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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)

# QUARTERLY RESULTS FOR THE THREE MONTHS ENDED 31 MARCH 2023

The Board of Directors of CSPC Pharmaceutical Group Limited (the "Company") is pleased to announce the unaudited consolidated results of the Company and its subsidiaries (the "Group") for the three months ended 31 March 2023.

FINANCIAL HIGHLIGHTS (in RMB'000, unless otherwise stated)				
	Three months ended 31 March			
	2023	2022	Change	
Revenue by business units: Finished drugs Bulk products Functional food and others	6,421,510 1,016,739 615,020	6,302,393 1,066,210 505,290	+1.9% -4.6% +21.7%	
Total revenue	8,053,269	7,873,893	+2.3%	
Profit attributable to shareholders As reported Underlying profit (note)	1,428,843 1,544,901	1,404,519 1,543,041	+1.7% +0.1%	
Earnings per shares (RMB cents) Basic Diluted	11.99 11.99	11.79 11.79	+1.7% +1.7%	

Note: Underlying profit attributable to shareholders, a non-HKFRS measure, represents profit before taking into account fair value loss on financial assets measured at FVTPL and employee share-based compensation expense. Reconciliation between the reported and underlying profit is provided on page 6 of this announcement.

## **RESULTS OF FIRST QUARTER 2023**

Revenue was RMB8,053 million, an increase of 2.3% compared with the same period in 2022.

Profit attributable to shareholders was RMB1,429 million, an increase of 1.7% compared with the same period in 2022.

Underlying profit attributable to shareholders, excluding fair value loss on financial assets measured at fair value through profit or loss ("FVTPL") and employee share-based compensation expense, was RMB1,545 million, an increase of 0.1% as compared with the same period in 2022.

#### **BUSINESS REVIEW**

# 1. Finished Drug Business

The finished drug business recorded revenue of RMB6,422 million (including licence fee income of RMB34.7 million) for the period, representing an increase of 1.9% year-on-year. Affected by the Covid disruption at the beginning of the year and the lowered price of Keaili after the centralised procurement renewal, sales of oncology product were weaker in the first quarter of 2023. On the other hand, the continuous ramp-up of new products has driven sales growth.

Sales of products by major therapeutic areas for the period are as follows:

Therapeutic Area	Sales	Change		
	(RMB' million)			
Nervous system	2,125	+9.8%		
Oncology	1,444	-33.1%		
Anti-infectives	1,230	+36.7%		
Cardiovascular	590	-24.9%		
Respiratory system	498	+271.5%		
Digestion and metabolism	196	+19.3%		
Others	304	+35.2%		

# 2. Bulk Product Business

The bulk products business recorded sales of RMB1,017 million for the period, a decrease of 4.6% year-on-year. Sales of vitamin C products were RMB551 million, down 21.3% compared with the first quarter of 2022. The decrease in sales and operating profit was primarily due to the downward trend in price since the third quarter of 2022. Driven by sales volume growth, sales of antibiotic products increased by 27.3% to RMB466 million.

# 3. Functional Food and Others Business

Mainly driven by the growth of caffeine products, revenue of the functional food and other business increased to RMB615 million, an increase of 21.7% as compared with the first quarter of 2022.

#### 4. SARS-CoV-2 mRNA vaccine

In March 2023, the SARS-CoV-2 mRNA vaccine (brand name: Duentai (度恩泰)) containing BA.5 key mutations independently developed by the Group has been included for emergency use in China for the prevention of COVID-19 caused by the infection of SARS-CoV-2. The vaccine adopts advanced technology with independent intellectual property rights, with the advantages of achieving higher production capacity, better process reproducibility, large-scale production and scale-up more easily. Also, it has good consistency of product quality and stability, and can be stored at 2-8°C for a long time. The Work Plan for Vaccination against Recent COVID-19 Infections issued by the Joint Prevention and Control Mechanism of the State Council on 10 April indicates that the focus of vaccination at this stage is to fill the gap of immunity level among different target groups and further reduce the risk of severe illness and death, and recommends the Group's SARS-CoV-2 mRNA vaccine as a priority for use as a booster for population aged 18 years or above. On 13 May, the first dose of Duentai was administered at a community healthcare centre in Shijiazhuang, the capital of Hebei Province, marking the launch of the nationwide promotion of SARS-CoV-2 mRNA vaccination.

The Group will continue to promote the development of new generations of SARS-CoV-2 mRNA vaccines against mutated strains to deal with the threat posed by the continuous mutation of the virus on people's life and health.

# 5. Research and Development

R&D expenses were RMB1,008 million for the period, an increase of 11.8% year-on-year, accounting for approximately 15.7% of the revenue of the finished drug business.

## Regulatory Updates:

#### China

- In March 2023, application for marketing approval of enlonstobart for injection (recombinant fully human anti-PD-1 monoclonal antibody) (SG001) for the treatment of recurrent or metastatic cervical cancer patients with positive PD-L1 expression who have failed at least first-line platinum-based chemotherapy was accepted 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 accepted.
- 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.

- In April 2023, application for marketing approval of prusogliptin tablets (DBPR108) for the treatment of type 2 diabetes was accepted.
- 6 innovative drugs candidates have obtained clinical trial approval for their first indications:
  - highly selective PRMT5 inhibitor SYH2045 for the treatment of advanced malignant tumors;
  - meloxicam nanocrystal injection for the treatment of moderate-to-severe pain for adults;
  - clevidipine injectable emulsion for the treatment of hypertension;
  - octreotide long-acting injection for the treatment of acromegaly;
  - NBL-020 (TNFR2 monoclonal antibody) for the treatment of advanced solid tumors;
  - antibody-drug conjugate SYS6010 for the treatment of advanced solid tumors.
- 7 clinical trial approvals obtained for additional indications of innovative drugs candidates:
  - SG001 for the first-line treatment of cervical cancer;
  - SG001 in combination with docetaxel for injection (albumin-bound) for the perioperative treatment of non-small cell lung cancer;
  - SG001 in combination with docetaxel for injection (albumin-bound) and cisplatin with concomitant radiotherapy for the treatment of locally advanced esophageal cancer;
  - docetaxel for injection (albumin-bound) for the neoadjuvant treatment of luminal breast cancer;
  - docetaxel for injection (albumin-bound) in combination with KN026 for injection for the first-line treatment of HER2 positive recurrent metastatic breast cancer;
  - deunirmatrelvir for the prevention of COVID-19;
  - paclitaxel cationic liposome for arterial infusion therapy in patients with advanced solid tumors who failed standard therapy.
- Generic drug apemilast tablets obtained drug registration approval.

### The U.S.

• Antibody-drug conjugate CPO301 obtained clinical trial approval.

# Major Clinical Trials Progress:

• In February 2023, the study results of Mingfule (銘復樂) (recombinant human TNK tissue-type plasminogen activator for injection, rhTNK-tPA) in a Phase III clinical study (TRACE-2) for the treatment of acute ischemic stroke were published in The Lancet (IF: 202.731), an international medical journal, demonstrating that Mingfule is non-inferior to alteplase in efficacy, while the safety profile is similar to alteplase.

- In March 2023, the first patient was dosed in a Phase III clinical trial conducted in China of Duoenda (多恩達) (mitoxantrone hydrochloride liposome injection) for the treatment of patients with recurrent metastatic nasopharyngeal carcinoma who have failed platinum-based therapy.
- In March 2023, a Phase III therapeutic bioequivalence study of recombinant anti-IgE monoclonal antibody for injection (SYSA1903) in comparison to the originator drug for the treatment of patients with chronic spontaneous urticaria who remain symptomatic despite H1 antihistamine treatment met its predefined endpoint.
- In March 2023, a randomized, double-blind and placebo-controlled Phase II/III clinical study was initiated on the efficacy and safety of CM310 (IL-4Rα antibody) for the treatment of moderate-to-severe asthma.
- In March 2023, a randomized, double-blind and placebo-controlled Phase II clinical study was initiated on the efficacy and safety of CM326 (TSLP antibody) for the treatment of moderate-to-severe asthma.

#### Patents:

• 9 international PCT applications and 106 patent applications (35 domestic and 71 overseas) have been filed, and 16 patents (5 domestic and 11 overseas) have been granted.

# 6. Business Development

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 U.S., 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.

#### 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:

	Three months ended 31 March		
	2023	2022	
	(RMB'000)	(RMB '000)	
Profit attributable to shareholders	1,428,843	1,404,519	
Adjustment for:			
- Fair value loss on financial assets measured at FVTPL(note a)	70,435	138,640	
- Employee share-based compensation expense (note b)	50,523	5,918	
– Effect of corresponding income tax	(4,900)	(6,036)	
Underlying profit attributable to shareholders	1,544,901	1,543,041	

#### Notes:

- (a) The fair value loss 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 recognized in the current period, RMB50,045,000 was in respect of share awards granted to selected employees of the Group by Key Honesty Limited, a shareholder of the Company (first quarter 2022: nil).

# CONDENSED CONSOLIDATED INCOME STATEMENT (UNAUDITED)

For the three months ended 31 March 2023

	Three months ended 31 March		
	2023	2022	
	RMB'000	RMB'000	
Revenue	8,053,269	7,873,893	
Cost of sales	(2,534,670)	(2,062,931)	
Gross profit	5,518,599	5,810,962	
Other income	117,770	83,546	
Other gains or losses, net	(59,269)	(139,087)	
Selling and distribution expenses	(2,487,600)	(2,823,884)	
Administrative expenses	(263,080)	(260,296)	
Research and development expenses	(1,007,649)	(901,517)	
Other expenses	(16,644)	(9,254)	
Share of results of associates	(12,045)	(8,464)	
Share of results of joint ventures	(4,692)	14,774	
Finance costs	(4,429)	(2,858)	
Profit before tax	1,780,961	1,763,922	
Income tax expense	(311,861)	(329,631)	
Profit for the period	1,469,100	1,434,291	
Profit for the period attributable to:			
Owners of the Company	1,428,843	1,404,519	
Non-controlling interests	40,257	29,772	
	1,469,100	1,434,291	
	RMB cents	RMB cents	
Earnings per share			
— Basic	11.99	11.79	
— Diluted	11.99	11.79	

# CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME (UNAUDITED)

For the three months ended 31 March 2023

	Three months ended 31 March		
	2023	2022	
	RMB'000	RMB'000	
Profit for the period	1,469,100	1,434,291	
Other comprehensive (expense) income			
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	1,890	(288)	
Item that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	(3,010)	6,452	
Other comprehensive (expense) income for the period,			
net of income tax	(1,120)	6,164	
Total comprehensive income for the period	1,467,980	1,440,455	
Total comprehensive income for the period attributable to:			
Owners of the Company	1,427,723	1,410,683	
Non-controlling interests	40,257	29,772	
	1,467,980	1,440,455	

#### **NOTES:**

## 1. Principal Accounting Policies

The principal accounting policies and methods of computation used in the preparation of the financial data for the three months ended 31 March 2023 are consistent with those followed in the preparation of the Group's financial statements for the year ended 31 December 2022.

#### 2. Revenue and Segment Information

Information reported to executive directors, being the chief operating decision maker, for the purposes of resources allocation and assessment of segment performance focuses on types of goods delivered. The reportable segments of the Group are as follows:

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

Bulk products of anhydrous glucose and acarbose were included in the Bulk Products (antibiotics and others) segment in prior years. With the aim of strengthening synergy in business development, the Group's operating segments have been reorganized. Bulk products of anhydrous glucose and acarbose are now being managed and reported in the Functional Food segment. Comparative figures have been restated to conform with current period's presentation.

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

Three months ended 31 March 2023:

				Functional			
	Finished	Finished Bulk products		food and	Segment		
	drugs	Vitamin C	Antibiotics	others	total	Eliminations	Consolidated
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
SEGMENT REVENUE							
External sales	6,386,810	551,046	465,693	615,020	8,018,569	_	8,018,569
Inter-segment sales	_	2,287	86,060	66,768	155,115	(155,115)	_
Licence fee income	34,700				34,700		34,700
TOTAL REVENUE	6,421,510	553,333	551,753	681,788	8,208,384	(155,115)	8,053,269
SEGMENT PROFIT	1,620,650	31,365	26,372	143,627	1,822,014		1,822,014
Unallocated income							95,001
Unallocated expenses							(114,888)
Share of results of associates							(12,045)
Share of results of joint ventures							(4,692)
Finance costs							(4,429)
Profit before tax							1,780,961

#### Three months ended 31 March 2022:

	Finished	Bulk pr	oducts	Functional food and	Segment		
	drugs	Vitamin C	Antibiotics	others	total	Eliminations	Consolidated
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
SEGMENT REVENUE							
External sales	6,302,393	700,272	365,938	505,290	7,873,893	_	7,873,893
Inter-segment sales		1,038	69,520	22,712	93,270	(93,270)	
TOTAL REVENUE	6,302,393	701,310	435,458	528,002	7,967,163	(93,270)	7,873,893
SEGMENT PROFIT	1,578,018	146,415	30,823	118,614	1,873,870		1,873,870
Unallocated income							56,568
Unallocated expenses							(169,968)
Share of results of associates							(8,464)
Share of results of joint ventures							14,774
Finance costs							(2,858)
Profit before tax							1,763,922

Segment profit represents the profit earned by each segment without allocation of interest income, fair value gain on structured bank deposits, fair value loss on financial assets measured at FVTPL, finance costs, central administrative expenses and share of results of associates and joint ventures. This is the measure reported to the executive directors for the purposes of resources allocation and performance assessment.

Inter-segment sales are charged at prevailing market rates.

#### 3. Profit for the Period

Three months ended 31 March 2023 2022 RMB'000 RMB'000 Profit for the period has been arrived at after charging (crediting): Depreciation of property, plant and equipment 202,096 197,324 Depreciation of right-of-use assets 42,112 32,904 Depreciation of investment property 826 430 Amortisation of intangible assets 13,041 8,336 Total depreciation and amortisation 258,075 238,994 Fair value loss on financial assets measured at FVTPL (included in other gains or losses) 70,435 138,640 Fair value gain on structured bank deposits (included in other gains or losses) (42,348)(19,183)Government grant income (included in other income) (39,944)(13,182)Interest income on bank balances (included in other income) (52,478)(41,507)

*Note:* Cost of inventories recognised as an expense approximated cost of sales as shown in the condensed consolidated income statement.

32,133

16,413

Net foreign exchange loss (included in other gains or losses)

#### **REVIEW OF RESULTS**

The financial data for the three months ended 31 March 2023 is based on the internal records and management accounts of the Group and has not been reviewed or audited by the external auditor of the Company.

By order of the Board

CSPC Pharmaceutical Group Limited

CAI Dongchen

Chairman

Hong Kong, 25 May 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.