements | **128,379** | 139,552 |
| Payables for staff related costs | **181,073** | 235,162 |
| Payables for purchase of property, plant and equipment | **42,617** | 58,469 |
| Dividends payable | **391,296** | – |
| Other tax payables | **63,336** | 60,950 |
| Others | **58,138** | 90,740 |
| | **1,336,174** | 1,323,343 |

*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

Dividends payable to equity shareholders of the Company attributable to the previous financial years, declared and approved during the period:

| | Six months ended June 30, | |
|---|---|---|
| | **2021** | 2020 |
| | ***RMB'000*** | *RMB'000* |
| Dividends in respect of previous financial years declared and approved during the interim period, RMB0.15 per share (six months ended June 30, 2021: nil) | **391,296** | – |

The directors did not recommend payment of interim dividends for the interim period (no interim dividend for the six months ended June 30, 2020).

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

Hong Kong, August 26, 2021

*As at the date of this announcement, the Board comprises Mr. REN Jinsheng as the Chairman and executive Director, Mr. WAN Yushan and Mr. TANG Renhong as the executive Directors; Mr. ZHAO John Huan as the non-executive Director; and Mr. SONG Ruilin, Mr. WANG Jianguo and Mr. WANG Xinhua as the independent non-executive Directors.*