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**Sincere 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, 2023**

**FINANCIAL HIGHLIGHTS**

For the six months ended June 30, 2023, the Group recorded the following unaudited financial results:

- Revenue was approximately RMB3,379 million, representing an increase of approximately 25.2% as compared to RMB2,700 million for the same period of 2022. The increase in revenue was mainly attributable to the rapid increase in revenue from innovative pharmaceuticals.
- Revenue from innovative pharmaceuticals was approximately RMB2,413 million, accounting for 71.4% of the total revenue and representing an increase of approximately 36.6% as compared to RMB1,767 million for the same period of 2022.
- Revenue was mainly derived from the therapeutic areas where the Group's businesses are focused, among which, revenue from the field of nervous system was approximately RMB1,055 million, accounting for 31.2% of the total revenue and representing a decrease of approximately 1.5% as compared with that for the same period of 2022. Revenue from the field of oncology was approximately RMB783 million, accounting for 23.2% of the total revenue and representing an increase of approximately 34.8% as compared with that for the same period of 2022. Revenue from the field of autoimmune was approximately RMB659 million, accounting for 19.5% of the total revenue and representing an increase of approximately 30.0% as compared with that for the same period of 2022. Revenue from other fields was approximately RMB882 million, accounting for 26.1% of the total revenue and representing an increase of approximately 63.0% as compared with that for the same period of 2022.

- Research and development expense was approximately RMB776 million, representing an increase of approximately RMB124 million or approximately 19.1% as compared to RMB652 million for the same period of 2022. The research and development expense as a percentage of revenue<sup>1</sup> was approximately 23.0% (approximately 24.1% for the same period of 2022).
- Profit for the period attributable to equity shareholders of the Company was approximately RMB2,275 million, representing a significant increase as compared to RMB64 million for the same period of 2022.
- Basic earnings per share was approximately RMB0.87, representing a significant increase as compared to RMB0.02 for the same period of 2022.

The board (the “**Board**”) of directors (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, 2023 (the “**Reporting Period**” or the “**Period**”), together with the comparative figures for the corresponding period in 2022. 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

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 proactive 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”.

The Group has six innovative drugs approved for marketing and sale (including one imported innovative drug) in the focus areas. As of June 30, 2023, the Group has 14 products recommended in guidelines and pathways issued by over 100 government authorities or prestigious professional associations, and has over 40 products included in the National Reimbursement Drug List (the “**NRDL**”).

The Group pays high attention to the establishment of innovative pharmaceutical R&D capability, and has established R&D innovation centers in Shanghai, Nanjing, Beijing and Boston, 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 from drug discovery, pre-clinical development, clinical trial to registration, and owns leading platforms of protein engineering, PAb/TCE, PAb/NKCE, AI-aided drug discovery and protein degradation. As of June 30, 2023, the Group had a R&D team of approximately 1,000 personnel in total with approximately 160 doctors and 500 masters.

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<sup>1</sup> Calculated as research and development expense divided by revenue.

The Group has a nationwide marketing network and leading commercialization capability, and will continuously strengthen its professional marketing capability, so as to enhance the coverage and accessibility of medicines. As of June 30, 2023, the Group's sales team divided into four business units (neuroscience, oncology, autoimmune & comprehensive and retail grassroots) and other support departments had a total of approximately 4,700 personnel across 32 provinces, municipalities and autonomous regions in China, with its products covering over 2,800 Class III hospitals, approximately 17,000 other hospitals and medical institutions as well as more than 200 large-scale national or regional chain pharmacies.

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 Group has put into use five PRC GMP certified production facilities for the manufacturing of its pharmaceutical products, and has received the EU GMP certification or passed the U.S. Food and Drug Administration ("FDA") inspection for some of its production workshops.

Driven by its in-house R&D efforts and synergistic innovation, the Group has established strategic cooperation partnerships with many innovative companies, research institutes and clinical centers at home and abroad, exploring multiple collaborative modes in various aspects such as cooperative R&D and achievement transfer, and continuously developing products that patients urgently need and have significant market potential. The Group has 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 industrial experiences to provide scientific advice for the Group's early drug discovery and clinical development. Meanwhile, the Group has planned and implemented the "Simcere Project X", aiming to attract professional leaders in the global life science to explore and create unprecedented treatments.

## MAJOR PRODUCTS

Nervous System Products	Sanbexin® (Edaravone and Dexborneol Concentrated Solution for Injection)
Oncology Products	Endostar® (Recombinant Human Endostatin Injection) ENWEIDA® (Envafolimab Injection) COSELA® (Trilaciclib Hydrochloride for Injection)
Autoimmune Products	Iremod® (Iguratimod Tablets) ANTINE® (Diclofenac Sodium Sustained Release Capsules/Gel)
Other Products	XIANNUOXIN® (Simnotrelvir Tablets/Ritonavir Tablets (co-packaged)) Newanti® (Biapenem for Injection) ZAILIN® (Amoxicillin/Amoxicillin and Clavulanate Potassium/Cefaclor/Cefprozil) BIQI® (Montmorillonite/Dispersible Tablets) Softan® (Rosuvastatin Calcium Tablets)

## MANAGEMENT DISCUSSION AND ANALYSIS

### INDUSTRY REVIEW

In the first half of 2023, the orientation of national pharmaceutical policies to encourage innovation became increasingly obvious and the compliance requirements were further strengthened, which brought new opportunities and challenges for the development of the pharmaceutical industry. The Work Standards for Accelerating the Review of Marketing Authorization Application of Innovative Drugs (《加快創新藥上市許可申請審評工作規範》) further encouraged the development of new drugs with actual clinical value and expedited their review and approval. Policies such as the Rules for Negotiating Renewal of Drugs (《談判藥品續約規則》) under the Work Plan for the Adjustment to 2023 Reimbursement Drug List were more moderate and favourable towards the price adjustment of innovative drugs. Policies such as the Guidelines on Price Formation of COVID-19 Therapy Pharmaceuticals (《新冠治療藥品價格形成指引》) and the implementation of classification administration of COVID-19 therapy pharmaceuticals conduct new explorations on the reasonable pricing and inclusion into medical insurance of innovative drugs. At the same time, a national unified platform for medical insurance information was officially launched and the reform of DRG/DIP healthcare insurance payment methods has been carrying out in more cities, coupled with more normalized and legalized supervision of medical insurance funds as well as policies such as the promulgation of the National Catalog of the Second Batch of Drugs under Close Monitoring of Rational Drug Use (《第二批國家重點監控合理用藥藥品目錄》), all of which have put forward higher requirements on rational and legitimate use of drugs. Pharmaceutical enterprises that continue to launch innovative drugs with high clinical value and attach high importance to compliance operations will be able to go faster and further in the future.

### BUSINESS REVIEW

**Innovative pharmaceutical products have been commercialized continuously, which bring long-term healthy growth momentum. For the six months ended June 30, 2023, revenue of the Group maintained a high growth and increased by approximately 25.2% as compared to the same period of 2022. The proportion of revenue from innovative pharmaceuticals had increased to 71.4%. Revenue from innovative pharmaceuticals amounted to RMB2,413 million, representing an increase of approximately 36.6% as compared to the same period of 2022. Innovative drugs that entered the commercialization stage increased to six (Endostar®, Iremod®, Sanbexin®, ENWEIDA®, COSELA® and XIANNUOXIN®) and the New Drug Application (“NDA”) of a new Sanbexin® sublingual tablets was accepted.**

- The localization, traditional approval and development of new indications of COSELA® (Trilaciclib Hydrochloride for Injection) has been progressing well: On January 13, 2023, the Group submitted a supplemental application in order to transfer the commercial supply of COSELA® to domestic production enterprises as soon as possible. On February 17, 2023, the application for traditional approval of COSELA® to be used in the first-line chemotherapy of extensive-stage small cell lung cancer (“ES-SCLC”) patients was accepted by the National Medical Products Administration (“NMPA”) and is currently under technological review. On August 14, 2023, the marketing application for the new indication of COSELA® was accepted by NMPA, which will expand the application of COSELA® in two or more lines of chemotherapy of ES-SCLC patients.

- The Group is expediting the development of Sanbexin® series products to cover the full-course treatments of stroke: On June 28, 2023, the NDA of Sanbexin® sublingual tablets to be used in Acute Ischemic Stroke (“AIS”) was accepted by NMPA. The unique dosage form of the product is expected to increase the flexibility of stroke treatment and improve medication compliance, which is expected to meet the clinical demands of immediate administration and administration outside hospitals after the onset of stroke in the future. On July 3, 2023, the phase II clinical trial of Sanbexin® injection for the use in hemorrhagic stroke completed the First-Patient-In (“FPI”). For the six months ended June 30, 2023, Sanbexin® injection covered approximately 560,000 patients and covers over 4,200 medical institutions currently, accounting for approximately 22% of the market share in stroke injection.
- On January 28, 2023, XIANNUOXIN® (Simnotrelvir Tablets/Ritonavir Tablets (co-packaged)) was conditionally approved for marketing for the treatment of adult patients infected with mild-to-moderate Coronavirus Disease 2019 (the “COVID-19”). After being included into the scope of medical insurance reimbursement temporarily in February 2023, the accessibility of XIANNUOXIN® has been quickly enhanced. As of the date of this announcement, the product has covered 32 provinces, 306 cities and over 2,500 hospitals nationwide. On July 11, 2023, the phase Ib clinical study results of XIANNUOXIN® was published online in a sub-journal of Lancet. On July 31, 2023, the supplemental application for extending the effective period and changing storage conditions of XIANNUOXIN® was duly accepted by NMPA.

**Based on the unmet clinical demands, the Group promotes the R&D pipelines of innovative pharmaceuticals effectively. As of the date of this announcement, the Group has over 60 R&D pipelines of innovative pharmaceuticals, and has added three new NDAs<sup>2</sup>, three PCC molecules<sup>3</sup>, three approved new drug INDs<sup>4</sup>, five completed FPIs/FIHs<sup>5</sup> and six LPIs<sup>6</sup>, and its clinical projects have enrolled over 640 subjects.**

- On April 27, 2023, the new indication of intracerebral hemorrhage (“ICH”) of Sanbexin® (Edaravone and Dexborneol Concentrated Solution for Injection) obtained the clinical trial approval issued by NMPA, which is intended for the multi-center, randomized, double-blind and placebo-controlled phase II clinical trial to evaluate the efficacy and safety of Edaravone and Dexborneol Concentrated Solution for Injection with different dosages in combination of conventional medical therapies to treat ICH patients.
- The development of hypnotics Daridorexant is progressing swiftly in China. On July 20, 2023, NMPA approved the initiation of phase I+III clinical trials of Daridorexant, which is indicated for the treatment of adult patients with insomnia characterised by symptoms present for at least three months and considerable impact on daytime functioning. On July 28, 2023, the Group cooperated with Ruijin Hainan Hospital of Shanghai Jiao Tong University School of Medicine (Hainan Bo’Ao Research Hospital) (上海交通大學醫學院附屬瑞金醫院海南醫院) (海南博鳌研究型醫院) to submit an application for applying the drug in Hainan Bo’Ao Lecheng International Medical Tourism Pilot Zone (海南博鳌樂城國際醫療旅遊先行區).

<sup>2</sup> Three NDAs were accepted, namely XIANNUOXIN® (mild-to-moderate COVID-19, January 16), Sanbexin® sublingual tablets (Acute Ischemic Stroke, June 28) and COSELA® (2L+ES-SCLC, August 14).

<sup>3</sup> Three new pre-clinical candidate compounds (“PCC”), namely SIM0500, SIM0505 and SIM0508.

<sup>4</sup> Three investigational new drug applications (“IND”) were approved, namely Sanbexin® (ICH, April 27), Daridorexant (Insomnia, July 20) and SIM0278 (moderate-to-severe Atopic Dermatitis, July 27).

<sup>5</sup> Two studies completed First-in-Human (“FIH”), namely SIM0237 (PD-L1/IL15v bispecific) and SIM0348 (TIGIT/PVRIG bispecific); Three studies completed FPI, namely XIANNUOXIN® (105 study, March 21), XIANNUOXIN® (108 study, April 11) and Sanbexin® (ICH, phase II, July 3).

<sup>6</sup> Six studies completed Last-Patient-In (“LPI”), namely XIANNUOXIN® (107 study, January 1), SIM0335 (phase IIa, January 12), SIM0800 (phase I, February 25), XIANNUOXIN® (105 study, May 16), XIANNUOXIN® (108 study, June 15) and Suvmeticug (SCORES Study, June 27).

- On July 27, 2023, SIM0278 injection, an IL-2 mutant Fc fusion protein independently developed by the Group, obtained the clinical trial approval issued by NMPA, which is indicated for moderate-to-severe Atopic Dermatitis.

**The Group has been improving its production capability and efficiency continuously, so as to adapt to the expanding business needs and strengthen its market competitiveness. At the same time, the Group continues to improve the production quality management system with international high standards to accelerate the integration with the international market.**

- For the six months ended June 30, 2023, the Group has established a commercial supply capability with respect to XIANNUOXIN® that can meet the demands of several million people per month, and has completed the establishment of production lines of Sanbexin® sublingual tablets in its Nanjing small molecule base. The localization of COSELA® is progressing well, so as to transfer the commercial supply to domestic production enterprises as soon as possible.
- On June 7, 2023, Hainan Simcere Pharmaceutical Co., Ltd. (海南先聲藥業有限公司) successfully passed the GMP recertification of the European Union and received the GMP certificate from the European Union. On June 30, 2023, Jiangsu Xiansheng Biology Medical Co., Ltd. (江蘇先盛生物醫藥有限公司) (a pharmaceutical ingredient base) has been successfully completed and its completion surveying has been expediting, which will be put into full operation in the second half of 2023, so as to guarantee the production and supply of the Group's pharmaceutical ingredients.

## KEY MILESTONES

During the six months ended June 30, 2023, the Group made a series of advances in respect of its product candidates and business operations, including the following key milestones and achievements:

January 28, 2023	XIANNUOXIN® was conditionally approved for marketing in China by NMPA (Approval No. H20230001) 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 COVID-19.
April 27, 2023	The new indication of ICH of Sanbexin® (Edaravone and Dexborneol Concentrated Solution for Injection) has obtained the clinical trial approval issued by NMPA, which is intended for the multi-center, randomized, double-blind and placebo-controlled phase II clinical trial to evaluate the efficacy and safety of Edaravone and Dexborneol Concentrated Solution for Injection with different dosages in combination of conventional medical therapies to treat ICH patients.
June 28, 2023	The NDA of the Sanbexin® sublingual tablets (Edaravone and Dexborneol sublingual tablets), which was jointly developed by the Group and Neurodawn Pharmaceutical Co., Ltd. (南京寧丹新藥技術有限公司) (“Neurodawn”), was accepted by NMPA to be used in the improvement of the neuro symptoms, the daily living abilities and dysfunction caused by AIS.

From the end of the Reporting Period and up to the date of this announcement, the Group has also reached the following milestones:

July 20, 2023	Daridorexant, a hypnotics jointly developed by the Group and Idorsia Pharmaceuticals Ltd. (“ <b>Idorsia</b> ”), has obtained the clinical trial approval issued by NMPA, which is indicated for the treatment of adult patients with insomnia characterised by symptoms present for at least three months and considerable impact on daytime functioning.
July 27, 2023	SIM0278 injection, an IL-2 mutant Fc fusion protein independently developed by the Group, has obtained the clinical trial approval issued by NMPA, which is indicated for moderate-to-severe Atopic Dermatitis.
August 14, 2023	The marketing application for new indications of COSELA® (Trilaciclib Hydrochloride for Injection) was accepted by NMPA for the use in ES-SCLC patients to administer before the treatment by topotecan-containing regimen, so as to reduce the incidence of chemotherapy-induced myelosuppression.
August 18, 2023	The Group entered into a cooperation agreement with Taizhou Mabtech Pharmaceutical Limited*(泰州邁博太科藥業有限公司) in respect of CMAB009, the Group obtained the exclusive commercial rights in respect of CMAB009 in the Chinese mainland.

For details of each milestone above, please refer to the following 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.

## **SUMMARY OF PRODUCT PIPELINES**

As of the date of this announcement, the Group has over 60 R&D pipelines of innovative drugs and is currently initiating clinical studies for 19 innovative drugs, among which, there are five launched products (new indications/ combined development, etc), three drug candidates that are in NDA/pivotal trial stage, 11 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, antibody-drug conjugate (“**ADC**”) and small molecule drugs, etc. The extensive pipeline reserves are expected to help more patients.

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



Product candidate (Target/Mechanism)	Pre-clinical	IND	Phase I	Phase II	Phase III	NDA/BLA	Approval
Oncology							
COSELA** (CDK4/6)	ES-SCLC (TRACES study)					Conditionally approved on July 12,	
	TNBC (PRESERVE 2 study)						
Endostar® New indication (Angiogenesis)	Thoracoabdominal effusions (COREMAP study)						
Suvmecitug* (VEGF)	OC,FTC and PPC (SCORES study)						
ENWEIDA**+ Suvmecitug* (PD-L1+VEGF)	Solid tumors						
Docetaxel polymeric micelles for injection * (Tubulin inhibitor)	Solid tumors						
SIM0395* (PI3K/mTOR)	Glioblastoma		(GBM AGILE study)				
SIM0270 (SERD BM)	Breast cancer						
SIM0235 (TNFR2)	Advanced solid tumor and CTCL (China)						
	Advanced solid tumor and CTCL (U.S.)						
SIM0272 (PRMT5)	Tumors						
SIM0237 (PD-L1/IL15v bispecific antibody)	Advanced solid tumor (U.S.)						
	Non-muscle invasive bladder cancer (China)						
SIM0348 (TIGIT/PVRIG bispecific antibody)	Advanced solid tumor						
SIM0323* (CD80/IL2)	Solid tumors						
SIM0500 (GPC5D-BCMA-CD3)	Multiple myeloma						
SIM0501 (USP1)	Solid tumors						
SIM0502	Solid tumors						
SIM0503	Solid tumors						
SIM0505	Solid tumors						
SIM0506 (SOS1)	Solid tumors						
SIM0508 (Polθ)	Solid tumors						
SIM0602	Solid tumors						
CMAB009 * (EGFR)	mCRC						
Nervous System							
Sanbexin® sublingual tablets* (Free radicals and inflammatory cytokines)	AIS					Approved for marketing in the United States and Europe	
	AIS (U.S.)						
Daridorexant* (DORA)	Insomnia						
Sanbexin® injection New Indication (Free radicals and inflammatory cytokines)	ICH						
	Alzheimer Disease						
SIM0801* (QPCT)	Stroke with cerebral edema						
SIM0800* (AQP4)	AIS etc.						
SIM0802* (PSD-95)							
Autoimmune							
SIM0295* (URAT1)	Gout with hyperuricemia						
SIM0278 (IL2muFc)	SLE, AD, etc.						
SIM0335 # (IL-17A-related pathways)	Psoriasis						
LNK01001 # (JAK1)	RA and AS						
SIM0708	AD, COPD, Asthma, etc.						
Others							
XIANNUOXIN** (3CL)	Mild-to-moderate COVID-19					Conditionally approved on January 28,	

\* License-In (development and commercialization right)

# Only commercialization right

Global pre-clinical trials with partners

Development status of R&D partner(s)



## INNOVATIVE DRUGS AT THE COMMERCIALIZATION STAGE

As of the date of this announcement, the commercialized innovative drugs in the portfolio increased into six successfully, spanning multiple therapeutic areas, including nervous system, oncology, autoimmune and anti-infection, which have significant market potentials and synergistic effects. For the six months ended June 30, 2023, revenue from innovative pharmaceuticals was approximately RMB2,413 million, accounting for 71.4% of the total revenue. Benefiting from the rapid increase in revenue from innovative pharmaceuticals during the Reporting Period, revenue of the Group was approximately RMB3,379 million, representing an increase of approximately 25.2% as compared to RMB2,700 million for the same period of 2022.

### 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 AIS. Sanbexin® was approved for marketing in China in July 2020 and has been included in the NRDL since December 2020. Results of the 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 an mRS score of 0-1 after 90 days of treatment, i.e. reduce the proportion of patients disabled by AIS. Sanbexin® was recommended by the Guidelines for Clinical Management of Cerebrovascular Diseases in China (《中國腦血管病臨床管理指南》), 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》), 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).

- On April 27, 2023, the new indication of ICH of Sanbexin® obtained the clinical trial approval issued by NMPA, which is intended for the multi-center, randomized, double-blind and placebo-controlled phase II clinical trial to evaluate the efficacy and safety of Edaravone and Dexborneol Concentrated Solution for Injection with different dosages in combination of conventional medical therapies to treat ICH patients. On July 3, 2023, the above phase II clinical trial completed the FPI in the First Affiliated Hospital of Sun Yat-sen University (中山大學附屬第一醫院).
- On May 19, 2023, the TASTE II study after the launch of Sanbexin®, led by Beijing Tiantan Hospital of the Capital Medical University (首都醫科大學附屬北京天壇醫院) with the participation of approximately 100 research centers in China, completed the follow-ups with the last subject. Such study aims at evaluating the efficacy and safety of Sanbexin® combined with reperfusion in the treatment of AIS patients, and has enrolled more than 1,300 AIS patients who had onset within 24 hours and undergone early endovascular recanalization therapy.

- On June 24, 2023, the Guidelines for Clinical Management of Cerebrovascular Diseases in China (second edition) (《中國腦血管病臨床管理指南(第2版)》) prepared and issued by the Chinese Stroke Association (中國卒中學會) upgraded the concept of “neurological protection” in the 2019 edition by the treatment of “brain cell protection” and recommended the use of Edaravone and Dexborneol. Based on the positive result of the TASTE study, i.e. “the Edaravone and Dexborneol Concentrated Solution for Injection can further improve the clinical outcomes of patients with AIS”, Sanbexin® becomes the only brain cell protection drug that received Level IIa recommendation in such guidelines currently (Class IIa, level B).
- On July 4, 2023, the EXPAND study, a post-market real-world study (“RWS”) led by Xuanwu Hospital of the Capital Medical University (首都醫科大學宣武醫院), has completed the enrollment of all 4,750 subjects. The primary objective of such a study is to observe the clinical effectiveness of AIS patients using Edaravone and Dexborneol in the real world environment, while its secondary objective is to monitor the safety of the clinical application of Edaravone and Dexborneol.
- For the six months ended June 30, 2023, Sanbexin® injection covered approximately 560,000 patients and covers over 4,200 medical institutions currently, accounting for approximately 22% of the market share in stroke injection.

## 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.

- In June 2023, the American Society of Clinical Oncology (“ASCO”) published two studies relating to the combination of Endostar® with immunotherapy: (1) Recombinant Human Endostatin in combination with PD-1 antibody and chemotherapy for the first-line treatment of EGFR/ALK-negative advanced or metastatic NSCLC: a real world study; and (2) as compared with ICIs in combination with chemotherapy, autoimmune treatment in combination with the second-line treatment of Recombinant Human Endostatin can better improve the clinical outcomes of advanced NSCLC, which provide a new efficient option for the first-line and second-line treatment of advanced NSCLC.

- On July 4, 2023, Guangdong Pharmaceutical Association (廣東省藥學會) published the Catalog for the Off-label Use of Drugs (2023) (《超藥品說明書用藥目錄(2023版)》), which included the Recombinant Human Endostatin Injection and its indication was NSCLC. The reference basis includes the “Guidelines for the Clinical Application of New Anti-tumor Drugs (2022)” (《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, etc.
- On July 18, 2023, Chinese Medical Association (中華醫學會) published the Guideline for Clinical Diagnosis and Treatment of Lung Cancer (2023) (《肺癌臨床診療指南(2023版)》), which recommended that during the treatment of negative patients with driver genes of non-squamous cell cancer, for those patients with a PS score of 0-1, patients with no contraindication can choose between Bevacizumab or Recombinant Human Endostatin in combination with chemotherapy and receive maintenance treatment (Class I or IIa).

#### *ENWEIDA® (Envafolimab Injection)*

ENWEIDA® is a single domain antibody against recombinant humanized PD-L1 and a protein fused with Fc, which was conditionally approved for marketing in China by NMPA on November 25, 2021. ENWEIDA® is the world's first PD-(L)1 antibody to be administered by subcutaneous injection and 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. (思路迪(北京)醫藥科技有限公司) and Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (江蘇康寧傑瑞生物製藥有限公司). 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 January 2023, two studies of ENWEIDA® relating to liver cancer and colorectal cancer were selected to exchange by way of posters in the ASCO Gastrointestinal Cancers Symposium and the title of the study was: (1) the treatment of MSS locally advanced rectal cancer by Envafolimab in combination with CAPEOX before neoadjuvant therapies and after radiotherapy in short regimens: an open-label and forward-looking single-arm study; and (2) the efficacy and safety of treating unresectable hepatocellular cancer by Envafolimab in combination with Lenvatinib and TACE: an open-label, single-arm, phase II CISLD-12 study.
- In April 2023, ENWEIDA® continued to be included in six CSCO important guidelines: CSCO Diagnosis and Treatment Guidelines for Gastric Cancer 2023 (《CSCO胃癌診療指南2023版》) (Class I, Level 2A); CSCO Diagnosis and Treatment Guidelines for Colorectal Cancer 2023 (《CSCO結直腸癌診療指南2023版》) (Class II, Level 2A); CSCO Immune Checkpoints Guidelines for Clinical Use of Inhibitors 2023 (《CSCO免疫檢查點抑制劑臨床應用指南2023版》) (Class I, Level 2A); CSCO Diagnosis and Treatment Guidelines for Endometrial Cancer 2023 (《CSCO子宮內膜癌診療指南2023版》) (Class II); CSCO Diagnosis and Treatment Guidelines for Cervical Cancer 2023 (《CSCO宮頸癌診療指南2023版》) (Class II); and CSCO Diagnosis and Treatment Guidelines for Ovarian cancer 2023 (《CSCO卵巢癌應用指南2023版》) (Class III, Level 2B).

- On April 13, 2023, the Gynecological Tumors Immune Checkpoints Guidelines for Clinical Use of Inhibitors 2023 (《婦科腫瘤免疫檢查點抑制劑臨床應用指南(2023版)》) was published, which recommended patients with gynecological tumors with advanced/recurrent MSI-H/dMMR who failed the previous treatments to use Envafolelimab (Level 2B).
- In June 2023, two relevant studies of ENWEIDA® were published in the annual meeting of the ASCO, which were related to gastric cancer and soft tissue sarcoma. In the study related to gastric cancer, the efficacy of using Envafolelimab in combination with SOX (Oxaliplatin and TGOP) for the first-line treatment of PD-L1 positive advanced gastric adenocarcinoma emerges, which has a promising future.
- On July 31, 2023, the Gynecological Oncology of Chinese Medical Association (中華醫學會婦科腫瘤學分會) published the 7<sup>th</sup> Edition of the Clinical Guidelines for Gynecological Oncology of Chinese Medical Association (2023) (《中華醫學會婦科腫瘤臨床指南7版(2023)》). ENWEIDA® (Level 2B) is recommended as a therapy drug for MSI-H/dMMR patients with advanced/recurrent endometrial cancer.

*COSELA® (trilaciclib hydrochloride for injection)*

COSELA® is an effective, selective and reversible cyclin-dependent kinases 4 and 6 (CDK4/6) inhibitor. COSELA® is the world's first-in-class comprehensive myeloprotection innovative drug that can be 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 COSELA® in Greater China. On February 13, 2021, the product was approved for marketing by FDA. On July 12, 2022, the marketing of COSELA® in China has obtained the conditional approval by NMPA. Currently, the product has been recommended by the related key guidelines of National Comprehensive Cancer Network Guidelines (NCCN), CSCO and other organizations.

- On January 13, 2023, the Group submitted a supplemental application in order to transfer the commercial supply of COSELA® to domestic production enterprises as soon as possible.
- On February 17, 2023, the application for traditional approval of COSELA® to be used in the first-line chemotherapy of ES-SCLC patients was accepted by NMPA and it is currently under technological review.
- On May 10, 2023, a phase II clinical trial led by G1 Therapeutics indicated that, COSELA®, for the use of patients with unresectable and locally advanced or metastatic triple-negative breast cancer ("TNBC"), decreased the incidence of various adverse events related to ADC by over 50%, including neutropenia, anemia and diarrhea. Trilaciclib generates targeted effects with clinical value, which provides important and long-term benefits to patients.
- In May 2023, a study analyzing the population pharmacokinetics of Trilaciclib in ES-SCLC and the relationship between the exposure and myeloprotection, anti-tumor and safety of Trilaciclib was published in the British Journal of Clinical Pharmacology (IF 3.7). Such analysis of the pharmacokinetics of Trilaciclib indicated that, under current clinical application scenarios, it is not necessary to adjust the dose pursuant to the difference in age, gender as well as liver and renal function. Under the recommended dose (240mg/m<sup>2</sup>), Trilaciclib can bring about stable myeloprotection.

- On May 11, 2023, the European Society for Medical Oncology Breast Cancer Symposium (ESMO BC) published the initial results of a phase II study in relation to the use of Trilaciclib in combination with sacituzumab govitecan-hziy (“**SG**”) in the treatment of metastatic triple-negative breast cancer (“**mTNBC**”). The study results indicate that, the combination of Trilaciclib before applying SG in the treatment of mTNBC may decrease the incidence of adverse events (AEs), such as neutropenia, anemia, nausea and diarrhea.
- On May 25, 2023, the study team from the Strategic Support Force Characteristic Medical Center of the People’s Liberation Army (解放軍戰略支援部隊特色醫學中心) (originally known as the 306 Hospital) and Chengdu Medical College (成都醫學院) published a Systematic Assessment and Meta analysis in the Frontiers in Pharmacology (IF: 5.6). The result showed that Trilaciclib was able to effectively reduce the incidence of CIMs like severe neutropenia (SN) and febrile neutropenia (FN), decrease the usage of supportive caring measures like red blood cell transfusions and transfusions of granulocyte colony-stimulating factors (G-CSF) and performed well in terms of safety.
- On June 2 to 6, 2023, the ASCO published two study results about Trilaciclib at its 59th annual meeting, namely the studies in the field of early TNBC and ES-SCLC respectively. During the early neoadjuvant therapies of TNBC, the data relating to the safety and tolerance of Trilaciclib in combination with AC/T ± Pembrolizumab ± carboplatin were encouraging and its preliminary efficacy results were in line with neoadjuvant chemotherapy regimen. The study compared the condition of ES-SCLC patients who have received Trilaciclib + PEA (PEAT) and have not received Trilaciclib (“**PEA**”) in the real world, results showed that Trilaciclib can improve the safety of PEA regimen to a certain extent while not affecting of the survival outcomes patients. As such, the study supports the use of Trilaciclib in combination with PEA for the treatment of ES-SCLC.
- On July 1, 2023, the Tumor Clinical Chemotherapy Professional Committee (腫瘤臨床化療專業委員會) and the Neoplastic Supportive-Care Professional Committee (腫瘤支持治療專業委員會) of China Anti-Cancer Association (中國抗癌協會) formulated and published the Consensus on clinical diagnosis, treatment, and prevention of chemotherapy-induced neutropenia in China (2023 edition) (《中國腫瘤化療導致的中性粒細胞減少診治專家共識(2023版)》), from which, COSELA® was included in the Consensus for the first time and it was recommended to be administered prior to chemotherapy in order to decrease the incidence of chemotherapy-induced myelosuppression (Class I).
- On August 14, 2023, the marketing application for the new indication of COSELA® was accepted by NMPA, which will expand the application of COSELA® in two or more lines of chemotherapy of ES-SCLC patients.

## 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 since 2017. The indication is the active rheumatoid arthritis. Since its launch 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 clinical practice guidelines and pathways issued by the NHC, Chinese Medical Association, Asia Pacific League of Associations for Rheumatology and Labor and Welfare of Japan.

- In March 2023, results of an observational study initiated by the team of Professor Bao Chunde at Renji Hospital of Shanghai JiaoTong University School of Medicine (上海交通大學醫學院附屬仁濟醫院) were published in the *Frontiers in Immunology* journal. The study applied the add-on design which the patients have been treated by at least one type of immunosuppressant before enrollment and have a base urine protein/creatinine ratio (UPCR) of >1.0. It was a study to investigate the efficacy and safety of Iguratimod (IGU) on refractory lupus nephritis (LN) on the basis of those immunosuppressants having poor responses to treatments (failure or onset) before continuous use.
- On May 31, 2023, the 2023 EULAR meeting published seven study results relating to Iguratimod, which involved indications like rheumatoid arthritis (“RA”) and secondary osteoporosis, osteoarthritis (OA), common interstitial pneumonia (ILD) relating to RA, axial spinal arthritis and systemic sclerosis. The study results of Iguratimod at the annual meeting of EULAR have explored more directions and new possibilities for patients to benefit from China’s clinical studies in the field of autoimmune.

## 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.

Results of the 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 log<sub>10</sub> 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 adult 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.

- On January 28, 2023, XIANNUOXIN® (Simnotrelvir Tablets/Ritonavir Tablets (co-packaged)) was conditionally approved for marketing in China by NMPA (Approval No. H20230001) 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 COVID-19.
- On February 8, 2023, the National Healthcare Security Administration issued a notice that the Simnotrelvir Tablets/Ritonavir Tablets (co-packaged) was included into the scope of medical insurance reimbursement temporarily.
- On March 2, 2023, the NHC and the National Administration of Traditional Chinese Medicine issued a notice that the Simnotrelvir Tablets/Ritonavir Tablets (co-packaged) was included in the Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia (Trial Version 10) (《新型冠狀病毒感染診療方案(試行第十版)》), which further improved the anti-virus and treatment protocol for Novel Coronavirus Pneumonia. On April 28, 2023, China Medicine Education Association (中國醫藥教育協會) published the Illustration on the Guidelines of Home Medication during Regular Prevention and Control of COVID-19 (《新冠病毒常態化防控居家用藥指南圖解系列》), which recommended the use of XIANNUOXIN® for mild-to-moderate COVID-19.



- On March 21, 2023, XIANNUOXIN 105 study completed the FPI and completed the enrollment of all 37 subjects on May 16, 2023. Such study is a multi-center, non-randomized, open, parallel and controlled phase I clinical study for evaluating the safety, tolerability and pharmacokinetic characteristics after single-dose administration of SIM0417 in combination with Ritonavir to subjects with mild-to-moderate renal insufficiency, moderate hepatic insufficiency, normal renal function and normal hepatic function.
- On April 11, 2023, XIANNUOXIN 108 study completed the FPI and completed the enrollment of all 14 subjects on June 15, 2023. Such study is a single-center, non-randomized and open phase I clinical study aiming at evaluating the safety and pharmacokinetic characteristics after single-dose administration of SIM0417 in combination with Ritonavir to healthy elderly subjects.
- On June 9, 2023, the first large-scale RWS targeted at marketed anti COVID-19 drugs was initiated in Beijing. 30 provinces, cities and autonomous regions, over 100 large hospitals and grass-root medical institutions in China participated in the study, and factual information of near 40,000 COVID-19 patients has been included. Such study will reflect the situation of China's COVID-19 treatment in terms of clinical plans, follow-up mechanisms and medical expenditures and further explore the efficacy, safety and pharmacoeconomic value of anti COVID-19 drugs, which provide support with first-hand information for the normalized management with measures against Class B infectious diseases in respect of COVID-19 and support the achievement of the objective of pandemic prevention and control, which is "safeguarding people's health and preventing severe cases". As of the publication date of this announcement, such RWS has enrolled more than 2,200 subjects.
- On July 11, 2023, The Lancet Regional Health - Western Pacific Magazine published a randomized, double-blind and placebo-controlled phase Ib trial in China online, which was relating to the exploration of the efficacy and safety of using Simnotrelvir Tablets/Ritonavir Tablets for the treatment of COVID-19. Results of such study showed that Simnotrelvir Tablets/Ritonavir Tablets has good efficacy and tolerance, and the clinically recommended dose is 750 mg of Simnotrelvir plus 100 mg of Ritonavir.
- On July 31, 2023, the supplemental application for extending the effective period and changing storage conditions of XIANNUOXIN® was duly accepted by NMPA.

## DRUG CANDIDATES AT THE NDA/PIVOTAL TRIAL STAGE

### Sanbexin® sublingual tablets

Sanbexin® sublingual tablets are solid formulations absorbed through the sublingual mucous containing Edaravone and Dexborneol that can be rapidly disintegrated under the tongue, absorbed into the blood through the sublingual venous plexus, exert anti-inflammatory and anti-free radical and other effects, thereby reducing stroke-induced neuronal injury. Such unique dosage form is expected to increase the flexibility of stroke treatment and improve medication compliance. In the future, Sanbexin® sublingual tablets are expected to form a sequential therapy combined with Sanbexin® (Edaravone and Dexborneol Concentrated Solution for Injection) which has been launched by the Company, facilitating patients to obtain a complete course of treatment. At the same time, sublingual tablets are not limited by medical site conditions and patient compliance, and are also more suitable to expand other indications for neurological diseases.

- On December 1, 2022, the phase III clinical trial of Sanbexin® sublingual tablets in the treatment of AIS completed Database Lock (DBL) and statistical analysis. The data showed that Sanbexin® sublingual tablets significantly improved neurological recovery and independent living ability of AIS patients after treatment compared with placebo, achieving the expected efficacy endpoints with a good safety profile. The detailed results are expected to be published in academic journals or conferences in the future. The success of such study confirmed the clinical value of Sanbexin® sublingual tablets in the treatment of AIS, and expected to bring new treatment options for the majority of AIS patients.
- On June 28, 2023, the NDA of the Sanbexin® sublingual tablets (Edaravone and Dexborneol sublingual tablets) was accepted by NMPA for the improvement of the neurological symptoms, activities of daily living and neurological dysfunction caused by AIS. Sanbexin® sublingual tablets are expected to meet the clinical needs in the field of administration at the first time after stroke onset and out-of-hospital administration and increase the accessibility of stroke patients to the whole course of treatment from in-hospital to out-of-hospital.

## **Suvemcitug**

Suvemcitug is a new generation of recombinant humanized anti-vascular endothelial growth factor (anti-VEGF) monoclonal antibody, and pre-clinical studies have showed that Suvemcitug has a stronger antitumor effect than bevacizumab at the same dose in multiple tumor models. Preliminary safety and efficacy signals have been shown in the phase Ib clinical trial for ovarian cancer that has been conducted in China.

- On June 27, 2023, the LPI for the phase III clinical trial (SCORES) of Suvemcitug combined with chemotherapy versus placebo combined with chemotherapy in patients recurrent epithelial Ovarian, fallopian tube cancer, or primary peritoneal cancer who had failed platinum-based chemotherapy was achieved and enrolled 421 subjects at 53 centers in China.

## **Daridorexant**

Daridorexant is a dual orexin receptor antagonist (“DORA”) that blocks orexin neuropeptides that promote wakefulness (orexin A and orexin B) from binding to their receptors. Unlike generally promoting sleep by calming the brain, Daridorexant only blocks orexin neuropeptide activation of orexin receptors. Thus, Daridorexant reduces the arousal drive and induces sleep development without altering sleep architecture. The phase III data has been published in *The Lancet Neurology*: the main studies demonstrated that Daridorexant significantly improved sleep onset, sleep maintenance and self-reported total sleep time compared with placebo during the first and third months of treatment without changing sleep architecture. In addition, Daridorexant was shown to be safe and well-tolerated with no evidence of dependence, rebound insomnia, withdrawal symptoms or drug abuse, distinguishing significantly from what has been reported with benzodiazepine receptor agonists. Daridorexant has clinical data available for up to 12 months of continuous treatment, supporting the long-term use of Daridorexant. In addition to improving nighttime sleep in the adult population with chronic insomnia disorder, Daridorexant also improves daytime functioning, which is the only DORA class insomnia drug approved by the European Medicines Agency (EMA). Daridorexant is currently approved in the United States, Great Britain, Italy, Germany, Switzerland and Canada. On November 16, 2022, the Group entered into an exclusive license agreement with Idorsia and the Group was granted exclusive right to the development and commercialization of Daridorexant in Greater China.

- On July 20, 2023, Daridorexant hydrochloride tablets received a notice of approval for Drug Clinical Trials issued by the National Medical Products Administration, which is intended for the treatment of adult insomnia patients who have persistent symptoms for at least three months and have an impact on daytime function.

- On July 28, 2023, the Group cooperated with Ruijin Hainan Hospital of Shanghai Jiao Tong University School of Medicine (Hainan Bo'ao Research Hospital) (上海交通大學醫學院附屬瑞金醫院海南醫院) (海南博鳌研究型醫院) to submit an application for applying the drug in Hainan Bo'ao Lecheng International Medical Tourism Pilot Zone (海南博鳌樂城國際醫療旅遊先行區).

## **DRUG CANDIDATES AT THE PHASE I/II STAGE**

### **SIM0278 (IL2 mu Fc)**

SIM0278 is an Fc fusion protein (IL2 mu Fc) with an IL-2 mutein of Regulatory T cells (“**Treg**”), developed based on the Group’s protein engineering technology platform. By introducing the mutation, the affinity of SIM0278 to effector T cells is reduced, while the high affinity of Treg cells is retained and then the selectivity of Treg cells is improved. Pre-clinical studies have showed that SIM0278 has significantly optimized PK properties and is able to selectively activate Treg cells without affecting effector T cells or NK cells, so as to achieve the effect of restoring the body’s immune balance and has the potential to be developed for the treatment of various autoimmune diseases. On September 28, 2022, the Group entered into a licensing agreement with Almirall, an international biopharmaceutical company. Under the agreement, the Group grants Almirall an exclusive rights and interests in the development and commercialization of SIM0278 outside Greater China, and retains all rights and interests in the Greater China Territory.

- On July 27, 2023, SIM0278 injection obtained the clinical trial approval issued by NMPA, which is indicated for moderate-to-severe Atopic Dermatitis.

### **SIM0395 (Paxalisib)**

SIM0395 is a PI3K/mTOR pathway inhibitor that crosses the blood-brain barrier. A phase II clinical study showed that Paxalisib shownend an encouraging signal of clinical efficacy in glioblastoma patients with unmethylated MGMT. Paxalisib was granted orphan drug designation for GBM by FDA in 2018 and fast track designation, diffuse intrinsic pontine glioma (DIPG) rare pediatric diseases, and orphan drug designation by FDA 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 Greater China. At present, the partner Kazia is conducting an international multi-center pivotal phase III clinical trial for glioblastoma (GBM AGILE Study).

## **SIM0270 (SERD)**

SIM0270 is a second-generation oral selective estrogen receptor degraders (“**SERD**”) inhibitor with blood-brain barrier penetration characteristics independently developed by the Group. SIM0270 was significantly more effective than fulvestrant a marketed intramuscular SERD product, in an in vivo model, comparable to the leading compound in the clinical trial phase, and reflected a brain-blood ratio significantly better than competitive compounds and showed a much better tumor inhibition drug therapy than fulvestrant in the orthotopic model of breast cancer brain. It is expected to be used for the treatment of breast cancer with brain metastases.

- On February 3, 2023, the NMPA issued a notice of approval for drug clinical trials of SIM0270 in combination with pibercept or everolimus in the treatment of estrogen receptor-positive breast cancer, and as of July 10, 2023, eight subjects were enrolled for dose escalation of the combination study.
- On June 30, 2023, the phase I clinical trial of SIM0270 monotherapy in SERD ER+/HER-2 negative breast cancer completed the enrollment for monotherapy dose escalation and RP2D dose selection stage, and the analysis results were used to obtain the appropriate recommended dose (RP2D).

## **SIM0235 (TNFR2)**

SIM0235 is a brand-new target of tumor immunity independently developed by the Group, human immunoglobulin G1 (“**IgG1**”) type humanized anti-tumor necrosis factor type 2 receptor (“**TNFR2**”) monoclonal antibody. The pre-clinical pharmacodynamic model showed 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, kill immunosuppressive cells such as Treg highly expressing of TNFR2 and bone marrow-derived suppressor cells (“**MDSC**”) through Fc terminal functions such as antibody dependent cell-mediated cytotoxicity (ADCC) and antibody dependent cell-mediated phagocytosis (ADCP), and 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 terminal of antibody.

- 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.
- As of the date of this announcement, the phase I clinical trial of SIM0235 for relapsed or refractory advanced solid tumors and cutaneous T-cell lymphoma (CTCL) progressed smoothly in China and the United States, with completion of enrollment of 29 and 6 subjects respectively. The enrollment of dose escalation stage for monotherapy was completed and the analysis results of which were intended for obtaining appropriate recommended dose (RD). It is expected that the dose exploration and expansion of combined study will initiate in the third quarter of 2023.

### **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. Pre-clinical pharmacokinetic studies revealed that SIM0272 tended to be distributed in the tumor, and the ratio of intratumoral drug concentration to plasma drug is about 10-fold higher than that of other PRMT5 inhibitors under development, showing proliferative 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.

- As of the date of this announcement, 25 patients have been enrolled in a multicenter phase I clinical trial evaluating the safety and tolerability, efficacy, and pharmacokinetics of SIM0272 in patients with advanced malignancies, and a single-agent dose escalation enrollment plan has been completed, and the analysis results are used to obtain the appropriate recommended dose (RD).

### **SIM0237 (PD-L1/IL15v bispecific antibody)**

SIM0237 is an anti-PD-L1 monoclonal antibody fused with IL-15/IL-15R  $\alpha$  sushi protein and independently developed based on the Group's protein engineering platform. It can block the PD-1/PD-L1 immunosuppressive pathway by binding to PD-L1 and activate the immune system through its IL-15 part, thus playing a dual synergistic role in relieving immunosuppression and initiating the immune system to exert anti-tumor effects. Pre-clinical studies showed that SIM0237 is more effective than PD-L1 or IL-15 mono treatment in mouse tumor models, predicting a high potential for clinical development.

- On March 8, 2023, a first-in-human, open-label, multi-center phase I study to evaluate the safety, tolerability, pharmacokinetics and preliminary anti-tumor activity of SIM0237 in adult subjects with advanced solid tumors reached the FPI in Hunan Cancer Hospital. Currently, SIM0237 is simultaneously carrying out MRCT clinical trials in China and the United States in advanced solid tumors.
- On July 24, 2023, the IND for the new indication of SIM0237 was accepted by NMPA, which was intended for non-muscle invasive bladder cancer.

### **SIM0348 (humanized TIGIT/PVRIG bispecific antibody)**

SIM0348 is a humanized TIGIT/PVRIG bispecific IgG1 antibody independently developed based on 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 TIGIT expression and dual TIGIT and PVRIG expression, while better mediating the activation and killing effect of NK cells and further enhancing the tumor-killing ability of dual antibodies.

- On March 29, 2023, a first-in-human, open-label and multi-center phase 1 study to evaluate the safety, tolerability, pharmacokinetics and preliminary anti-tumor activity of SIM0348 in advanced solid tumors reached the FPI in the Cancer Center of Sun Yat-sen University (中山大學).

### **SIM0801 (QPCT)**

SIM0801 is an oral small molecule inhibitor targeting glutamine acyl cyclase (“QPCT”). 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. for the development and commercialization of SIM0801 and other drugs in the Greater China region. In December 2021, FDA granted “Fast Track” accreditation to the candidate drug.

- Currently, SIM0801 has obtained the Clinical Trial Approval issued by NMPA, which is intended for the treatment of mild cognitive impairment (MCI) or mild dementia caused by Alzheimer's disease (AD) and the support of initiating phase I and phase II clinical trials in China.



### **SIM0800 (AQP4)**

SIM0800 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 SIM0800 in the Greater China region.

- On February 25, 2023, the phase I clinical trial of SIM0800 enrolled the last subject. The phase I data showed that the drug had good safety and tolerance.

### **SIM0335 (IL-17A related pathways)**

SIM0335 is a drug candidate developed by BCY Pharm Co., Ltd. (江蘇博創園生物醫藥科技有限公司, “BCY”) that controls fatty acid metabolism and works on IL-17A-related pathways. SIM0335 is a topical ointment with 3-Ocyclohexanecarbonyl-11-keto- $\beta$  boswellic acid (CKBA) being the active ingredient. Results of the phase I clinical trial showed that the systemic exposure was low and the systemic safety risk was expected to be small.

- On January 12, 2023, the phase IIa clinical trial of SIM0335 for the treatment of plaque psoriasis completed the enrollment of all patients. The study is designed to evaluate the safety, efficacy, and pharmacokinetics of SIM0335 in mild-to-moderate plaque psoriasis patients.
- On March 2, 2023, Guangdong Taienkang Pharmaceutical Co., Ltd. (廣東泰恩康醫藥股份有限公司) acquired 50% equity interests in BCY and BCY was no longer a subsidiary of the Group.

## **SELECTED DRUG CANDIDATES AT THE PRE-CLINICAL STAGE**

The Group has nine pre-clinical candidates at the IND enabling stage and its 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 Group. Certain research and development assets with high potential are as follows.

### **SIM0323 (CD80/IL2)**

SIM0323 is the first-in-class CD80/IL-2 bifunctional fusion protein developed by the Group in cooperation with GI Innovation, Inc. The pre-clinical pharmacodynamic model showed significant single-agent efficacy and the potential to be used in combination with PD-1 and chemotherapeutic drugs. In 2021, the partner obtained the approvals of clinical trials from the Korean Ministry of Food and Drug Safety and the FDA respectively to be allowed to conduct phase I/II clinical trial studies of the drug.

### **SIM0419 (PSD-95)**

SIM0419 (PSD-95) 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), whose 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.

### **SIM0500 (GPCR5D-BCMA-CD3)**

SIM0500 is a GPCR5D/BCMA/CD3 multispecific antibody belonging to category I innovative drug independently developed by the Group with global intellectual property rights, and it is a potential best-in-class drug in the treatment of multiple myeloma. Through the research and development platform of multispecific antibody drugs with the Group’s own T-cell engagers, SIM0500 series combines with the antibody with anti-tumor associated antigen through the Group’s self-developed CD3 antibody activated by low affinity and high targetability, which forms the tumor-targeted T-cell activating drugs. It has the advantages of excellent tumor-killing effect and good tolerance. SIM0500 can potentially overcome the drug resistance caused by the existing treatment methods, increase the drug coverage, and show excellent anti-tumor activity in various animal pharmacodynamic models with different expression levels before clinical practice, and has multiple advantages such as low effective dose and no recurrence of tumors after drug withdrawal. The Group plans to submit the first IND application to NMPA and FDA in the fourth quarter of 2023.

#### **SIM0501 (USP1 small molecule inhibitor)**

SIM0501 is an effective and selective USP1 small molecule inhibitor independently developed by the Group with global intellectual property rights. USP1 is a protein that repairs DNA damage response (“**DDR**”) differently with PARP inhibitors and other methods. Studies showed that USP1 or downstream signaling pathways do make HRD tumor cells more sensitive to PARP inhibitor. Pre-clinical research results suggest that USP1i mono treatment or in combination with PARPi can slow down DNA replication and block cell cycle until the inducement of cell death. It can be used in clinical applications such as the mono treatment for various solid tumors with HRD or BRCA mutation, overcoming PARPi drug resistance, synergizing with PARPi or the combination of radiotherapy with chemotherapy as a potential new treatment option for patients who are unmet in a variety of cancers. The Group plans to submit the IND to NMPA and FDA in the fourth quarter of 2023.

#### **SIM0506 (SOS1 small molecule inhibitor)**

SIM0506 is an effective and highly selective SOS1 inhibitor independently developed by the Group with global intellectual property rights for the treatment of various solid tumors. SOS1 is one of the main targets that indirectly inhibits the activity of KRAS, catalyze GTP to swap with GDP in RAS, thus activating KRAS. Pre-clinical studies showed that SIM0506 demonstrates pan-KRAS inhibitory activity and its synergistic effect was remarkable after combination, which is safe and tolerant with low effective dose and good anti-tumor effect. The combination with KRAS and MEK inhibitors both showed good synergistic effect. In clinical applications, it can be used in combination with KRAS inhibitors or ERK inhibitors or MEK inhibitors or chemotherapeutics for the treatment of solid tumors with KRAS mutation. The Group plans to submit the IND to NMPA in the fourth quarter of 2023.

#### **SIM0508 (Pol θ small molecule inhibitor)**

Pol θ is a DNA polymerase, whose mediation of MMEJ repair pathway is one of the important approaches for repairing DNA double strand breaks. When tumor cells experience homologous recombination repair deficiency (HRD), MMEJ, a major compensation pathway, is upregulated to help tumors escape from DNA damage and reduce the synthetic lethal effect of PARP inhibitor and HRD. Through the combined use of Pol θ inhibitor and PARP inhibitor, the repair pathways of single-chain recovery and double-chain compensation in HRD tumor cells can be inhibited at the same time, which will lead to the accumulation of a large amount of DNA damages and induce the death of tumor cells, thereby creating enhanced synergistic effects. As compared with other DDR targets, Pol θ inhibitors has relatively less impacts on normal cells. In addition, while Pol θ inhibitors can enhance efficacy when using in combination with PARP inhibitors, the possibility of creating additional safety risk is relatively lower. For patients with solid tumors of various HRDs, it is a new therapeutic strategy which is potentially effective and safe. The Group plans to submit the IND to NMPA and FDA in the first half of 2024.

## GENERIC PHARMACEUTICALS

For the six months ended June 30, 2023, the Group obtained additional approvals for three generic pharmaceuticals including bedaquiline fumarate tablets (0.1g (calculated by  $C_{32}H_{31}BrN_2O_2$ )), sevelamer carbonate tablets (0.8g) and posaconazole injection (16.7ml:0.3g) and one consistency evaluation application regarding Palonosetron Hydrochloride Injection (5ml:0.25mg (calculated by  $C_{19}H_{24}N_2O$ )). In addition, the supplemental application of Tofacitinib Citrate Tablets (5mg (calculated by  $C_{16}H_{20}N_6O$ )) for additional indication (active psoriatic arthritis) has been approved.

## INTELLECTUAL PROPERTY RIGHTS

Meanwhile, the Group attaches great importance to the protection of intellectual property rights. For the six months ended June 30, 2023, the Group had 158 new patent applications (including domestic and overseas unpublished patent applications), being 153 invention patents and five appearance design patents. As of June 30, 2023, the Group has accumulatively obtained 234 invention patents, 82 utility model patents and 21 appearance design patents.

## IMPACT OF COVID-19

Since January 8, 2023, COVID-19 has been formally categorised and treated by China as a “category B” infectious disease. In order to respond to the government’s objective of “safeguarding people’s health, preventing severe cases, take corresponding measures to protect people’s lives, safety and health and minimize the impacts of the pandemic on economic and social development to the greatest extent”, the Group made swift decisions to conduct R&D and successfully developed 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 put into production promptly after being conditionally approved to marketing on January 28, 2023 and successively supplied to various medical organizations. The change in the pandemic has not caused significant impacts on the Group’s business operation and financial condition. The Group’s liquidity of capital and adequacy of 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 pandemic (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 various 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, the Group will follow the applicable regulatory guidelines on clinical trials during the COVID-19 pandemic, strive to reduce delays and interruptions, and take relevant measures to minimize the pandemic’s impact.

## **PROSPECTS**

The Group will improve the market shares and accessibility of launched products through professional promotion and put emphasis on multi-channel development to benefit more patients in the current financial year. Besides, the Group will also promote the development and launch of innovative drugs with clinical values while strengthening the gradient of pipelines and evidence-based verification for products. The Group will continue to explore the registration and clinical trials of products in overseas markets in order to pursue global interests. The Group will pay attention to products with huge clinical demands, be synergistic and innovative as well as expedite business development and collaborations.

## **PROFIT ATTRIBUTABLE TO EQUITY SHAREHOLDERS OF THE COMPANY**

For the six months ended June 30, 2023, the Group recorded a profit attributable to equity shareholders of the Company of approximately RMB2,275 million, representing a significant increase from RMB64 million for the same period of 2022. Such change in profit attributable to equity shareholders of the Company was mainly attributable to the following items: (a) net realized and unrealized gains (before tax) on financial assets at fair value through profit or loss of approximately RMB1,149 million recorded for the six months ended June 30, 2023 due to the change in fair value of the investment portfolio held by the Group, including the change in fair value of the investment in the shares of 3D Medicines Inc. (“**3D Medicines**”), which is measured based on the closing price of the shares of 3D Medicines as of December 31, 2022 and June 30, 2023, while the net realized and unrealized losses (before tax) on financial assets at fair value through profit or loss recorded for the same period of 2022 was approximately RMB331 million; (b) one-off gain (before tax) of approximately RMB789 million recorded by the Group from the disposal of interest in subsidiaries in the first half of 2023; and (c) a certain extent of negative impact on the Company’s gross profit margin in the first half of 2023 caused by the change in the sales structure of innovative pharmaceuticals portfolio.

## **LIQUIDITY AND FINANCIAL RESOURCES**

The Group maintained a sound financial position. As of June 30, 2023, the Group had cash and cash equivalents of approximately RMB2,446 million (as of December 31, 2022: approximately RMB1,658 million), time deposits of approximately RMB11 million (as of December 31, 2022: approximately RMB975 million). As of June 30, 2023, the Group had a balance of bank loans of approximately RMB910 million (as of December 31, 2022: approximately RMB1,292 million), of which approximately RMB460 million (as of December 31, 2022: approximately RMB1,292 million) would mature within one year and approximately RMB450 million (as of December 31, 2022: nil) would mature after one year but within two years. As of June 30, 2023, all of the Group’s bank loan balances bore interest at fixed rates, and the effective interest rate range for these loans was 1.0% to 2.70% per annum. As of June 30, 2023, the gearing ratio of the Group (calculated as total liabilities divided by total assets) was approximately 28.7% (as of December 31, 2022: approximately 33.7%).

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 under the centralized management.

The assets and liabilities of the Group were denominated in RMB, USD, GBP and HKD. During the Reporting Period, the Group did not employ any financial derivative instrument or enter into any foreign derivative contract to hedge against foreign exchange risk. However, the Group managed the foreign exchange risk by closely monitoring the net exposure of foreign exchange risk, so as to minimize the impact of foreign exchange fluctuations.

### **PLEDGE OF GROUP'S ASSETS**

As of June 30, 2023, the Group pledged bills receivable of approximately RMB169 million for issuance of bank acceptance bills and pledged bank deposits of approximately RMB18 million for issuance of letter of guarantee. Save as disclosed above, as of June 30, 2023, none of the Group's assets were pledged.

### **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. As of the date of this announcement, this claim is still at an early stage. Based on the legal advice and available evidences, the Directors do not believe it probable that the court will find against the Company. No provision has therefore been made in respect of this claim.

Save as disclosed above, as of June 30, 2023, the Group had no other contingent liabilities.

### **SIGNIFICANT INVESTMENTS HELD**

As of June 30, 2023, the Company had a significant investment in 3D Medicines, with a value of 5% or more of the Company's total assets.

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 June 30, 2023, the total investment amount of the Company in 3D Medicines amounted to USD40.0 million, with 23,047,468 shares of 3D Medicines held by the Company, representing 9.00% of the total issued share capital of 3D Medicines. As of June 30, 2023, the fair value of the Company's interests in 3D Medicines amounted to approximately RMB2,055 million, representing approximately 16.2% of the total assets of the Group as of June 30, 2023.

For the six months ended June 30, 2023, the unrealised gain recognised on the Company's investment in 3D Medicines amounted to approximately RMB1,134 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 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 June 30, 2023, the Group did not have any other future plans for material investments and capital assets.

#### **MATERIAL ACQUISITIONS AND DISPOSALS**

During the six months ended June 30, 2023, the Group had no material acquisition or disposal of subsidiaries, associates or joint ventures.

#### **EMPLOYEES AND REMUNERATION POLICY**

As of June 30, 2023, the Group had a total of 7,661 full-time employees. The Group attached great importance to the recruitment, training and retention of outstanding employees, maintaining 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 Directors and senior management who worked full time for the Company shall be determined by the remuneration and appraisal committee of the Company under the Board with reference to the principal duties, the results of performance assessment as well as the remuneration level in the market of the relevant managerial positions. During the six months ended June 30, 2023, staff costs of the Group (including emoluments, social insurance and other benefits of the Directors) amounted to approximately RMB1,252 million. The Group established Simcere Institute, which provides 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 adopted a restricted share unit scheme on May 20, 2021 (the “**2021 RSU Scheme**”). The purposes of the 2021 RSU Scheme are to (i) incentivize the existing and incoming directors, senior management and employees for their contribution to the Group; and (ii) 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. The 2021 RSU Scheme shall be valid and effective for a period of ten (10) years commencing from the date of adoption. In light of the amended Chapter 17 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “**Listing Rules**”) taking into effect from January 1, 2023, the Company has amended the 2021 RSU Scheme and adopted the scheme mandate limit (as defined in the Listing Rules) of the 2021 RSU Scheme, which were approved at the annual general meeting of the Company held on June 15, 2023. For details of the amendments to the 2021 RSU Scheme, please refer to the announcements and circular of the Company dated March 31, 2023, May 25, 2023 and June 15, 2023, respectively.

During the Reporting Period, the Board resolved on June 28, 2023 to grant an aggregate of 4,378,000 RSUs, representing 4,378,000 underlying Shares, to an aggregate of 59 eligible participants, who are employees of the Group, under the 2021 RSU Scheme at nil consideration. For details of such grant, please refer to the announcement of Company dated June 28, 2023. The number of Shares available for grant under the scheme mandate limit of the 2021 RSU Scheme was 262,026,561 as of June 30, 2023.

#### **INTERIM DIVIDEND**

The Board resolved not to declare any interim dividend for the six months ended June 30, 2023.

#### **USE OF PROCEEDS FROM THE LISTING**

The net proceeds from the initial public offering of the shares of the Company (the “**Shares**”) 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 to approximately HK\$3,513.09 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 June 30, 2023 and the expected timeline for utilization:

Purpose	Percentage of the total amount	Actual amount of the Net Proceeds (HK\$ in million)	Amount of the Net Proceeds utilized during the six months ended June 30, 2023 (HK\$ in million)	Accumulated amount of the Net Proceeds utilized as of June 30, 2023 (HK\$ in million)	Amount of the Net Proceeds unutilized as of June 30, 2023 (HK\$ in million)	Expected timeline for utilization
Continuous research and development of the Group's selected product candidates in its strategically focused therapeutic areas	60%	2,107.85	258.92	1,455.83	652.02	The actual Net Proceeds are expected to be fully utilized by 2027.
Reinforcement of the Group's sales and marketing capabilities	10%	351.31	–	351.31	–	The actual Net Proceeds have been fully utilized.
Investment in companies in the pharmaceutical or biotechnology sector	10%	351.31	–	351.31	–	The actual Net Proceeds have been fully utilized.
Repayment of certain of the Group's outstanding bank loans	10%	351.31	–	351.31	–	The actual Net Proceeds have been fully utilized.
Working capital and other general corporate purpose	10%	351.31	–	351.31	–	The actual Net Proceeds have been fully utilized.
<b>Total</b>	<b>100%</b>	<b>3,513.09</b>	<b>258.92</b>	<b>2,861.07</b>	<b>652.02</b>	

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 Micelles 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 candidates 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 relevant 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 June 30, 2023, the Net Proceeds utilized was approximately HK\$2,861.07 million and the Net Proceeds unutilized was approximately HK\$652.02 million. The Company intends to apply the unutilized Net Proceeds as of June 30, 2023 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

The Directors have been granted a general mandate by the shareholders of the Company (the “Shareholders”) at the annual general meeting of the Company held on June 15, 2023 (the “2022 AGM”) to repurchase up to 266,404,561 Shares on the Stock Exchange (the “Repurchase Mandate”), representing 10% of the total number of issued Shares as at the date of the 2022 AGM. During the Reporting Period, the Company repurchased a total of 7,043,000 Shares on the Stock Exchange pursuant to the Repurchase Mandate at a total consideration (excluding expenses) of HK\$53,079,460.00 (the “Share Repurchase”), which was funded by internal resources of the Company. As of the date of this announcement, 7,043,000 Shares repurchased by the Company during the Reporting Period have not been cancelled. Details of the Shares repurchased by the Company during the Reporting Period are as follows:

Month of Share repurchase	Total number of Shares repurchased	The highest purchase price per Share (HK\$)	The lowest purchase price per Share (HK\$)	Total consideration (excluding expenses) (HK\$)
June 2023	<u>7,043,000</u>	7.77	7.20	<u>53,079,460.00</u>
<b>Total</b>	<u>7,043,000</u>	–	–	<u>53,079,460.00</u>

The Board believes that the Share Repurchase demonstrates the Company's confidence in its own business outlook and prospects and would, ultimately, benefit the Company and create value to the Shareholders. In addition, the Board believes that the current financial resources of the Company enables it to implement the Share Repurchase while maintaining a solid financial position.

Save as disclosed above, during the Reporting Period, neither the Company nor any of its subsidiaries had purchased, sold or redeemed any of the Company's listed securities.

### IMPORTANT EVENTS AFTER THE REPORTING PERIOD

After the Reporting Period and up to the date of this announcement, there were no material events affecting the Company or any of its subsidiaries.

## 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 strength 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 Listing Rules.

Save as disclosed below, the Group has complied with the code provisions contained in the CG Code during the Reporting Period.

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 June 30, 2023, the roles of chairman of the Board (the "**Chairman**") and chief executive officer of the Company (the "**Chief Executive Officer**") were not separated and Mr. REN Jinsheng ("**Mr. REN**") currently performs these two roles. Mr. REN is the founder of the Group, the Chairman and the Chief Executive Officer. He has been primarily responsible for 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 and the Chief Executive Officer 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, 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, given that: (i) any decision to be made by the Board requires approval by at least a majority of the Directors; (ii) Mr. REN and other Directors are aware of and undertake to fulfill their fiduciary duties as the 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) as of the date of this announcement, 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 (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, all the Directors confirmed that they have strictly complied with the Model Code during the Reporting Period.

## **AUDIT COMMITTEE AND REVIEW OF FINANCIAL INFORMATION**

The Group established the Audit Committee with written terms of reference in compliance with the CG Code. As at the date of this announcement, the Audit Committee consists of three 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, who 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 the 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, 2023, 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, 2023 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](http://www.hkexnews.hk)) as well as the website of the Group ([www.simcere.com](http://www.simcere.com)). The Group’s 2023 interim report will be dispatched to the Shareholders and will be published on the aforementioned websites in due course.

# **CONSOLIDATED STATEMENT OF PROFIT OR LOSS**

*For the six months ended June 30, 2023 – unaudited*

		<b>Six months ended June 30,</b>	
	<i>Note</i>	<b>2023</b>	<b>2022</b>
		<b>RMB'000</b>	<b>RMB'000</b>
<b>Revenue</b>	<b>4</b>	<b>3,379,329</b>	2,699,650
Cost of sales		<u>(818,029)</u>	<u>(557,371)</u>
<b>Gross profit</b>		<b>2,561,300</b>	2,142,279
Other income	5(a)	<b>76,446</b>	87,131
Other net gain/(loss)	5(b)	<b>1,953,152</b>	(338,979)
Research and development costs		<b>(775,892)</b>	(651,537)
Selling and distribution expenses		<b>(1,247,302)</b>	(1,029,335)
Administrative and other operating expenses		<b>(256,634)</b>	(188,481)
Reversals of impairment loss on trade and other receivables		<u><b>939</b></u>	<u>20,033</u>
<b>Profit from operations</b>		<b>2,312,009</b>	41,111
Finance income	6(a)	<b>30,936</b>	30,260
Finance costs	6(a)	<u><b>(18,155)</b></u>	<u>(18,514)</u>
Net finance income		<b>12,781</b>	11,746
Share of loss of an associate		<b>(793)</b>	(387)
Share of profits of joint ventures		<u><b>1,186</b></u>	<u>53</u>

**CONSOLIDATED STATEMENT OF PROFIT OR LOSS (CONTINUED)***For the six months ended June 30, 2023 – unaudited*

	<i>Note</i>	<b>Six months ended June 30,</b>	
		<b>2023</b>	<b>2022</b>
		<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
<b>Profit before taxation</b>	<b>6</b>	<b>2,325,183</b>	<b>52,523</b>
Income tax	7	<u>(51,346)</u>	<u>9,398</u>
<b>Profit for the period</b>		<b><u>2,273,837</u></b>	<b><u>61,921</u></b>
<b>Attributable to:</b>			
Equity shareholders of the Company		<b>2,274,648</b>	63,784
Non-controlling interest		<u>(811)</u>	<u>(1,863)</u>
<b>Profit for the period</b>		<b><u>2,273,837</u></b>	<b><u>61,921</u></b>
<b>Earnings per share</b>	<b>8</b>		
Basic (RMB)		<u><b>0.87</b></u>	<u>0.02</u>
Diluted (RMB)		<u><b>0.86</b></u>	<u>0.02</u>

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

*For the six months ended June 30, 2023 – unaudited*

	<b>Six months ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
	<b>RMB'000</b>	<b>RMB'000</b>
<b>Profit for the period</b>	<b>2,273,837</b>	<b>61,921</b>
<b>Other comprehensive income for the period</b> <b>(after tax adjustments)</b>		
<i>Items that will not be reclassified to profit or loss:</i>		
Financial assets at fair value through other comprehensive income (FVOCI) – net movement in fair value reserves (non-recycling), net of tax	(5,159)	(124,652)
Exchange difference on translation of financial statements	71,534	71,589
<b>Other comprehensive income for the period</b>	<b>66,375</b>	<b>(53,063)</b>
<b>Total comprehensive income for the period</b>	<b>2,340,212</b>	<b>8,858</b>
<b>Attributable to:</b>		
Equity shareholders of the Company	2,341,023	10,721
Non-controlling interest	(811)	(1,863)
<b>Total comprehensive income for the period</b>	<b>2,340,212</b>	<b>8,858</b>



# **CONSOLIDATED STATEMENT OF FINANCIAL POSITION**

*As at June 30, 2023 – unaudited*

	<i>Note</i>	<b>June 30, 2023 RMB'000</b>	<b>December 31, 2022 RMB'000</b>
<b>Non-current assets</b>			
Property, plant and equipment		<b>2,142,785</b>	2,135,781
Intangible assets		<b>544,224</b>	379,896
Goodwill		<b>142,474</b>	172,788
Interest in an associate		<b>4,186</b>	4,978
Interest in joint ventures		<b>96,663</b>	4,477
Prepayments, deposits and other receivables	<i>10</i>	<b>62,513</b>	97,470
Financial assets at fair value through other comprehensive income		<b>131,690</b>	137,774
Financial assets at fair value through profit or loss		<b>3,321,161</b>	2,056,700
Time deposits	<i>11(c)</i>	<b>–</b>	10,752
Deferred tax assets		<b>354,429</b>	326,713
		<b>6,800,125</b>	5,327,329
<b>Current assets</b>			
Inventories		<b>673,442</b>	302,373
Trade and bills receivables	<i>9</i>	<b>2,387,761</b>	2,337,443
Prepayments, deposits and other receivables	<i>10</i>	<b>333,835</b>	165,698
Taxation recoverable		<b>–</b>	6,506
Pledged deposits	<i>11(b)</i>	<b>18,126</b>	560
Restricted deposits	<i>11(b)</i>	<b>19,106</b>	19,378
Time deposits	<i>11(c)</i>	<b>10,943</b>	964,226
Cash and cash equivalents	<i>11(a)</i>	<b>2,446,295</b>	1,657,600
		<b>5,889,508</b>	5,453,784

# **CONSOLIDATED STATEMENT OF FINANCIAL POSITION (CONTINUED)**

*As at June 30, 2023 – unaudited*

	<i>Note</i>	<b>June 30, 2023 RMB'000</b>	<b>December 31, 2022 RMB'000</b>
<b>Current liabilities</b>			
Bank loans	12	459,553	1,292,067
Lease liabilities		78,125	58,756
Trade and bills payables	13	457,191	334,444
Other payables and accruals	14	1,467,027	1,267,899
Taxation payable		43,374	10,562
		<u>2,505,270</u>	<u>2,963,728</u>
<b>Net current assets</b>		<u>3,384,238</u>	<u>2,490,056</u>
<b>Total assets less current liabilities</b>		<u>10,184,363</u>	<u>7,817,385</u>
<b>Non-current liabilities</b>			
Bank loans	12	450,000	–
Lease liabilities		168,723	155,921
Deferred income		382,941	403,350
Deferred tax liabilities		129,451	115,291
		<u>1,131,115</u>	<u>674,562</u>
<b>NET ASSETS</b>		<u>9,053,248</u>	<u>7,142,823</u>
<b>CAPITAL AND RESERVES</b>			
Share capital		3,094,608	3,081,131
Reserves		5,958,640	4,045,630
<b>Total equity attributable to equity shareholders of the Company</b>		<u>9,053,248</u>	<u>7,126,761</u>
<b>Non-controlling interest</b>		<u>–</u>	<u>16,062</u>
<b>TOTAL EQUITY</b>		<u>9,053,248</u>	<u>7,142,823</u>

# NOTES TO THE UNAUDITED INTERIM FINANCIAL REPORT

(Expressed in Renminbi)

## 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, 2023.

The 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, *Interim financial reporting*, 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 2022 annual financial statements, except for the accounting policy changes that are expected to be reflected in the 2023 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.

The 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 2022 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 December 31, 2022 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 December 31, 2022 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 the interim financial report for the current accounting period:

- HKAS 17, *Insurance contracts*
- Amendments to HKAS 8, *Accounting policies, changes in accounting estimates and errors: Definition of accounting estimates*
- Amendments to HKAS 12, *Income taxes: Deferred tax related to assets and liabilities arising from a single transaction*
- Amendments to HKAS 12, *Income taxes: International tax reform – Pillar Two model rules*

In July 2023, the HKICPA published “Accounting implications of the abolition of the MPF-LSP offsetting mechanism in Hong Kong” that provides guidance on the accounting considerations relating to the offsetting mechanism and the abolition of the mechanism.

Apart from the impacts of the adoption of the new and amended HKFRSs discussed below, 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 the interim financial report. The Group has not applied any new standard or interpretation that is not yet effective for the current accounting period.

#### *Amendments to HKAS 12, Income taxes: Deferred tax related to assets and liabilities arising from a single transaction*

The amendments narrow the scope of the initial recognition exemption such that it does not apply to transactions that give rise to equal and offsetting temporary differences on initial recognition such as leases and decommissioning liabilities. For leases and decommissioning liabilities, the associated deferred tax assets and liabilities are required to be recognised from the beginning of the earliest comparative period presented, with any cumulative effect recognised as an adjustment to retained earnings or other components of equity at that date. For all other transactions, the amendments are applied to those transactions that occur after the beginning of the earliest period presented.

Prior to the amendments, the Group did not apply the initial recognition exemption to lease transactions and had recognised the related deferred tax, except that the Group previously determined the temporary difference arising from a right-of-use asset and the related lease liability on a net basis on the basis they arise from a single transaction. Following the amendments, the Group has determined the temporary differences in relation to right-of-use assets and lease liabilities separately. The change primarily impacts disclosures of components of deferred tax assets and liabilities in the annual financial statements, but does not impact the overall deferred tax balances presented in the consolidated statement of financial position as the related deferred tax balances qualify for offsetting under HKAS 12.

#### 4 REVENUE AND SEGMENT REPORTING

##### (a) Revenue

###### *Disaggregation of revenue*

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

	Six months ended June 30,	
	2023	2022
	RMB'000	RMB'000
<b>Revenue from contracts with customers within the scope of HKFRS 15</b>		
Sales of pharmaceutical products	3,060,125	2,436,754
Promotion service income	319,204	262,896
	<u>3,379,329</u>	<u>2,699,650</u>

The Group's revenue from contracts with customers was recognized at point in time for the six months ended June 30, 2023.

##### (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 INCOME AND OTHER NET GAIN/(LOSS)

### (a) Other income

	Six months ended June 30,	
	2023	2022
	RMB'000	RMB'000
Government grants	59,844	67,394
Rental income	4,517	8,835
Property management income	5,436	2,685
Consulting and technology service income	1,754	4,253
Others	4,895	3,964
	<u>76,446</u>	<u>87,131</u>

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

	Six months ended June 30,	
	2023	2022
	RMB'000	RMB'000
Net foreign exchange gain/(loss)	14,279	(8,318)
Net gain/(loss) on disposal of property, plant and equipment	582	(2)
Net realized and unrealized gain/(loss) on financial assets at fair value through profit or loss	1,148,800	(330,659)
Net gain on disposal of interest in subsidiaries (Note)	789,491	—
	<u>1,953,152</u>	<u>(338,979)</u>

#### Note:

On February 24, 2023, the Group entered into an agreement with a third party to dispose its 50% equity interest in BCY Pharm Co., Ltd. (“BCY”), one of its controlled subsidiaries, at consideration of RMB200,000,000. Upon the completion of the disposal in March 2023, the Group lost its control on BCY and recognized the remaining 13.57% equity interest in BCY, which amounted to RMB54,150,000, as a financial asset measured at fair value through profit or loss. The net gain on disposal of interest in BCY was RMB197,222,000.

On April 13, 2023, the Group entered into an agreement with a third party to dispose its total equity interest in Simcere (Shanghai) Pharmaceutical Co., Ltd. (“Sincere (Shanghai)”) at consideration of RMB926,865,000. The disposal was completed in May 2023. The net gain on disposal of interest in Simcere (Shanghai) was RMB592,269,000.

## 6 PROFIT BEFORE TAXATION

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

### (a) Net finance income

	Six months ended June 30,	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Interest income from bank deposits	<u>(30,936)</u>	<u>(30,260)</u>
Finance income	<u>(30,936)</u>	<u>(30,260)</u>
Interest expenses on bank loans	14,546	15,846
Interest expenses on lease liabilities	<u>3,609</u>	<u>2,668</u>
Finance costs	<u>18,155</u>	<u>18,514</u>
Net finance income	<u>(12,781)</u>	<u>(11,746)</u>

### (b) Other items

	Six months ended June 30,	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Depreciation charge		
– owned property, plant and equipment	109,129	104,480
– right-of-use assets	36,048	21,308
Amortization of intangible assets	5,428	8,362
Provision for write-down of inventories	<u>3,163</u>	<u>13,349</u>

## 7 INCOME TAX

Taxation in the consolidated statements of profit or loss represents:

	Six months ended June 30,	
	2023	2022
	RMB'000	RMB'000
<b>Current tax</b>		
<i>PRC Corporate Income Tax</i>		
Provision for the period	52,706	12,686
Over – provision in respect of prior years	(4,927)	(13,493)
	<u>47,779</u>	<u>(807)</u>
<i>Overseas Corporate Income Tax</i>		
Provision for the period	1,928	–
<b>Deferred tax</b>		
Origination and reversal of temporary differences	<u>1,639</u>	<u>(8,591)</u>
<b>Total income tax</b>	<u>51,346</u>	<u>(9,398)</u>

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.

Taxation for overseas subsidiaries is similarly calculated using the estimated annual effective rates of taxation that are expected to be applicable in the relevant countries.

## 8 EARNINGS PER SHARE

### (a) Basic earnings per share

The calculation of basic earnings per share is based on the profit attributable to ordinary equity shareholders of the Company of RMB2,274,648,000 (six months ended June 30, 2022: RMB63,784,000) and the weighted average of 2,618,949,497 ordinary shares (six months ended June 30, 2022: 2,608,641,618 ordinary shares) in issue during the interim period.

### (b) Diluted earnings per share

The calculation of diluted earnings per share is based on the profit attributable to ordinary equity shareholders of the Company of RMB2,274,648,000 (six months ended June 30, 2022: RMB63,784,000) and the weighted average of 2,629,759,497 ordinary shares (six months ended June 30, 2022: 2,618,372,285 shares).



**9 TRADE AND BILLS RECEIVABLES**

	<b>June 30, 2023 RMB'000</b>	<b>December 31, 2022 RMB'000</b>
Trade receivables	<b>1,994,820</b>	1,871,314
Bills receivable	<b>416,184</b>	490,804
	<b>2,411,004</b>	2,362,118
Less: loss allowance	<b>(23,243)</b>	(24,675)
	<b>2,387,761</b>	2,337,443

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

As at June 30, 2023, bills receivable of RMB168,998,000 were pledged for issuance of bills payable (2022: RMB115,465,000).

**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:

	<b>June 30, 2023 RMB'000</b>	<b>December 31, 2022 RMB'000</b>
Within 3 months	<b>2,052,938</b>	1,818,648
Over 3 months but within 12 months	<b>334,095</b>	518,145
Over 12 months	<b>728</b>	650
	<b>2,387,761</b>	2,337,443

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

**10 PREPAYMENTS, DEPOSITS AND OTHER RECEIVABLES**

	<b>June 30, 2023 RMB'000</b>	<b>December 31, 2022 RMB'000</b>
<b>Current</b>		
Prepayments for raw materials and expenses	<b>152,217</b>	66,789
Value added tax recoverable	<b>61,876</b>	33,608
Other deposits and receivables	<b>120,545</b>	65,611
	<b>334,638</b>	166,008
Less: loss allowance	<b>(803)</b>	(310)
	<b>333,835</b>	165,698
<b>Non-current</b>		
Prepayments for property, plant and equipment	<b>41,829</b>	36,129
Deposits for investment	<b>–</b>	43,680
Other deposits and receivables	<b>20,684</b>	17,661
	<b>62,513</b>	97,470

All of prepayments, deposits and other receivables current balances are expected to be recovered or recognized as expense within one year.

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

## (a) Cash and cash equivalents comprise:

	June 30, 2023 RMB'000	December 31, 2022 RMB'000
Cash at bank	<u>2,446,295</u>	<u>1,657,600</u>

As of the end of the reporting period, cash and cash equivalents situated in Chinese Mainland amounted to RMB2,348,500,000 (2022: RMB1,495,666,000). Remittance of funds out of Chinese Mainland is subject to relevant rules and regulations of foreign exchange control.

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

	June 30, 2023 RMB'000	December 31, 2022 RMB'000
Pledged deposits for		
– issuance of letter of guarantee	<u>18,126</u>	<u>560</u>

	June 30, 2023 RMB'000	December 31, 2022 RMB'000
Restricted deposits for		
– 2021 RSU Scheme	6,642	5,943
– research and development projects	<u>12,464</u>	<u>13,435</u>
	<u>19,106</u>	<u>19,378</u>

## (c) Time deposits:

	June 30, 2023 RMB'000	December 31, 2022 RMB'000
Current portion	10,943	964,226
Non-current portion	<u>–</u>	<u>10,752</u>
	<u>10,943</u>	<u>974,978</u>

## 12 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, 2023 RMB'000	December 31, 2022 RMB'000
Short-term bank loans	449,834	1,183,700
Current portion of long-term bank loans	9,719	108,367
Within 1 year or on demand	459,553	1,292,067
After 1 year but within 2 years	450,000	—
	909,553	1,292,067

The bank loans were secured as follows:

	June 30, 2023 RMB'000	December 31, 2022 RMB'000
Bank loans		
– Unsecured	909,553	1,292,067

## 13 TRADE AND BILLS PAYABLES

	June 30, 2023 RMB'000	December 31, 2022 RMB'000
Trade payables	301,933	226,159
Bills payable	155,258	108,285
	457,191	334,444

**13 TRADE AND BILLS PAYABLES (CONTINUED)**

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

	<b>June 30, 2023 RMB'000</b>	December 31, 2022 RMB'000
Within 3 months	355,951	239,712
3 to 12 months	100,187	93,289
Over 12 months	1,053	1,443
	<u>457,191</u>	<u>334,444</u>

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

**14 OTHER PAYABLES AND ACCRUALS**

	<b>June 30, 2023 RMB'000</b>	December 31, 2022 RMB'000
Accrued expenses ( <i>Note i</i> )	448,171	583,739
Contract liabilities ( <i>Note ii</i> )	24,103	63,338
Payable for employee reimbursements	16,211	28,884
Payables for staff related costs	320,642	335,384
Payables for purchase of property, plant and equipment	18,368	21,877
Dividends payable	419,218	–
Other tax payables	132,959	133,859
Payables for research and development	31,780	41,695
Others	55,575	59,123
	<u>1,467,027</u>	<u>1,267,899</u>

*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.

## 15 DIVIDENDS

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

	<b>Six months ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
	<b>RMB'000</b>	<b>RMB'000</b>
Dividends in respect of previous financial years declared and approved during the interim period, RMB0.16 per share (six months ended June 30, 2022: RMB0.15 per share)	<b>426,247</b>	397,036
Less: Dividends attributable to unvested shares under 2021 RSU scheme	<b>(7,029)</b>	(5,740)
	<b>419,218</b>	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, 2022).

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

Hong Kong, August 21, 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.*