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# **CSPC PHARMACEUTICAL GROUP LIMITED**

石藥集團有限公司

(Incorporated in Hong Kong with limited liability) (Stock code: 1093)

# ANNUAL RESULTS FOR THE YEAR ENDED 31 DECEMBER 2022

FINANCIAL HIGHLIGHTS			
(in RMB'000, unless otherwise stated)	2022	2021	Change
Revenue by business units:			
Finished drugs	24,520,067	22,681,444	+8.1%
Bulk products	4,450,936	3,819,209	+16.5%
Functional food and others	1,965,901	1,366,217	+43.9%
Total revenue	30,936,904	27,866,870	+11.0%
Profit attributable to shareholders			
As reported	6,091,390	5,605,185	+8.7%
Underlying profit (Note)	6,105,725	5,417,900	+12.7%
Earnings per share (RMB cents)			
Basic	51.11	46.89	+9.0%
Diluted	51.11	46.89	+9.0%
Final dividend per share (HK cents)	11.00	10.00	+10.0%
Full-year dividend per share (HK cents)	21.00	18.00	+16.7%

Note: Underlying profit attributable to shareholders, a non-HKFRS measure, represents profit before taking into account fair value gain on financial assets measured at fair value through profit or loss, employee sharebased compensation expense, gains on deemed disposal of partial interest in an associate and a joint venture and gain on disposal of a joint venture. Reconciliation between the reported and underlying profit is provided on pages 21 and 22 of this announcement.

#### **CHAIRMAN'S STATEMENT**

#### RESULTS

For the financial year ended 31 December 2022, the revenue of the Group grew by 11.0% to RMB30,937 million, and profit attributable to shareholders increased by 8.7% to RMB6,091 million. Basic earnings per share increased similarly to RMB51.11 cents.

The Group's underlying profit attributable to shareholders, excluding fair value gain on financial assets measured at fair value through profit or loss ("FVTPL"), employee share-based compensation expense, gains on deemed disposal of partial interest in an associate and a joint venture and gain on disposal of a joint venture, amounted to RMB6,106 million, an increase of 12.7% as compared to 2021.

#### DIVIDEND

The Board of Directors recommended a final dividend of HK11 cents per share for 2022. Subject to the approval of shareholders at the forthcoming annual general meeting, the proposed final dividend will be paid on 28 June 2023 to shareholders whose names appear on the register of members on 9 June 2023. Together with an interim dividend of HK10 cents per share, the full-year dividend for 2022 amounted to HK21 cents per share, an increase of 16.7% as compared to 2021.

#### **INDUSTRY REVIEW**

In 2022, amid the continuous disruption from the Covid-19 pandemic and adjustments in the prevention and control policies, the whole industry faced unprecedented difficulties and challenges and business operations were affected to a certain extent. With the continuous mutation of the virus, wave after wave of infection peaks have occurred. On the other hand, the industry has made encouraging development in its fight against the coronavirus. The mRNA technology has shown its advantages in the development of vaccines against mutant strains. The pandemic has become the catalyst for driving the industry into an era of nucleic acid drugs. The Group seized the opportunity and actively developed the nucleic acid drug platform, establishing a solid technology foundation for the long-term development in the future.

With the policies of drug approval, volume-based procurement and medical insurance gradually becoming more mature, China's pharmaceutical ecosystem is entering a positive cycle. The "14th Five-Year Plan for the Development of Pharmaceutical Industry" sets out the specific development goals of the pharmaceutical industry and establishes the development direction of innovation-driven transformation and upgrade of industry chain quality in the next five years. The positive driving force of the industry will promote the optimisation and integration as well as high-quality development of the industry. Large-scale pharmaceutical companies with integrated advantages in research and development, production and sales will benefit from the industry's integration and upgrade and continue to thrive.

Following the lifting of Covid-19 pandemic prevention and control measures, China has entered the postpandemic era with the economy and daily life gradually returning to normal. With the revival of medical services provision and growth driver supported by innovation, the industry will embrace the recovery and development opportunities in the post-pandemic era.

# **BUSINESS REVIEW**

2022 was a year full of challenges and uncertainties. Pandemic, macroeconomy and international environment changes have all brought new requirements and challenges to the industry. Based on the development needs of the Group, the board of directors has put forward an operation strategy of "strong innovation, strong team, strong management and stable growth". With the ongoing enhancement of "innovation, team and management" and the efforts of all employees, the Group achieved the goal of "stable growth" and delivered satisfactory results.

The finished drug business maintained steady growth in 2022, with a continued increase in contribution from new products. Duoenda (mitoxantrone hydrochloride liposome injection), a globally exclusive innovative formulation drug, and Copiktra (duvelisib capsules), the first approved PI3K inhibitor in China, were commercially launched in January and November, respectively. Moreover, a number of newly launched generic drugs were selected at national volume-based procurements with rapid sales ramp-up. These new products brought in new sales contribution as well as a more balanced product portfolio to our business. In March 2023, COVID-19 mRNA vaccine (SYS6006) has been included for emergency use in China for the prevention of COVID-19 caused by the infection of SARS-CoV-2.

The clinical development of the Group's innovative drugs were progressing according to plan. Research and development efficiency continued to improve, the number of patients enrolled in clinical studies has exceeded that of 2021. Among the new drugs under development, over 50 are in clinical stage, of which 9 have filed application for marketing approval and 16 are in pivotal clinical trial stage. The Group has established various innovative research and development platforms, covering small molecules, large molecules, nano-formulation, antibody-drug conjugates (ADC), mRNA vaccines and siRNA drugs, providing a solid foundation for the Group's innovative research and development. Among them, the nano-formulation technology platform has established a leading position in the world. It has successfully developed 4 key nano-formulation drugs, and its current pipeline of drug candidates has more than 5 key products with global patents and great market potential.

The Group has also made good progress in its business development initiative with two projects of product license-in and acquisition completed. With support from the Group's strong capabilities in clinical development, registration and commercialisation, they will bring new momentum to the future growth. Moreover, two projects of license-out have been completed, both of which are globally competitive self-developed innovative ADC drug candidates of the Group, marking the global recognition of the Group's innovation capabilities and an important milestone for the expansion of the Group's self-developed innovative products into the overseas market.

CSPC attaches great importance to the improvement of our ESG standard and is committed to creating a green, harmonious and sustainable development path, improving corporate governance and actively giving back to society. In the most recent ESG rating of MSCI in 2022, the rating of the Company remains at A.

# OUTLOOK

2023 is the first year of fully implementing the spirit of the 20th National Congress of the Communist Party of China and a crucial year for the implementation of the "14th Five-Year Plan". It is also the year for the Group to strive for strong innovation, strong team, strong management and stable growth under the guidance of China's national policies. The Group will actively seize the opportunities from policy and adhere to the strategy of innovation and globalization, aiming to become an innovative pharmaceutical company with international influence.

#### Innovation

With the adoption of clinical value-oriented approach, we will continue to develop new therapeutic targets, new technology platforms and increase investment in R&D to ensure that the Group's competitive advantage remains industry-leading. Other than product innovation, we will accelerate management innovation and culture innovation to support the comprehensive needs for the Group's growth.

- Rapidly advance the drugs under development to pivotal clinical trial stage and strive to launch more drugs in order to achieve realization of results, and focus on major therapeutic areas and development of products for major indications to enhance product value.
- (ii) Focus on cutting-edge technology, combine independent innovation and licensing-in, and attain differentiated competition. Currently, drug research and development has rapidly expanded to nucleic acid drugs. The Group will make use of its existing nanodrug platform to break through the bottleneck in nucleic acid drug technology and establish a leading position in nano-delivery technology and nucleic acid drugs. At the same time, we will also target emerging technologies such as gene therapy and cell therapy, and develop cutting-edge technologies such as in vivo reprogramming of immune cells. The Group will further integrate internal resources to develop new CAR-T cell therapies.
- (iii) Strengthen the overseas research and development ("R&D") team, select projects with competitive edge for overseas development, and accelerate the approval and marketing of key innovative drugs in the U.S. and other overseas markets with new and unique development paths.

#### **Business development**

Apart from the efforts to ensure rapid development of our in-house pipelines, we will also focus on raising our business development (BD) capabilities and building an internationalised BD team and ecosystem. We will actively look for global cooperation opportunities with the aim of supplementing our product pipelines, expanding therapeutic areas and indications, and introducing cutting-edge technology platforms. We will also strengthen cooperation with European and U.S. funds focused on biotechnology/medicine to link up the Chinese market with overseas first-in-class (FIC) and best-in-class (BIC) projects. Moreover, we will strengthen the out-licensing of our in-house developed innovative products in order to develop the international market with overseas partners and achieve win-win results.

#### Internationalisation

The Group will continue to step up its efforts in internationalisation in the areas of R&D, business development and commercialization. Other than striving to enhance the R&D capabilities of our overseas R&D centres, we will also strengthen cooperation with overseas pharmaceutical enterprises and increase the contribution of overseas businesses, so as to improve the Group's competitiveness and industry position on the international stage.

#### APPRECIATION

I would like to take this opportunity to express my gratitude to all staff for their dedication and diligence, and to all our shareholders, business partners and customers for their continued support.

CAI Dongchen Chairman

22 March 2023

#### MANAGEMENT DISCUSSION AND ANALYSIS

#### **OVERVIEW**

The Group is an innovation-driven pharmaceutical enterprise with integrated R&D, manufacture and sales capabilities. With the corporate mission of "All for Better Medicines, All for a Healthier World", the Group is committed to developing innovative products to address unmet clinical needs and provide innovative therapies for patients.

The Group has built an internationalised R&D team with more than 2,000 members and five key R&D centres in Shijiazhuang, Shanghai, Beijing and the U.S., focusing on six key therapeutic areas of oncology, psychiatry and neurology, cardiovascular, immunology and respiratory, digestion and metabolism, and anti-infectives. Eight innovative technology R&D platforms have been established encompassing nano-formulation, mRNA, siRNA, monoclonal antibody, bispecific antibody and ADC, and the continuous investment will provide strong support for the research and development of innovative drugs. The Group is also actively involved in the prevention and treatment of Covid-19, with one mRNA vaccine and two therapeutic drugs approved to commence clinical trials in 2022, striving to provide vaccines and drugs for the prevention and control of the pandemic, help address the concerns of the country and alleviate difficulties for the people. Among them, the mRNA vaccine with broad-spectrum protection against variants has been granted emergency use authorization in March this year. The Group currently has over 110 innovative drugs and 30 new-formulation drugs. Within the next 5 years, more than 40 innovative drugs are expected to be approved, which will provide continuous momentum for the Group's development.

The Group has strong commercialisation capabilities. Its professional sales force currently has over 10,000 team members, covering more than 35,000 medical institutions across the country, with coverage rate of over 90% in Class III hospitals and over 70% in Class II hospitals. We are also actively strengthening our efforts in lower-tier market penetration and developing the potential of county-level markets to provide quality drugs to the grass roots. Through patient-centric and clinical-data-driven academic promotion, the Group's sales team has successfully nurtured market-leading core products such as NBP, Duomeisu, Jinyouli, Keaili and Xuanning. Leveraging on the strong sales team and successful commercialisation experience, the Group will be able to ensure the rapid sales ramp-up and sales performance of innovative drugs to be commercially launched in the future. In addition, the Group has been actively strengthening the retail sales channel and internet medicine platform, and exploring the promotion model for chronic disease management.

#### **BUSINESS REVIEW**

#### **Finished Drug Business**

In 2022, the finished drug business maintained stable growth. The Group continued to adopt strategies of professional academic promotion, hospital development, lower-tier market penetration and expansion of indications to drive the growth of key finished drug products. During the year, market development activities of the newly launched innovative drugs were initiated and a number of newly launched generic drugs were selected at volume-based procurement with rapid sales ramp-up, which has brought in new sales contribution and a more balanced product portfolio.

The finished drug business recorded revenue of RMB24,520 million (including licence fee income of RMB186 million) for the year, an increase of 8.1% compared to last year. Sales by major therapeutic areas are as follows:

Therapeutic Area	Sales	Change	
	(RMB' million)	_	
Nervous system	8,108	+7.5%	
Oncology	7,415	-3.8%	
Anti-infectives	3,540	+20.1%	
Cardiovascular	2,889	+4.5%	
Respiratory system	621	+54.5%	
Digestion and metabolism	755	+51.9%	
Others	1,006	+31.5%	

#### Nervous System

Major products include NBP (恩必普<sup>®</sup>) (butylphthalide soft capsules and butylphthalide and sodium chloride injection), Shuanling (舒安靈<sup>®</sup>) (pentoxifylline extended-release tablets and pentoxifylline injection), Enliwei (恩理維<sup>®</sup>) (lacosamide injection/tablets), Enxi (恩悉<sup>®</sup>) (pramipexole dihydrochloride tablets) and Oulaining (歐來寧<sup>®</sup>) (oxiracetam capsules and oxiracetam for injection).

• NBP is a Class 1 new chemical drug in China and a patent-protected exclusive product mainly used for the treatment of acute ischemic stroke. It is a recommended drug in the guidelines of various professional organisations such as the Chinese Medical Association and the Chinese Stroke Association for the treatment of acute ischemic stroke, and is also listed in more than twenty domestic authoritative clinical guidelines and expert consensuses. In 2022, NBP maintained a stable sales growth. With the new NRDL renewal price to be implemented in March 2023, accessibility of the product will be further improved. The ongoing efforts to develop new indications will bring new growth opportunities for butylphthalide.

• Shuanling is a non-selective phosphodiesterase inhibitor that can comprehensively improve microcirculation through multiple mechanisms of action. In 2022, Shuanling continued to record rapid sales growth, and was listed in the Catalogue of Off-label Usage (2022 Edition) of Jilin, Liaoning and Heilongjiang provinces, the Male Infertility Guideline (2022) and the Consensus of Multi-disciplinary Chinese Experts on Diabetes Complicated with Male Erectile Dysfunction (2022).

# Oncology

On top of the three existing core products, namely Duomeisu (多美素<sup>®</sup>) (doxorubicin hydrochloride liposome injection), Jinyouli (津優力<sup>®</sup>) (PEG-rhGCSF injection) and Keaili (克艾力<sup>®</sup>) (paclitaxel for injection (albumin-bound), the Group continuously enriches the product portfolio by adding new products such as Duoenda (多恩達<sup>®</sup>) (mitoxantrone hydrochloride liposome injection) and Copiktra (克必妥<sup>®</sup>) (duvelisib capsules), bringing in new business growth drivers to this therapeutic area.

- Duomeisu is a product developed by the National Key Laboratory for New Pharmaceutical Preparations and Excipients of the Group and supported by the Major New Drug Development project in China. It is recommended by the U.S. National Comprehensive Cancer Network (NCCN) Guidelines and the Chinese Society of Clinical Oncology (CSCO) for the first-line treatment of lymphoma, ovarian cancer, relapsed or metastatic breast cancer, soft tissue sarcoma and AIDS-related Kaposi's sarcoma. Duomeisu is a leading brand of liposomal doxorubicin in China and is the first to pass the consistency evaluation in May 2021. Affected by the pandemic prevention and control measures and the adjustment of reimbursement drug list in certain provinces, sales of Duomeisu decreased in 2022. The Group will vigorously expand the broad market of prefecture-level cities and counties, with the target of increasing the proportion of sales from this broad market to 40%, providing more opportunities for patients to use Duomeisu and driving product's growth.
  - Jinyouli is the first long-acting white blood cell booster drug developed in China. It is used to prevent and treat incidence of infection and pyrexia due to low neutrophil count in patients receiving chemotherapy, thus ensuring the administration of standardised dosage of chemotherapy. It earns unanimous recommendations in domestic and foreign guidelines. In 2022, the growth rate of Jinyouli has slowed down due to certain factors such as pandemic prevention and control. Currently, short-acting white blood cell booster drugs still have a rather significant market share in China, especially in cities other than the provincial capital. The Group will continue to promote the use of long-acting white blood cell booster drugs and further expand the coverage of core hospitals in prefecture-level cities and county-level markets. Jinyouli was selected at the volume-based procurement of Guangdong Alliance in 2022. We will leverage the advantage from the policy to increase the market share of Jinyouli in those procurement regions.

- Keaili is the first-to-market generic of new generation paclitaxel chemotherapy drug in China with the consistency evaluation passed. It has been unanimously recommended by domestic and foreign guidelines and expert consensus for breast cancer, lung cancer, gastric cancer and gynaecological tumours. In 2022, Keaili has completed contract renewal at the volume-based procurement of Henan Alliance with a significant price reduction, leading to a decrease in sales. With the volume-based procurement renewal price being fully implemented in other provinces in 2023, sales of Keaili will be under further pressure. Other than continued effort to promote the replacement of conventional paclitaxel drugs, the Group will vigorously expand the presence of Keaili in those provinces where it has not been selected at procurement before.
- Duoenda is a class 2 new drug developed by the Group with patents in several countries. The product obtained official marketing approval for the treatment of relapsed/refractory peripheral T-cell lymphoma in January 2022. It was included into the CSCO Guidelines for Lymphoma in April 2022 which recommends its usage for the treatment of relapsed/refractory peripheral T-cell lymphoma (Grade 2A) and NKT lymphoma (Grade 2B). The newly established haematology sales team of the Group is responsible for the sales and promotion of Duoenda, which has now covered more than 500 hospitals.
- Copiktra is the first approved dual PI3K  $\delta/\gamma$  dual-target inhibitor in China. It achieves a balance between efficacy and safety by specifically acting on the  $\delta$  and  $\gamma$  dual targets of PI3K signaling pathway, with recommendation by many domestic and foreign guidelines. After approval, sale and promotion of Copiktra has been incorporated into the haematology product pipeline. With the synergy from Duoenda, the product is entering into market rapidly.

# Anti-infective products

Major products include Anfulike (安復利克<sup>®</sup>) (amphotericin B cholesteryl sulfate complex for injection), Shuluoke (舒羅克<sup>®</sup>) (meropenem for injection), Nuomoling (諾莫靈<sup>®</sup>) (amoxicillin capsules), Xianqu/Shiyao (先曲<sup>®</sup>/石藥<sup>®</sup>) (ceftriaxone sodium for injection), Xianwu (先伍<sup>®</sup>) (cefazolin sodium for injection), Zhongnuo Lixin (中諾立新<sup>®</sup>) (cefuroxime sodium for injection), Xinweihong (新維宏<sup>®</sup>) (azithromycin tablets) and Weihong (維宏<sup>®</sup>) (azithromycin dispersible tablets/capsules/enteric tablets). Anfulike is recommended jointly by the State Ministry of Industry and Health Care Commission as a "clinically urgent, market-deficient" product. It was granted drug registration approval with priority review in March 2021 for the treatment of patients with invasive fungal infections. With modification of the product's lipid structure, the metabolism and distribution characteristics of amphotericin B have been altered to reduce the incidence of nephrotoxicity and hypokalaemia. It can be used for the treatment of patients with renal impairment or drug toxicity which precludes the use of effective dose of amphotericin B, or patients who have failed in prior amphotericin B deoxycholate treatment. The drug accessibility of Anfulike is improved with its inclusion into the NRDL in December 2021. In the first year of its launch, the Group was dedicated to promoting the knowledge of the clinical benefits of the product among doctors. We are currently making every effort to expand the product's market coverage and expand the clinical application in blood/infection/respiration diseases to accelerate the product's growth.

# Cardiovascular

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Major products include Xuanning (玄寧<sup>®</sup>) (maleate levamlodipine tablets and dispersible tablets), Mingfule (銘復樂<sup>®</sup>) (recombinant human TNK tissue-type plasminogen activator for injection), Encun (恩存<sup>®</sup>) (clopidogrel bisulfate tablets), Daxinning (達新寧<sup>®</sup>) (dronedarone hydrochloride tablets), Abikang (阿比康<sup>®</sup>) (aspirin enteric tablets) and Meiluolin (美洛林<sup>®</sup>) (ticagrelor tablets).

- Xuanning is mainly used for the treatment of hypertension, chronic stable angina and variant angina, and is a product in the NRDL and essential drug list. It is listed in the Guidelines for the Prevention and Treatment of Hypertension in China, Guidelines for the Rational Use of Drugs in Hypertension and other authoritative guidelines in China. Xuanning has obtained marketing approval from the U.S. Food and Drug Administration (FDA) in December 2019, becoming the first Chinese innovative drug to be granted full approval by the FDA. The sales team of Xuanning adopts an integrated sales model of direct, cooperative and retail sales. It is also developing e-commerce sales channel in order to accelerate sales growth. In 2022, the sales of Xuanning remained stable.
  - Mingfule is a third-generation thrombolytic drug with proprietary intellectual property mainly used for the thrombolysis treatment in patients with acute myocardial infarction. It has been listed as a recommended thrombolytic drug in the Chinese Expert Consensus on Pre-hospital Thrombolysis, Guidelines for Rational Use of Drugs for STEMI (201902) and other authoritative guidelines. Moreover, the Chinese Expert Consensus on Teneplase Intravenous Thrombolytic Therapy for Acute Ischemic Stroke published in December 2022 provides a basis for the clinical promotion of TNK as a thrombolytic drug. In 2022, the new indication application for marketing approval of Mingfule for the thrombolytic treatment in patients with acute ischemic stroke was submitted. The approval of this indication will greatly expand the market potential for the product.

# Respiratory

Major products include Qixiao (琦效<sup>®</sup>) (arbidol hydrochloride tablets), Zhongnuo Like (中諾立克<sup>®</sup>) (ambroxol hydrochloride oral solution), Zhongnuoping (中諾平<sup>®</sup>) (ambroxol hydrochloride extended release tablets), Qixin (琦昕<sup>®</sup>) (Oseltamivir phosphate capsules) and Nuoyian (諾一安<sup>®</sup>)(montelukast sodium tablets/ chewable tablets).

#### Digestion and metabolism

Major products include Linmeixin (林美欣<sup>®</sup>) (glimepiride dispersible tablets), Shuanglexin (雙樂欣<sup>®</sup>) (metformin hydrochloride tablets/extended-release tablets) and Xinweiping (欣維平<sup>®</sup>) (acarbose tablets).

#### Other therapeutic areas

Major products include Gubang (固邦®) (alendronate sodium tablets/enteric tablets), Xianpai (先派®) (omeprazole injections) and Qimaite (奇邁特®) (tramadol hydrochloride tablets).

#### **Bulk Product Business**

#### Vitamin C

Sales amounted to RMB2,529 million in 2022, representing an increase of 17.7%. During the year, both the production volume and sales volume have increased, with the global market share further expanded. However, product price has decreased due to changes in market environment. The Group will continue to develop new market, optimise customer structure, expand overseas sales channel and focus on brand building to enhance its overall competitive strength.

#### Antibiotics and Others

Sales amounted to RMB1,922 million in 2022, representing an increase of 15.1%, which was mainly attributable to the increase in sales volume and prices of certain products. The Group will continue to enhance product chain and product complementarity, promote registration in high-end market and steadily improve product quality.

# Functional Food and Other Businesses

Sales from the business amounted to RMB1,966 million in 2022, representing an increase of 43.9%. During the year, caffeine products recorded a satisfactory growth in both sales volume and average selling price, while sales of Guoweikang (vitamin C health supplement product) declined to a certain extent. The Group will maintain stable business growth through technology enhancement, cost control and market development.

#### **Research and Development**

The Group strongly believes that innovative research and development is the most important driver for future development and continues to increase its investment in research and development. R&D expenses for the year 2022 amounted to RMB3,987 million (charged to income statement), representing an increase of 16.1% over 2021 and accounting for approximately 16.3% of the revenue of the finished drug business. Currently, more than 50 key drug candidates have entered clinical trial or registration stage, of which 9 have filed application for marketing approval, 16 have entered pivotal clinical trial or about to file application for marketing approval.

# Regulatory Updates:

# China

- In January 2022, Duoenda (多恩達<sup>®</sup>) (mitoxantrone hydrochloride liposome injection), a self-developed oncology nanodrug of the Group, obtained marketing approval for the treatment of peripheral T-cell lymphoma (PTCL). Clinical studies have indicated that it has a significantly better efficacy than other drugs in treating patients with relapsed or refractory PTCL.
- In March 2022, Copiktra (克必妥<sup>®</sup>) (duvelisib capsules) obtained marketing approval for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies. The product is the first approved orally available dual PI3K-δ and PI3K-γ inhibitor worldwide, and is also the first approved PI3K selective inhibitor in China.
- In March 2023, COVID-19 mRNA vaccine (SYS6006) has been included for emergency use in China for the prevention of COVID-19 caused by the infection of SARS-CoV-2.
- In January 2022, application for marketing approval of desvenlafaxine extended-release tablets for the treatment of depression was submitted (being the first submission of this product type in China).
- In April 2022, application for marketing approval of nanodrug irinotecan liposome for injection for the treatment of metastatic pancreatic cancer was submitted.
- In June 2022, application for marketing approval of narlumosbart for injection (JMT103) (recombinant fully human anti-RANKL monoclonal antibody for injection) for the treatment of unresectable or surgically difficult giant cell tumor of bone was submitted with priority review granted. The product is the first IgG4 subtype fully human monoclonal antibody against RANKL filing BLA in the world.
- In October 2022, application for marketing approval of paclitaxel for injection (albumin-bound) (II) for the treatment of breast cancer was submitted.

- In November 2022, new indication application for marketing approval of Mingfule (銘復樂<sup>®</sup>) (recombinant human TNK tissue-type plasminogen activator for injection) for the thrombolytic treatment in patients with acute ischemic stroke was submitted.
- In March 2023, application for marketing approval of enlonstobart for injection (recombinant fully human anti-PD-1 monoclonal antibody) for the treatment of recurrent or metastatic cervical cancer patients with positive PD-L1 expression who have failed first-line platinum-based chemotherapy was submitted with eligibility for conditional approval pathway.
- In March 2023, application for marketing approval of amphotericin B liposome for injection for the treatment of invasive fungal infection was submitted.
- In March 2023, pre-NDA meeting with Centre for Drug Evaluation (CDE) of prusogliptin tablets (DBPR108) for the treatment of type 2 diabetes was completed.
- In March 2023, application for pre-BLA meeting of recombinant anti-IgE monoclonal antibody for injection (SYSA1903) for the treatment of chronic spontaneous urticaria was submitted.
- Since the beginning of 2022, 14 innovative drugs candidates have obtained clinical trial approval for their first indications and 10 additional indications have obtained clinical trial approval.

Drug candidate	Indication
SYHA1908 for injection	Advanced solid tumors
Daunorubicin cytarabine liposome for injection	Acute myeloid leukemia
Ustekinumab injection	Psoriasis
SYS6006 for injection (SARS-COV-2 mRNA vaccine)	Prevention of Covid-19 infection
Cisplatin micelle injection	Advanced solid tumors
SYHX2005 tablets (FGFR4)	Advanced solid tumors
SYHX2009 tablets (NTRK, ROS1)	Advanced solid tumors
SYS6002 injection (Nectin-4 ADC)	Advanced solid tumors
SYH2055 tablets (3CL)	Covid-19 infection
SYH2043 tablets (CDK2/4/6)	Advanced solid tumors
SYH2045 tablets (PRMT5)	Advanced solid tumors
Meloxicam nanocrystal injection	Postoperative analgesics
Clevidipine injectable emulsion	Hypertension
Octreotide long-acting injection	Acromegaly/NET

#### First indication:

#### Additional indication:

Indication
Contrast-induced acute kidney injury
Neuromyelitis optica spectrum disorder
Advanced nasopharyngeal cancer
Non-alcoholic steatohepatitis
Alzheimer's disease
Salivary gland carcinomas
Severe COVID-19
Osteoarthritis
First-line treatment of cervical cancer
Combined therapy with SG001 and platinum agents (carboplatin/cisplatin) for perioperative treatment of NSCLC

Since the beginning of 2022, 16 generic drugs have obtained drug registration approvals, including lenvatinib mesilate capsules, donepezil hydrochloride tablets, vortioxetine hydrobromide tablets, nifedipine controlled-release tablets, pramipexole dihydrochloride sustained-release tablets, lacosamide injection, zoledronic acid injection, doxofylline injection, tenofovir alafenamide fumarate tablets, esomeprazole sodium for injection, gabapentin capsules, moxifloxacin hydrochloride and sodium chloride injection, lenalidomide capsules, baloxavir marboxil tablets, tofacitinib citrate extended-release tablets and argatroban injection.

# The U.S.

- In January 2022, JMT601 (CPO107) was granted fast track designation for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma. The drug candidate is the world's first bispecific SIRPα fusion protein with synergised target binding effect which has entered clinical stage of development. Therapeutic targets include CD20 and CD47.
- In July 2022, docetaxel for injection (albumin-bound) was granted orphan-drug designation for the treatment of gastric cancer including cancer of gastroesophageal junction.
- Since the beginning of 2022, 2 innovative drug candidates, namely SYS6002 injection (Nectin-4 ADC) and NBL-020 injection (TNFR2), have obtained clinical trial approval.

#### Major Clinical Trials Progress:

# SARS-CoV-2 mRNA vaccine (SYS6006)

• Phase I, II clinical studies and a heterologous booster immunization clinical study in China have been completed. With more than 5,500 people enrolled, the clinical studies have demonstrated its efficacy and safety. The Group has built a GMP-compliant production plant. Key raw materials and excipients are produced by the Group, which enables independent control in the supply chain and significantly lower production cost.

# Duoenda (多恩達®) (mitoxantrone hydrochloride liposome injection)

- At the annual meeting of the American Society of Clinical Oncology (ASCO) in June 2022, the results of a Phase Ib clinical trial for the treatment of platinum-refractory or platinum-resistant recurrent ovarian cancer were presented in E-poster; and the results of a Phase Ib clinical trial for the treatment of recurrent/metastatic squamous cell carcinoma of head and neck were presented online. Preliminary results indicate that Duoenda has a controllable safety profile and observable efficacy in both indications.
- At the annual meeting of the European Society for Medical Oncology (ESMO) in September 2022, the results of a "dose escalation and dose expansion study of mitoxantrone hydrochloride liposome injection in combination with pegaspargase for the treatment of extranodal NK/T-cell lymphoma (ENKTCL)" were presented in the Mini Oral session. Preliminary results indicate that Duoenda in combination with pegaspargase has significant efficacy, especially for patients with primary ENKTCL, with controllable safety risks.
- A number of clinical trials in hematological tumors and solid tumors are currently underway. Of which, the first patient has been dosed in a phase III clinical trial for the treatment of patients with recurrent metastatic nasopharyngeal carcinoma who have failed platinum-based therapy.

# Mingfule (銘復樂®) (recombinant human TNK tissue-type plasminogen activator for injection)

• In July 2022, Mingfule has met its predefined primary endpoint (the proportion of subjects with a mRS of 0 to 1 at 90 days) in a Phase III clinical study for the treatment of acute ischemic stroke, demonstrating that Mingfule is non-inferior to alteplase in efficacy and has a trend of enhancement in efficacy, while the safety profile is similar to alteplase. The study results were published at the World Stroke Congress in Singapore in October 2022 and in The Lancet (IF202.731), a top international medical journal, in February 2023. This marked the first time for a cerebrovascular drug of a Chinese company with independent intellectual property rights to be reported in a top international medical journal.

• A number of investigational studies initiated by experts in China are currently underway for the treatment of cerebral infarction, including bridging therapy, anti-bridging therapy, and therapy of extended thrombolytic time window. It is expected that results of these studies and the Phase III clinical trial will be able to change the relevant diagnosis and treatment guidelines.

#### Narlumosbart for injection (JMT103)

• In March 2022, JMT103 has met its predefined endpoint in a pivotal trial for the treatment of unresectable or surgically difficult giant cell tumor of bone, demonstrating that JMT103 has a better clinical efficacy with a tumor response rate of 93.5%, and a trend higher than that of the denosumab group. Moreover, JMT103 showed a good safety profile with controllable safety risks.

# Prusogliptin tablets (DBPR108)

• In August 2022, DBPR108 has met its predefined endpoints in two Phase III pivotal clinical trials for the treatment of type 2 diabetes. Results of the monotherapy trial demonstrated that in respect of the primary efficacy endpoint of the change in HbA1c between the end of 24 weeks and the baseline period, the DBPR108 group was significantly superior to the placebo group and was non-inferior to the active group of sitagliptin. Results of the combination trial demonstrated that in respect of the primary efficacy endpoint of the change in HbA1c between the end of 24 weeks and the baseline period, the DBPR108 group was significantly superior to the end of 24 weeks and the baseline period, the DBPR108 group was significantly superior to the placebo group. In addition, safety profile of the DBPR108 group in the study was similar to the sitagliptin group and placebo group.

# SYHA1813 oral liquid

• At the annual meeting of the European Society of Medical Oncology (ESMO) in September 2022, the results of a dose escalation study of "Phase I clinical trial to evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy of SYHA1813 oral liquid in treating patients with relapsed or advanced solid tumors" were presented in E-poster. Preliminary results indicated acceptable tolerability and preliminary antitumor activity for patients with relapsed high-grade glioma taking 15mg SYHA1813 oral liquid once every day.

# Recombinant anti-IgE monoclonal antibody for injection (SYSA1903)

• In March 2023, a phase III therapeutic bioequivalence study in comparison to the originator drug for the treatment of patients with chronic spontaneous urticaria who remain symptomatic despite H1 antihistamine treatment has met its predefined endpoint.

# Registration and pivotal trial stage:

Drug candidate	Туре	Target	Indication	Status
Narlumosbart for injection (Recombinant fully human anti-RANKL monoclonal antibody for injection)	Biological drug (monoclonal antibody)	RANKL	Giant cell tumor of bone	BLA submitted
Irinotecan liposome for injection	Nanodrug	DNA topoisomerase inhibitors	Pancreatic cancer	NDA submitted
Desvenlafaxine succinate extended release tablets	Chemical drug	5-Hydroxytryptamine and norepinephrine reuptake inhibitors	Depression	NDA submitted
Rezetinib mesylate capsules	Chemical drug	EGFR	Non-small cell lung cancer	NDA submitted
Recombinant human TNK tissue-type plasminogen activator for injection (rhTNK-tPA)	Biological drug (recombinant protein)	Plasminogen	Acute ischemic stroke	BLA submitted
Paclitaxel for injection (albumin-bound) (II)	Nanodrug	Microtubule inhibitor	Breast cancer	NDA submitted
Amphotericin B liposome for injection	Nanodrug	Anti-infective, nonspecific drug	Invasive fungal infection	NDA submitted
Enlonstobart (recombinant fully human anti-PD-1 monoclonal antibody for njection)	Biological drug (monoclonal antibody)	PD-1	Cervical cancer	BLA submitted
SYS6006 for injection (SARS-CoV-2 mRNA vaccine)	Biological drug (vaccine)	Spike protein of SARS- CoV-2	COVID-19 prevention	applying for emergency use authorization
Prusogliptin tablets (DBPR108)	Chemical drug	DPP-4 inhibitor	Diabetes	Pre-NDA submitted
Recombinant anti-IgE monoclonal antibody for injection	Biological drug (monoclonal antibody)	IgE	Urticaria	Pre-BLA submitted
Batoclimab (HBM9161)	Biological drug (monoclonal antibody)	FcRn	Myasthenia gravis	Pre-BLA submitted
Recombinant humanized anti-epidermal growth factor receptor monoclonal antibody for injection (JMT101)	Biological drug (monoclonal antibody)	EGFR	EGFR exon 20 insertion mutation in non-small cell lung cancer	Pivotal trial
KN026 for injection	Biological drug (bispecific antibody)	HER2 bispecific antibody	Gastric cancer	Pivotal trial
Recombinant humanized anti-HER2 nonoclonal antibody-MMAE conjugate for injection (DP303c) SYSA1501 for njection SYSA1801 for injection	Biological drugs (ADC)	HER2 ADC	Breast cancer	Pivotal trial
Pertuzumab for injection	Biological drug (monoclonal antibody)	HER2	HER2 positive breast cancer	Pivotal trial
SKLB1028 capsules	Chemical drug	FLT3, Abl, Lyn, EGFR	Acute myeloid leukaemia	Pivotal trial
HA121-28 tablets	Chemical drug	RET, EGFR, VEGFR, FGFR	Non-small cell lung cancer with RET gene fusion mutation	Pivotal trial

Drug candidate	Туре	Target	Indication	Status
SYH2055 tablets	Chemical drug	3CL protease inhibitor	High risk COVID-19	Pivotal trial
Daunorubicin cytarabine liposome for injection	Nanodrug	RNA polymerase inhibitor DNA polymerase inhibitor	Leukemia	Pivotal trial
Docetaxel for injection (albumin-bound)	Nanodrug	Microtubule inhibitor	Pancreatic cancer, head and neck squamous cell carcinoma	Pivotal trial
TG103 injection	Biological drug (monoclonal antibody)	GLP1-Fc	Weight loss	Pivotal trial
Butylphthalide soft capsules	Chemical drug		Vascular dementia	Pivotal trial
Clevidipine injectable emulsion	Nanodrug	Calcium channel blocker	Hypertension	Pivotal trial
Meloxicam nanocrystal injection	Nanodrug	Cyclooxygenase-2 (COX-2) inhibitor	Chronic pain	Pivotal trial

#### Products in other clinical stage:

Drug candidate	Туре	Therapeutic Area
Ammuxetine hydrochloride enteric tablets	Chemical drug	Psychiatry
Butylphthalide soft capsules (China and US)	Chemical drug	Neurology
Simmitinib hydrochloride tablets, SYHA1801 capsules,	Chemical drug	Oncology
SYHA1803 capsules, SYHA1807 capsules, SYHA1811 tablets, SYHA1813 oral liquid, SYHA1815 tablets, SYHX1903 tablets, SYHX2001 tablets, SYHX2005 tablets, SYHX2009 tablets, SYHX2043 tablets, SYHX2045 tablets		
SYHA1402 tablets, SYHA1805 tablets	Chemical drug	Metabolism
SYHX1901 tablets	Chemical drug	Immunity
Octreotide long-acting injection	Chemical drug	Endocrine
JMT601 for injection (China and US)	Biological drug (bispecific antibody)	Oncology
SYS6002 for injection, SYSA1801 for injection (China and US)	Biological drug (ADC)	Oncology
ALMB0168 for injection, NBL-015 for injection (China and US), NBL-020 for injection (China and US)	Biological drug (monoclonal antibody)	Oncology
ALMB0166 for injection	Biological drug (monoclonal antibody)	Central nervous system
CM310 for injection, CM326 for injection, NBL-012 for injection (China and US), ustekinumab injection	Biological drug (monoclonal antibody)	Immunity
Paclitaxel cationic liposome for injection, sirolimus for injection (albumin-bound), SYHA1908 for injection, cisplatin micelle injection	Nanodrug	Oncology
Prostaglandin liposome for injection	Nanodrug	Cardiovascular

# Awards and Patents:

- In January 2022, CSPC was rated excellent with number six in overall ranking and number one in the pharmaceutical industry in the evaluation results of the 2021 National Enterprise Technology Center released by the National Development and Reform Commission.
- In April 2022, the project "Key Technology and Industrialization Research of Albumin-bound Nanodrug Delivery" once again won the Science and Technology Progress First Class Award of Hebei Province (河 北省科技進步一等獎), winning the highest honour of provincial science and technology award for two consecutive years.
- 41 international PCT applications and 214 patent applications (148 domestic and 66 overseas) have been filed, and 58 patents (36 domestic and 22 overseas) have been granted.

The Group is expected to launch more than 40 innovative and new-formulation drugs, and over 60 generic drugs within the next five years. Of which, mitoxantrone liposomes, docetaxel albumin nanoparticles, sirolimus albumin nanoparticles, cisplatin micelle, and paclitaxel albumin nanoparticles (fast-dissolving) developed based on the nanotechnology platform, the ultra-long-acting GLP1-IgD/IgG4 Fc fusion protein in the field of metabolism, the world's new CX43 inhibiting and antagonizing antibody, the new ADC and ISAC based on enzymatic site-specific conjugation, the CD20/CD47 bispecific antibodies based on novel asymmetric structure, as well as the mRNA vaccine which offers protection against Covid-19 variants and small nucleic acid drugs (dosed semi-annually) are all heavyweight products with global patents and great market value. The launch of these new products will provide strong support to the Group's high-quality growth in the future.

# **Business Development**

While continuing to enhance in-house innovation and R&D capabilities, the Group is also driving forward its business development efforts. We will seek to further strengthen the product pipeline and create new growth drivers through cooperation with biotech companies having high-quality drug candidates. In addition, we will actively promote internationalisation of the business by out-licensing the Group's innovative products.

# Equity Acquisition:

• In February 2022, the Group completed the acquisition of 51% equity interest in Guangzhou Recomgen Biotech Co., Ltd. (now renamed as CSPC Recomgen Pharmaceutical (Guangzhou) Co., Ltd. with equity interest increasing to 54.8%). Its marketed product Mingfule (銘復樂®) (recombinant human TNK tissue-type plasminogen activator for injection) is a third-generation specific thrombolytic drug with intellectual property rights.

# In-Licensing:

• In October 2022, the Group entered into an exclusive license agreement with Harbour Biomed (Shanghai) Co., Ltd., to obtain the right to develop, manufacture and commercialize batoclimab (HBM9161) in Greater China. The Phase III clinical trial for the indication of myasthenia gravis (MG) has achieved positive topline results, meeting the primary endpoint and the key secondary endpoint. Application for pre-BLA meeting has been submitted. There are five other indications in different clinical stages. The product has the potential to be a breakthrough treatment for a wide spectrum of autoimmune diseases in Greater China.

# **Out-Licensing:**

- In July 2022, the Group entered into an exclusive license agreement with Elevation Oncology, Inc. in the U.S. to out-license the development and commercialization rights of the Group's SYSA1801 (Claudin 18.2 ADC) outside of Greater China. The Group has received an upfront payment of US\$27 million and is also eligible to receive up to US\$148 million in potential development and regulatory milestone payments and up to US\$1.02 billion in potential sales milestone payments, as well as tiered sales royalties.
- In January 2023, the Group entered into an exclusive license agreement with Corbus Pharmaceuticals, Inc. in the U.S. to out-license the development and commercialization rights of the Group's SYS6002 (Nectin-4 ADC) in the United States, EU countries, United Kingdom, Canada, Australia, Iceland, Liechtenstein, Norway and Switzerland. The Group will receive upfront payments of US\$7.5 million and is also eligible to receive up to US\$130 million in potential development and regulatory milestone payments and up to US\$555 million in potential sales milestone payments, as well as tiered sales royalties.

# **FINANCIAL REVIEW**

#### **Financial Results**

# **Revenue and Gross Profit Margin**

Revenue for the year amounted to RMB30,937 million, an increase of 11.0% compared to RMB27,867 million in 2021. The increase was mainly due to the 8.1%, 16.5% and 43.9% growth in the finished drug business, bulk product business and functional food and others business, respectively. Gross profit margin decreased by 3.9 percentage point to 71.9%, which was mainly attributable to the change in revenue mix and decline in selling prices of vitamin C products during the year.

# **Other Income**

Other income for the year amounted to RMB604 million (2021: RMB411 million), mainly consisting of interest income on bank balances of RMB243 million (2021: RMB183 million) and government grant income of RMB195 million (2021: RMB96 million).

#### Other gains and losses

Other gains and losses for the year reported a net gain of RMB291 million (2021: RMB243 million), mainly consisting of fair value gain on financial assets measured at FVTPL of RMB101 million (2021: RMB205 million), fair value gain on structured deposits of RMB117 million (2021: RMB82 million) and net foreign exchange gain of RMB118 million (2021: loss of RMB36 million).

# **Operating Expenses**

Selling and distribution expenses for the year amounted to RMB10,337 million, a slight decrease of 1.0% compared to RMB10,443 million in 2021. During the year, the Group continued to further grow its market coverage and promote the newly launched finished drug products. With efforts made by the Group to enhance the efficiency of the marketing activities, a lower ratio of selling and distribution expenses to revenue has been achieved in 2022.

Administrative expenses for the year amounted to RMB1,173 million, an increase of 16.1% compared to RMB1,010 million in 2021. The increase was mainly due to the expanding operation of the Group and employee share-based compensation expense recognised in respect of the share awards granted to selected employees of the Group by Key Honesty Limited (a shareholder of the Company) during 2022.

R&D expenses for the year amounted to RMB3,987 million, an increase of 16.1% compared to RMB3,433 million in 2021. The increase was primarily attributable to the increased spending on ongoing and newly initiated clinical trials.

# Income tax expense

Income tax expenses for the year amounted to RMB1,350 million (2021: RMB1,159 million), which represented provision of income tax expense based on the taxable income of the subsidiaries and PRC withholding tax on dividend distributions by certain subsidiaries.

# Non-HKFRS Measure

For the purpose of assessing the performance of the Group, the Company has also presented the underlying profit attributable to shareholders as an additional financial measure, which is not required by, or presented in accordance with the Hong Kong Financial Reporting Standards ("HKFRS"). The Group believes that this non-HKFRS financial measure better reflects the underlying operational performance of the Group by eliminating certain non-cash and/or non-operating items which the Group does not consider indicative of the Group's operational performance. However, the presentation of this non-HKFRS financial measure is not intended to be a substitute for, or superior to, the financial information prepared and presented in accordance with HKFRS.

Additional information is provided below to reconcile the profit attributable to shareholders as reported and the underlying profit attributable to shareholders (a non-HKFRS financial measure):

	2022	2021
	(RMB'000)	(RMB'000)
Profit attributable to shareholders	6,091,390	5,605,185
Adjustment for:		
- Fair value gain on financial assets measured at FVTPL (note a)	(100,905)	(205,040)
– Employee share-based compensation expense (note b)	160,726	17,732
- Gains on deemed disposal of partial interest in an associate		
and a joint venture	(48,065)	(13,092)
- Gain on disposal of a joint venture	_	(24,273)
- Effect of corresponding income tax	2,579	37,388
Underlying profit attributable to shareholders	6,105,725	5,417,900

Notes:

- (a) Fair value gain on financial assets measured at FVTPL is arisen from the measurement of the Group's investments in certain partnerships, funds and listed equity securities at fair value.
- (b) Out of the total employee share-based compensation expense recognised in 2022, RMB150 million was in respect of share awards granted to selected employees of the Group by Key Honesty Limited (a shareholder of the Company) during 2022.

# Liquidity and Financial Position

For the year ended 31 December 2022, the Group's operating activities generated a cash inflow of RMB7,627 million (2021: RMB4,637 million). Turnover days of trade receivables (ratio of balance of trade receivables to sales, inclusive of value added tax for sales in China) were 44 days compared to 40 days in 2021. Turnover days of inventories (ratio of balance of inventories to cost of sales) decreased from 134 days in 2021 to 107 days. Current ratio was 2.7 as of 31 December 2022, slightly lower than 2.8 a year ago. Capital expenditure for the year amounted to RMB1,823 million, which were mainly spent to construct production facilities and improve production efficiency.

The Group's financial position remained solid. As of 31 December 2022, the Group had bank balances, deposits and cash of RMB10,498 million (2021: RMB9,684 million), structured bank deposits of RMB3,575 million (2021: RMB1,443 million) and bank borrowings of RMB182 million (2021: nil). As of 31 December 2022, gearing ratio (ratio of bank borrowings to total equity) was 0.6% (2021: nil).

The Group's sales are primarily denominated in Renminbi for domestic sales in China and US dollars for export sales. The Group manages its foreign exchange risks by closely monitoring its foreign exchange exposures and mitigating the impact of foreign currency fluctuations by using appropriate hedging arrangements when considered necessary.

#### **Pledge of Assets**

None of the Group's assets were charged to any third parties as of 31 December 2022.

# **Contingent Liabilities**

The Group did not have any material contingent liabilities as of 31 December 2022.

# **Dividend Policy**

It is the present intention of the Board to provide shareholders with regular dividends with a normal target payout ratio of not less than 30 per cent of the Group's core profit on a full year basis. The actual amount of dividend will depend on a number of factors including but not limited to financial results, financial position and funding needs of the Group.

# Employees

The Group employed a total of 24,837 employees as of 31 December 2022, with a majority of them employed in mainland China. The Group continues to offer competitive remuneration packages, discretionary share options, share awards and bonuses to eligible staff, based on the performance of the Group and the individual employee.

In order to retain and motivate the employees of the Group for its continual operation and development, Key Honesty Limited ("Key Honesty"), a shareholder of the Company which is indirectly wholly-owned by Mr. Cai Dongchen (Chairman of the Board), has granted conditional share awards to selected employees of the Group during 2022 in respect of the existing issued shares of the Company held by Key Honesty. The respective awarded shares will be vested and transferred to the grantees within 3 to 5 years from the date of grant at a transfer price of HK\$2.95 per share subject to the fulfilment of certain conditions. As of 31 December 2022, there were 206,050,000 unvested awarded shares.

# CONSOLIDATION FINANCIAL STATEMENTS

# CONSOLIDATED STATEMENT OF PROFIT OR LOSS

For the year ended 31 December 2022

	Notes	2022 <i>RMB'000</i>	2021 <i>RMB '000</i>
Revenue	3	30,936,904	27,866,870
Cost of sales	5	(8,680,490)	(6,731,776)
Gross profit		22,256,414	21,135,094
Other income		603,799	411,223
Other gains or losses, net		291,383	242,675
Selling and distribution expenses		(10,337,423)	(10,443,422)
Administrative expenses		(1,172,842)	(1,009,824)
Research and development expenses		(3,986,516)	(3,432,590)
Other expenses		(80,333)	(108,204)
Share of results of associates		(42,509)	(23,894)
Share of results of joint ventures		27,114	46,337
Gains on deemed disposal of partial interest in an associa	ate		
and a joint venture		48,065	13,092
Gain on disposal of a joint venture		_	24,273
Finance costs		(24,891)	(7,664)
Profit before tax		7,582,261	6,847,096
Income tax expense	5	(1,350,211)	(1,158,972)
Profit for the year	4	6,232,050	5,688,124
Profit for the year attributable to:			
Owners of the Company		6,091,390	5,605,185
Non-controlling interests		140,660	82,939
		6,232,050	5,688,124
		RMB cents	RMB cents
Earnings per share			
— Basic	6	51.11	46.89
— Diluted	6	51.11	46.89

# CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the year ended 31 December 2022

	2022	2021
	RMB'000	RMB '000
Profit for the year	6,232,050	5,688,124
Other comprehensive income (expense):		
Item that will not be reclassified to profit or loss:		
Fair value gain (loss) on financial assets measured at fair value through		
other comprehensive income, net of income tax	13,013	(19,723)
Item that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	50,493	7,800
Other comprehensive income (expense) for the year, net of income tax	63,506	(11,923)
Total comprehensive income for the year	6,295,556	5,676,201
Total comprehensive income for the year attributable to:		
Owners of the Company	6,154,896	5,593,262
Non-controlling interests	140,660	82,939
=	6,295,556	5,676,201

# CONSOLIDATED STATEMENT OF FINANCIAL POSITION

At 31 December 2022

	Notes	As at 31 December 2022 <i>RMB'000</i>	As at 31 December 2021 <i>RMB</i> '000
Non-current assets			
Property, plant and equipment		9,582,060	8,529,370
Right-of-use assets		1,394,859	1,034,549
Investment property		62,737	33,687
Goodwill		234,904	149,983
Intangible assets		1,908,112	467,854
Interests in associates		685,290	650,956
Interests in joint ventures		709,482	292,505
Amounts due from joint ventures		-	253,953
Financial assets		2,125,574	1,979,345
Deferred tax assets		113,026	43,000
Deposits, prepayments and other receivables	9	796,570	569,871
Bank deposits		200,000	400,000
		17,812,614	14,405,073
Current assets			
Inventories		2,554,861	2,480,369
Trade receivables	8	3,937,967	3,309,148
Deposits, prepayments and other receivables	9	693,224	580,425
Bills receivables	10	2,602,551	3,099,188
Amounts due from related companies		195,643	100,135
Amount due from an associate		_	400
Amounts due from joint ventures		100,048	39,783
Structured bank deposits		3,574,859	1,443,413
Bank balances, deposits and cash		10,298,007	9,283,642
		23,957,160	20,336,503

	Notes	As at 31 December 2022 <i>RMB</i> '000	As at 31 December 2021 <i>RMB</i> '000
Current liabilities			
Trade payables	11	1,507,986	1,481,359
Other payables	12	5,355,516	4,680,829
Contract liabilities		799,458	428,404
Bills payables	13	502,079	141,258
Amounts due to related companies		104,938	58,910
Amounts due to joint ventures		130,860	136,127
Lease liabilities		142,071	38,424
Tax liabilities		261,608	260,732
Bank borrowings		153,484	
		8,958,000	7,226,043
Net current assets		14,999,160	13,110,460
Total assets less current liabilities		32,811,774	27,515,533
Non-current liabilities			
Other payables	12	270,917	250,198
Lease liabilities		258,039	55,620
Deferred tax liabilities		611,993	381,484
Bank borrowings		28,950	
		1,169,899	687,302
Net assets		31,641,875	26,828,231
Capital and reserves			
Share capital		10,899,412	10,899,412
Reserves		19,298,122	15,087,260
Equity attributable to owners of the Company		30,197,534	25,986,672
Non-controlling interests		1,444,341	841,559
Total equity		31,641,875	26,828,231

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Basis of Preparation

The consolidated financial statements have been prepared in accordance with Hong Kong Financial Reporting Standards ("HKFRSs") issued by the Hong Kong Institute of Certified Public Accountants (the "HKICPA") and on the historical cost basis except for certain financial instruments that are measured at fair value at the end of the reporting period.

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

- The Company has delivered the financial statements for the year ended 31 December 2021 to the Registrar of Companies as required by section 662(3) of, and Part 3 of Schedule 6 to, the Hong Kong Companies Ordinance and will deliver the financial statements for the year ended 31 December 2022 in due course.
- The Company's auditor has reported on the financial statements of the Group for the years ended 31 December 2022 and 2021. The auditor's reports for both years were unqualified; did not include a reference to any matters to which the auditor drew attention by way of emphasis without qualifying its reports; and did not contain a statement under sections 406(2), 407(2) or (3) of the Hong Kong Companies Ordinance.

The consolidated financial statements are presented in Renminbi ("RMB"), which is also the functional currency of the Company.

#### 2. Application of New and Amendments to HKFRSs

#### Amendments to HKFRSs that are mandatorily effective for the current year

In the current year, the Group has applied the following amendments to HKFRSs issued by the HKICPA for the first time, which are mandatorily effective for the Group's annual period beginning on 1 January 2022 for the preparation of the consolidated financial statements:

Amendments to HKFRS 3	Reference to the Conceptual Framework
Amendment to HKFRS 16	Covid-19-Related Rent Concessions beyond 30 June 2021
Amendments to HKAS 16	Property, Plant and Equipment - Proceeds before Intended Use
Amendments to HKAS 37	Onerous Contracts - Cost of Fulfilling a Contract
Amendments to HKFRSs	Annual Improvements to HKFRSs 2018 - 2020

The application of the amendments to HKFRSs in the current year has had no material impact on the Group's financial positions and performance for the current and prior years and/or on the disclosures set out in these consolidated financial statements.

	2022 <i>RMB'000</i>	2021 <i>RMB</i> '000
Sale of goods Licence fee income	30,751,087 185,817	27,818,345 48,525
	30,936,904	27,866,870

Information reported to executive directors, being collectively the chief operating decision maker ("CODM"), for the purposes of resource allocation and assessment of segment performance focuses on types of goods delivered.

The Group's reportable segments under HKFRS 8 Operating Segments are as follows:

- (a) Finished drugs research and development, manufacture and sale of pharmaceutical products and licence fee income;
- (b) Bulk products manufacture and sale of vitamin C, antibiotic and other products in bulk powder form; and
- (c) Functional food and others manufacture and sale of functional food products (including caffeine additives and vitamin supplements), provision of healthcare services and others.

#### Sales of goods

Revenue is recognised at a point of time upon control of the goods has transferred, being when the goods have been delivered to the customer's specific location. Following delivery, the customer bears the risks of obsolescence and loss in relation to the goods. The normal credit term is 90 days upon delivery.

The transaction price received by the Group is recognised as a contract liability until the goods have been delivered to the customer.

As at 31 December 2022, all outstanding sales contracts are expected to be fulfilled within one year. As permitted under HKFRS 15, the transaction price allocated to these unsatisfied contracts is not disclosed.

#### Licence fee income

The Group provides licence of its patented intellectual property ("IP") or commercialisation licence to customers and revenue is recognised when the customers obtain rights to access or use the underlying IP or licence. Licence fee income is recognised at a point of time upon the customer obtains control of IP or if control is transferred over time, e.g. commercialisation licence to customers for a term of period, revenue is recognised over time by reference to the progress towards complete satisfaction of the relevant performance obligation.

#### Segment revenues and results

The following is an analysis of the Group's revenue and results by operating and reportable segments.

# For the year ended 31 December 2022:

		Bulk pr	oducts				
	Finished		Antibiotics and	Functional food and	Segment		
	drugs	Vitamin C	others	others	total	Eliminations	Consolidated
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
SEGMENT REVENUE							
External sales	24,334,250	2,529,126	1,921,810	1,965,901	30,751,087	-	30,751,087
Inter-segment sales	-	4,285	290,797	80,191	375,273	(375,273)	-
Licence fee income	185,817				185,817		185,817
TOTAL REVENUE	24,520,067	2,533,411	2,212,607	2,046,092	31,312,177	(375,273)	30,936,904
SEGMENT PROFIT	6,067,844	442,574	189,760	571,819	7,271,997		7,271,997
Unallocated income							535,440
Unallocated expenses							(232,955)
Share of results of associates							(42,509)
Share of results of joint ventures							27,114
Gains on deemed disposal of partial interest in an associate							
and a joint venture							48,065
Finance costs							(24,891)
Profit before tax							7,582,261

		Bulk pr	oducts				
			Antibiotics	Functional			
	Finished		and	food and	Segment		
	drugs	Vitamin C	others	others	total	Eliminations	Consolidated
	RMB '000	RMB '000	RMB '000	RMB '000	RMB '000	RMB'000	RMB '000
SEGMENT REVENUE							
External sales	22,632,919	2,149,099	1,670,110	1,366,217	27,818,345	_	27,818,345
Inter-segment sales	-	11,537	176,182	28,320	216,039	(216,039)	-
Licence fee income	48,525				48,525		48,525
TOTAL REVENUE	22,681,444	2,160,636	1,846,292	1,394,537	28,082,909	(216,039)	27,866,870
SEGMENT PROFIT	5,216,239	741,808	143,110	315,597	6,416,754		6,416,754
Unallocated income							479,651
Unallocated expenses							(101,453)
Share of results of associates							(23,894)
Share of results of joint ventures							46,337
Gain on deemed disposal of							
partial interest in an associate							13,092
Gain on disposal of a joint venture							24,273
Finance costs							(7,664)
Profit before tax							6,847,096

Segment profit represents the profit earned by each segment without allocation of interest income, fair value changes on structured bank deposits, fair value changes on financial assets measured at fair value through profit or loss ("FVTPL"), finance costs, central administrative expenses, share of results of associates and joint ventures, gain on deemed disposal of partial interest in an associate and a joint venture and gain on disposal of a joint venture. This is the measure reported to the CODM for the purposes of resource allocation and performance assessment.

Inter-segment sales are charged at prevailing market rates.

The CODM makes decisions according to operating results of each segment. No analysis of segment asset and segment liability is presented as the CODM does not regularly review such information for the purposes of resources allocation and performance assessment. Therefore, only segment revenue and segment results are presented.

#### Geographical information

Information about the Group's revenue from external customers is presented based on the geographical location of customers:

	2022	2021
	<i>RMB'000</i>	RMB '000
$T_{1}$ , $D_{2}$ , $D_{2}$ , $D_{2}$ , $D_{1}$ , $C_{1}$ , $C_{2}$ , $C_{1}$ , $C_{2}$ , $C$	26 120 400	24 288 7(0
The People's Republic of China (the "PRC") (country of domicile)	26,139,499	24,288,769
Other Asian regions	1,735,668	1,474,553
Americas	1,509,755	1,159,269
Europe	1,268,015	700,267
Others	283,967	244,012
	30,936,904	27,866,870

The Group's operations are substantially based in the PRC and majority of the Group's non-current assets are located in the PRC. Therefore, no further analysis of geographical information is presented.

None of the Group's customers contributed over 10% of the total revenue of the Group for both years.

#### 4. **Profit for the Year**

	2022	2021
	RMB'000	RMB '000
Profit for the year has been arrived at after charging (crediting):		
Staff costs, including directors' and chief executive's remuneration		
	4,307,962	3,456,607
contribution to retirement benefit schemes	254,686	212,608
— employee share-based compensation benefits (note a)	160,726	17,732
Total staff costs	4,723,374	3,686,947
Depreciation of property, plant and equipment	802,592	700,408
Depreciation of right-of-use assets	152,869	137,983
Depreciation of investment property	2,126	1,719
Amortisation of intangible assets	90,352	25,361
Total depreciation and amortisation	1,047,939	865,471
Auditor's remuneration	7,806	9,941
Government grant income (included in other income)	(195,005)	(96,252)
Impairment losses (reversed) recognised under expected credit		
loss model (included in other gains or losses)	(25,734)	4,070
Impairment loss recognised on intangible asset		
(included in other expenses)	72,105	50,000
Interest income on bank balances (included in other income)	(242,528)	(183,240)
Fair value gain on financial assets measured at FVTPL		
(included in other gains or losses)	(100,905)	(205,040)
Fair value gain on structured bank deposits		
(included in other gains or losses)	(117,435)	(81,532)
Loss on disposal of property, plant and equipment		
(included in other gains or losses)	7,361	10,786
Net foreign exchange loss (included in other gains or losses)	(118,127)	35,961

#### Notes:

- (a) The amount mainly included employee share-based compensation expenses of RMB6,904,000 in respect of share awards granted under the Share Award Scheme of the Company and RMB149,780,000 in respect of share awards granted by a shareholder of the Company involving the existing shares of the Company held by the shareholder.
- (b) Cost of inventories recognised as an expense approximated cost of sales as shown in the consolidated statement of profit or loss and other comprehensive income for the years ended 31 December 2022 and 2021.

#### 5. Income Tax Expense

	2022	2021
	<i>RMB'000</i>	RMB'000
Current taxation:		
— PRC Enterprise Income Tax	1,189,308	880,441
- PRC withholding tax on dividends distributed by subsidiaries	133,187	94,750
— United States of America ("USA") Federal and State Income tax	12,965	6,787
	1,335,460	981,978
Deferred taxation –	14,751	176,994
=	1,350,211	1,158,972

The calculation of Hong Kong Profits Tax for the Company and its subsidiaries incorporated in Hong Kong is based on the prevailing tax rates in Hong Kong. No Hong Kong Profits Tax has been recognised as the Company and its subsidiaries incorporated in Hong Kong had no assessable profits for both years.

The basic tax rate of the Company's PRC subsidiaries is 25% under the law of the PRC on Enterprise Income Tax (the "EIT Law") and implementation regulations of the EIT Law. Certain subsidiaries of the Company are qualified as advanced technology enterprises and have obtained approvals from the relevant tax authorities for the applicable tax rate reduced to 15% up to 2023.

The calculation of USA Federal and State Income Tax is based on the prevailing tax rates in the USA.

#### 6. Earnings Per Share

The calculation of the basic and diluted earnings per share attributable to the owners of the Company is based on the following data:

	2022 <i>RMB'000</i>	2021 <i>RMB</i> '000
<b>Earnings</b> Earnings for the purpose of basic and diluted earnings per share	6,091,390	5,605,185
Number of shares	2022 '000	2021 '000
Weighted average number of ordinary shares for the purpose of basic earnings per share	11,917,204	11,953,486
Effect of dilutive potential ordinary shares: Unvested shares under the Company's share award scheme	1,319	353
Weighted average number of ordinary shares for the purpose of diluted earnings per share	11,918,523	11,953,839

The weighted average numbers of ordinary shares for the calculation of basic earnings per share for both periods have been adjusted for the shares held by the trustee pursuant to the share award scheme of the Company.

#### 7. Dividends

	2022 RMB'000	2021 <i>RMB</i> '000
Dividends recognised as distribution during the year:		
Interim dividend paid:		
2022: HK10 cents (approximately RMB9.0 cents) (2021: HK8 cents (approximately RMB6.6 cents)) per share	1,079,240	705 058
Final dividend paid:	1,079,240	795,058
2021: HK10 cents (approximately RMB8.6 cents)		
(2020: HK9 cents (approximately RMB7.5 cents)) per share	1,020,529	898,320
Less: Dividend for shares held under Share Award Scheme	(2,808)	(2,615)
	2,096,961	1,690,763

The final dividend for current year proposed after the end of the reporting period has not been recognised as a liability at the end of the reporting period.

#### 8. Trade Receivables

	2022 <i>RMB'000</i>	2021 <i>RMB</i> '000
Trade receivables Less: allowance for impairment	3,961,692 (23,725)	3,358,607 (49,459)
	3,937,967	3,309,148

The Group allows a general credit period of 90 days to its trade customers. The following is an aged analysis of trade receivables (net of allowance for impairment) at the end of the reporting period presented based on the invoice dates which approximated the respective revenue recognition dates:

	2022 <i>RMB'000</i>	2021 <i>RMB</i> '000
0 to 90 days	3,664,707	3,122,761
91 to 180 days	261,185	175,494
181 to 365 days	9,562	8,578
More than 365 days	2,513	2,315
	3,937,967	3,309,148

Trade receivables with aggregate carrying amount of RMB273,260,000 (2021: RMB186,387,000) are past due as at the reporting date. The amounts are not considered as in default because there has not been significant change in credit quality and the amounts are still considered recoverable. The Group does not hold any collateral or other credit enhancements over these balances nor does it has a legal right of offset against any amounts owed by the Group to the counterparty.

#### 9. Deposits, Prepayments and Other Receivables

	2022 <i>RMB</i> '000	2021 <i>RMB</i> '000
Prepayments for raw materials and		
research and development expenses	207,224	177,753
Prepayment for acquisition of intangible assets	150,000	304,289
Deposits paid for property, plant and equipments and		
right-of-use assets	646,570	265,582
Other taxes recoverable	189,037	199,534
Others	296,963	203,138
	1,489,794	1,150,296
Analysed as:		
Current	693,224	580,425
Non-current	796,570	569,871
	1,489,794	1,150,296

#### 10. Bills Receivables

All bills receivables of the Group are with a maturity period of less than 365 days (2021: less than 365 days) and not yet due at the end of the reporting period. The management considers the default rate is low based on historical information, experience and forward looking information that is available without undue cost of effort.

#### 11. Trade Payables

The following is an aged analysis of trade payables at the end of the reporting period presented based on the invoice dates:

	2022 <i>RMB'000</i>	2021 <i>RMB</i> '000
0 to 90 days	1,333,746	1,262,830
91 to 180 days	51,978	82,438
More than 180 days	122,262	136,091
	1,507,986	1,481,359

The general credit period on purchases of goods is up to 90 days (2021: 90 days). The Group has financial risk management policies in place to ensure that all payables are settled within the credit timeframe.

#### 12. Other Payables

	2022 RMB'000	2021 <i>RMB</i> '000
Other taxes payable	181,238	102,507
Payables arising from construction and		
acquisition of property, plant and equipment	818,967	790,696
Deferred government grants	411,958	467,545
Salaries, wages and staff welfare payable	546,927	416,749
Selling expense payable	3,049,003	2,500,679
Research and development expense payable	126,516	143,644
Others	491,824	509,207
	5,626,433	4,931,027
Analysed as:		
Current	5,355,516	4,680,829
Non-current — deferred government grants	270,917	250,198
	5,626,433	4,931,027

#### 13. Bills Payables

All bills payables of the Group are aged within 365 days (2021: 365 days) and not yet due at the end of the reporting period.

# SUSTAINABLE DEVELOPMENT STRATEGIES

The Group will continue to pursue the development strategies of (i) active development of innovative drug business; (ii) continuation of products internationalization; and (iii) consolidation of leadership in bulk drug business in order to achieve long-term sustainable growth.

#### **CORPORATE GOVERNANCE**

The Company has complied with all the code provisions in the Corporate Governance Code (the "Code") contained in Appendix 14 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "Listing Rules") throughout the year ended 31 December 2022 except the deviation from code provision C.2.1 as set out below.

Code provision C.2.1 of the Code stipulates that the roles of chairman and chief executive should be separate and should not be performed by the same individual. During the period from 1 January 2022 to 27 May 2022, Mr. Cai Dongchen, the Company's Chairman, also assumed the role of chief executive of the Company. The Company believes that vesting both roles in Mr. Cai would allow for more effective planning and execution of business strategies. As all major decisions are made in consultation with members of the Board, the Company believes that there is adequate balance of power and authority in place. On 27 May 2022, Mr. Zhang Cuilong was appointed as the Chief Executive Officer in place of Mr. Cai Dongchen, and Mr. Cai Dongchen would remain as an executive director and Chairman of the Company. Thereafter, Mr. Cai Dongchen no longer performs the roles of chairman and chief executive concurrently and the Company has complied with code provision C.2.1 of the Code.

Following the resignation of Ms. Wu Guizhen as an independent non-executive director on 1 August 2022, the Company has a single gender board which does not meet the requirement under Rule 13.92 of the Listing Rules. With the appointment of Ms. Li Quan as independent non-executive director on 8 November 2022, the Board has achieved gender diversity and thus fulfils the requirement under Rule 13.92 of the Listing Rules.

#### **REVIEW OF ANNUAL RESULTS**

The consolidated financial statements of the Company and its subsidiaries for the year ended 31 December 2022 have been reviewed by the Audit Committee of the Company and audited by the Company's auditor.

# **CLOSURE OF REGISTER OF MEMBERS**

The register of members of the Company will be closed from Thursday, 25 May 2023 to Wednesday, 31 May 2023, both days inclusive, during which period no transfer of shares will be effected. In order to determine the identity of members who are entitled to attend and vote at the annual general meeting to be held on Wednesday, 31 May 2023, all share transfer documents accompanied by the relevant share certificates must be lodged with the Company's share registrar, Tricor Secretaries Limited, at 17/F, Far East Finance Centre, 16 Harcourt Road, Hong Kong for registration not later than 4:30 p.m. on Wednesday, 24 May 2023.

The register of members of the Company will be closed from Wednesday, 7 June 2023 to Friday, 9 June 2023, both dates inclusive, during which period no transfer of shares will be effected. In order to qualify for the proposed final dividend, all share transfer documents accompanied by the relevant share certificates must be lodged with the Company's share registrar, Tricor Secretaries Limited, at 17/F, Far East Finance Centre, 16 Harcourt Road, Hong Kong, for registration not later than 4:30 p.m. on Tuesday, 6 June 2023.

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

During the year, the Company repurchased its own shares on The Stock Exchange of Hong Kong Limited as follows:

	Number of shares	Highest purchase price	Lowest purchase price	Aggregate consideration (before
Date	repurchased	per share HK\$	per share HK\$	expenses) HK\$
January 2022	2,054,000	8.49	8.44	17,409,000

The shares repurchased were cancelled upon delivery of the share certificates in January 2022.

The repurchase of shares was made for the benefit of the shareholders with a view to enhancing the earnings per share as well as maximizing shareholders' return.

Saved as disclosed above, neither the Company nor any of its subsidiaries has purchased, sold or redeemed any of the listed securities of the Company during the year.

By order of the Board CAI Dongchen Chairman

Hong Kong, 22 March 2023

As at the date of this announcement, the Board comprises Mr. CAI Dongchen, Mr. ZHANG Cuilong, Mr. WANG Zhenguo, Mr. PAN Weidong, Mr. WANG Huaiyu, Dr. LI Chunlei, Dr. WANG Qingxi, Mr. CHAK Kin Man and Dr. JIANG Hao as executive directors; and Mr. WANG Bo, Mr. CHEN Chuan, Prof. WANG Hongguang, Mr. AU Chun Kwok Alan, Mr. LAW Cheuk Kin Stephen and Ms. LI Quan as independent non-executive directors.