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 NINE MONTHS ENDED 30 SEPTEMBER 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 nine months ended 30 September 2023.

FINANCIAL HIGHLIGHTS

(in RMB'000, unless otherwise stated)

	Nine months ended 30 September		
	2023 (Unaudited)	2022 (Unaudited)	Change
Revenue by business units:			
Finished drugs	**19,338,055**	18,612,579	+3.9%
Bulk products	**2,875,233**	3,133,308	-8.2%
Functional food and others	**1,651,788**	1,749,631	-5.6%
Total revenue	**23,865,076**	23,495,518	+1.6%
Profit attributable to shareholders			
As reported	**4,494,641**	4,467,837	+0.6%
Underlying profit *(Note)*	**4,715,187**	4,623,720	+2.0%
Earnings per share *(RMB cents)*			
Basic	**37.84**	37.49	+0.9%
Diluted	**37.83**	37.49	+0.9%

Note: Underlying profit attributable to shareholders, a non-HKFRS measure, represents profit before taking into account fair value loss on financial assets measured at fair value through profit or loss, employee share-based compensation expense and gain on deemed disposal of partial interest in an associate. Reconciliation between the reported and underlying profit is provided on pages 7 to 8 of this announcement.

RESULTS FOR THE FIRST NINE MONTHS OF 2023

Revenue amounted to RMB23,865 million, an increase of 1.6% compared to the same period last year.

Underlying profit attributable to shareholders amounted to RMB4,715 million, an increase of 2.0% compared to the same period last year.

Profit attributable to shareholders amounted to RMB4,495 million, an increase of 0.6% compared to the same period last year.

BUSINESS REVIEW

1. Finished Drug Business

The finished drug business maintained stable growth with revenue amounting to RMB19,338 million (including license fee income of RMB35 million) for the period, an increase of 3.9% year-on-year. The decrease in sales of oncology products was primarily due to the lowered price of Keaili after the centralized drug procurement renewal. On the other hand, the continuous ramp-up in sales of newly launched products has become a new driver of growth. Sales by major therapeutic areas are as follows:

Therapeutic Area	**Sales** *(RMB' million)*	**Change**
Nervous system	6,926	+15.2%
Oncology	4,624	-21.2%
Anti-infectives	3,143	+18.8%
Cardiovascular	1,836	-15.5%
Respiratory system	1,159	+163.5%
Digestion and metabolism	662	+17.4%
Others	953	+31.3%

2. Bulk Product Business

The bulk product business recorded sales of RMB2,875 million for the period, a decrease of 8.2% year-on-year. Sales of vitamin C products decreased by 23.5% to RMB1,513 million, mainly due to the weakening price of vitamin C products. Meanwhile, sales of antibiotic products increased by 17.9% to RMB1,362 million, driven by the growth in sales volume.

3. Functional Food Business and Others

Functional food business and others recorded sales of RMB1,652 million for the period, a decrease of 5.6% year-on-year. There was certain decline in the prices of caffeine products during the period, with sales volume maintaining a stable growth.

4. Research and Development

R&D expenses for the period amounted to RMB3,678 million, an increase of 25.9% year-on-year, accounting for approximately 19.0% of the revenue of the finished drug business. Currently, approximately 60 key drug candidates have entered clinical trial or registration stage, of which 7 have filed marketing approval application, and 17 have entered pivotal clinical trial or were about to file marketing approval application.

Regulatory Updates:

China

- The SARS-CoV-2 mRNA vaccine (brand name: Duentai) containing BA.5 key mutations independently developed by the Group was included for emergency use in China for the prevention of COVID-19 caused by the infection of SARS-CoV-2 in March 2023.

- Class 1 new drug Narlumosbart for Injection (JMT103) (brand name: Jinlisheng (津立生)) for the treatment of giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity obtained marketing approval in September 2023.

- Irinotecan Hydrochloride Liposome Injection (brand name: Duoenyi (多恩益)), in combination with 5-fluorouracil (5-FU) and leucovorin (LV), for the treatment of patients with metastatic pancreatic cancer after disease progression following gemcitabine-based threapy obtained marketing approval in September 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 marketing approval of Prusogliptin Tablets (DBPR108) for the treatment of type 2 diabetes was accepted in April 2023.

- Biologic license application of Omalizumab for Injection for the treatment of chronic spontaneous urticaria was accepted in June 2023.

- Biologic license application of Batoclimab (HBM9161) for the treatment of generalized myasthenia gravis (gMG) was accepted in June 2023.

- KN026 (recombinant humanised anti-HER2 bispecific antibody for injection) for the intended indication of combination chemotherapy for the treatment of HER-2 positive locally advanced, recurrent or metastatic gastric cancer (including gastroesophageal junction cancer) who have failed standard first-line treatment (trastuzumab combination chemeotheraphy) was granted Breakthrough Therapy Designation in November 2023.

- Since the beginning of 2023, 15 innovative drug candidates have obtained clinical trial approval for their first indication and 13 additional indications have obtained clinical trial approval:

First Indication

Drug candidate	**Indication**
SYH2045 (PRMT5 inhibitor)	Advanced malignant tumors
Meloxicam nanocrystal injection	Moderate-to-severe pain in adults
Clevidipine injectable emulsion	Hypertension
Octreotide long-acting injection	Acromegaly
NBL-020 (TNFR2 monoclonal antibody)	Advanced solid tumors
SYS6010 (ADC)	Advanced solid tumors
SYH2051 (ATM inhibitor)	Solid tumors
JMT203 (GFRAL monoclonal antibody)	Tumor cachexia
Semaglutide injection	Type 2 diabetes
NBL-028 (CLDN6-CD137 bispecific antibody)	Advanced tumors
SYS6006.32 (bivalent COVID-19 mRNA vaccine)	Prevention of COVID-19
Secukinumab injection (IL-17A)	Moderate-to-severe plaque psoriasis
SYS6011	Solid tumors
SYH2038 (SOS1)	Advanced solid tumors
SYH2053 injection	Primary hypercholesterolaemia or mixed dyslipidaemia in adults

Additional Indication

Drug candidate	Indication
KN026 for injection	In combination with docetaxel (albumin-bound) for the treatment of first-line HER2 positive recurrent and metastatic breast cancer
Docetaxel for injection (albumin-bound)	In combination with SG001 (PD-1) for the perioperative treatment of non-small cell lung cancer
Docetaxel for injection (albumin-bound)	In combination with SG001 (PD-1) and cisplatin with concomitant radiotherapy for the treatment of locally advanced esophageal cancer
Docetaxel for injection (albumin-bound)	In combination with cisplatin with concomitant radiotherapy for the treatment of locally advanced unresectable non-small cell lung cancer
Docetaxel for injection (albumin-bound)	Neoadjuvant therapy for luminal breast cancer
SYH2055 tablets	Prevention of COVID-19
Enlonstobart for injection (SG001) (PD-1)	In combination with chemotherapy for first-line cervical cancer
CM326	Chronic obstructive pulmonary disease
CM310	Chronic obstructive pulmonary disease
Paclitaxel cationic liposome for injection	Arterial perfusion therapy in patients with advanced solid tumors who failed standard treatment
Simmitinib tablets	In combination with SG001 (PD-1) for the treatment of solid tumors
JMT101 injection	In combination with SG001 and irinotecan for treatment of colorectal cancer
ALMB-0166	Acute ischemic stroke

- Since the beginning of 2023, 7 generic drugs have obtained drug registration approvals, namely Apremilast Tablets, Mirabegron Extended-release Tablets, Paliperidone Extended-release Tablets, Tedizolid Phosphate for Injection, Rabeprazole Sodium Enteric-coated Tablets, Desvenlafaxine Succinate Extended-release Tablets and Sacubitril Valsartan Sodium Tablets.

North America

- CPO301 (antibody-drug conjugate) obtained clinical trial approval in the US in April 2023.
- CPO301 (antibody-drug conjugate) was granted Fast Track Designation in the US in June 2023.
- CPO301 (antibody-drug conjugate) obtained clinical trial approval in Canada in June 2023.

Major Clinical Trials Progress:

- In February 2023, the study results of Mingfule (recombinant human TNK tissue-type plasminogen activator for injection, rhTNK-tPA) in a Phase III clinical trial 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 and the safety profile is similar to alteplase.

- In March 2023, the first patient was dosed in a phase III clinical trial of Duoenda (mitoxantrone hydrochloride liposome injection) in China 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 Omalizumab 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, placebo-controlled Phase II/III clinical study on the efficacy and safety of CM310 (IL-4Rα antibody) for the treatment of moderate to severe asthma was launched, enrolment is ongoing with the first patient enrolled in April 2023.

- In March 2023, a randomized, double-blind, placebo-controlled Phase II clinical study on the efficacy and safety of CM326 (TSLP antibody) for the treatment of moderate to severe asthma was launched, enrolment is ongoing with the first patient enrolled in May 2023.

- In June 2023, the clinical data of ALMB-0168 (Cx43 hemichannel antibody agonist) for the treatment of osteosarcoma was announced at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. Preliminary results indicate that ALMB-0168 demonstrates encouraging efficacy and tolerable safety in patients with metastatic or unresectable osteosarcoma after receiving standard chemotherapy in a Phase I dose-escalation trial.

- In June 2023, the Phase I clinical results of SYSA1801 (CLDN18.2 ADC) for the treatment of advanced malignant solid tumors with CLDN18.2 expression were presented at the 2023 ASCO Annual Meeting. Preliminary results indicate that SYSA1801 demonstrates promising anti-tumor efficacy in treating advanced malignant solid tumors with CLDN18.2 expression, especially in gastric cancer.

- In October 2023, the Phase I clinical results of SYHA1813 in treating patients with recurrent or advanced solid tumors were presented at the Mini Oral Session of the European Society for Medical Oncology (ESMO) Congress 2023 (No.: 506MO). The preliminary results indicate that SYHA1813 demonstrates an encouraging objective response and good tolerability in subjects with recurrent meningioma enrolled.

- In October 2023, the Phase I clinical results of DP303c for the treatment of patients with HER2-expressing advanced solid tumors were presented at the Mini Oral Session of the ESMO Congress 2023 (No.: 385MO). The preliminary results indicate that DP303c monotherapy demonstrates significant efficacy, with a good safety profile, for the treatment of HER2-positive advanced solid tumors.

Patents:

- Since the beginning of 2023, a total of 20 international PCT applications have been submitted by the Group, with 182 patent applications filed (108 domestic and 74 overseas). Out of these, 58 patents have been granted (29 domestic and 29 overseas).

Business Development

- In January 2023, the Group entered into an exclusive license agreement with Corbus Pharmaceuticals, Inc., a company based in the US, to out-license the development and commercialization rights of SYS6002 (Nectin-4 ADC) in the US, EU countries, UK, Canada, Australia, Iceland, Liechtenstein, Norway and Switzerland. The Group will receive upfront payments of US$7.5 million and is also entitled 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.

- In June 2023, the Group and Pfizer signed a strategic partnership agreement to launch a local brand of the COVID-19 oral antiviral therapeutic treatment Nirmatrelvir/Ritonavir in China, jointly aiming to improve access of this treatment to Chinese patients.

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-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:

	Nine months ended 30 September	
	2023	2022
	(RMB'000)	*(RMB'000)*
Profit attributable to shareholders	**4,494,641**	4,467,837
Adjustment for:		
– Fair value loss on financial assets measured at FVTPL *(note a)*	**88,932**	26,113
– Employee share-based compensation expenses *(note b)*	**169,297**	132,110
– Gain on deemed disposal of partial interest in an associate	**(32,861)**	–
– Effect of corresponding income tax	**(4,822)**	(2,340)
Underlying profit attributable to shareholders	**4,715,187**	4,623,720

Notes:

(a) 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 expenses recognised for the period, RMB147,926,000 (first nine months of 2022: RMB121,472,000) was in respect of share awards granted to selected employees of the Group by Key Honesty Limited, a shareholder of the Company.

CONDENSED CONSOLIDATED INCOME STATEMENT

For the nine months ended 30 September 2023 – Unaudited

	Nine months ended 30 September	
	2023	2022
	RMB'000	*RMB'000*
Revenue	**23,865,076**	23,495,518
Cost of sales	**(7,072,976)**	(6,413,214)
Gross profit	**16,792,100**	17,082,304
Other income	**464,997**	336,615
Other gains or losses, net	**22,158**	163,260
Selling and distribution expenses	**(7,031,806)**	(8,113,821)
Administrative expenses	**(855,973)**	(874,160)
Research and development expenses	**(3,677,949)**	(2,920,249)
Other expenses	**(81,279)**	(56,964)
Share of results of associates	**(32,970)**	(46,476)
Share of results of joint ventures	**(5,503)**	41,559
Gain on deemed disposal of partial interest in an associate	**32,861**	–
Finance costs	**(16,877)**	(15,000)
Profit before tax	**5,609,759**	5,597,068
Income tax expense	**(964,743)**	(1,026,123)
Profit for the period	**4,645,016**	4,570,945
Profit for the period attributable to:		
Owners of the Company	**4,494,641**	4,467,837
Non-controlling interests	**150,375**	103,108
	4,645,016	4,570,945
	RMB cents	*RMB cents*
Earnings per share		
– Basic	**37.84**	37.49
– Diluted	**37.83**	37.49

CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

For the nine months ended 30 September 2023 – Unaudited

	Nine months ended 30 September	
	2023	2022
	RMB'000	*RMB'000*
Profit for the period	**4,645,016**	4,570,945
Other comprehensive income:		
Item that will not be reclassified to profit or loss:		
Fair value gain on financial assets measured at fair value through other comprehensive income, net of income tax	**4,416**	19,915
Item that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of foreign operations	**4,697**	90,570
Other comprehensive income for the period, net of income tax	**9,113**	110,485
Total comprehensive income for the period	**4,654,129**	4,681,430
Total comprehensive income for the period attributable to:		
Owners of the Company	**4,503,754**	4,578,322
Non-controlling interests	**150,375**	103,108
	4,654,129	4,681,430

NOTES:

1. Principal Accounting Policies

The principal accounting policies and methods of computation used in the preparation of the financial data for the nine months ended 30 September 2023 are consistent with those followed in the preparation of the Group's interim financial statements for the six months ended 30 June 2023.

2. Revenue and Segment Information

(i) Disaggregation of revenue from contracts with customers

	Nine months ended 30 September	
	2023	2022
	RMB'000	*RMB'000*
Sales of goods	**23,830,376**	23,309,701
Licence fee income	**34,700**	185,817
	23,865,076	23,495,518

(ii) Segment information

Information reported to the executive directors, being the chief operating decision makers, for the purpose of resources allocation and assessment of segment performance focuses on types of goods delivered. The Group's reportable segments 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 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 reorganised. Bulk products of anhydrous glucose and acarbose are now being managed and reported in the Functional and 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.

Nine months ended 30 September 2023

	Finished drugs	Bulk products		Functional food and others	Segment total	Eliminations	Consolidated
		Vitamin C	Antibiotics				
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
SEGMENT REVENUE							
External sales	**19,303,355**	**1,512,917**	**1,362,316**	**1,651,788**	**23,830,376**	**–**	**23,830,376**
Inter-segment sales	**–**	**5,664**	**243,739**	**213,627**	**463,030**	**(463,030)**	**–**
License fee income	**34,700**	**–**	**–**	**–**	**34,700**	**–**	**34,700**
TOTAL REVENUE	**19,338,055**	**1,518,581**	**1,606,055**	**1,865,415**	**24,328,106**	**(463,030)**	**23,865,076**
SEGMENT PROFIT	**4,959,021**	**51,528**	**103,584**	**439,527**			**5,553,660**
Unallocated income							**269,273**
Unallocated expenses							**(190,685)**
Share of results of associates							**(32,970)**
Share of results of joint ventures							**(5,503)**
Gain on deemed disposal of partial interest in an associate							**32,861**
Finance costs							**(16,877)**
Profit before tax							**5,609,759**

Nine months ended 30 September 2022 (restated)

	Finished drugs	Bulk products		Functional food and others	Segment total	Eliminations	Consolidated
		Vitamin C	Antibiotics				
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
SEGMENT REVENUE							
External sales	18,426,762	1,977,875	1,155,433	1,749,631	23,309,701	—	23,309,701
Inter-segment sales	—	3,474	160,281	95,717	259,472	(259,472)	—
License fee income	185,817	—	—	—	185,817	—	185,817
TOTAL REVENUE	18,612,579	1,981,349	1,315,714	1,845,348	23,754,990	(259,472)	23,495,518
SEGMENT PROFIT	4,587,188	403,345	89,205	475,920			5,555,658
Unallocated income							241,798
Unallocated expenses							(180,471)
Share of results of associates							(46,476)
Share of results of joint ventures							41,559
Finance costs							(15,000)
Profit before tax							5,597,068

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, and gain on deemed disposal of partial interest in an associate. This is the measure reported to the executive directors for the purposes of resource allocation and performance assessment.

Inter-segment sales are charged at prevailing market rates.

3. Profit Before Tax

	Nine months ended 30 September	
	2023	2022
	RMB'000	*RMB'000*
Profit before tax has been arrived at after charging (crediting):		
Depreciation of property, plant and equipment	**629,108**	585,214
Depreciation of right-of-use assets	**126,669**	110,142
Depreciation of investment property	**2,479**	1,290
Amortisation of intangible assets	**53,594**	33,108
Total depreciation and amortisation	**811,850**	729,754
Employee share-based compensation expenses *(note a)*	**169,297**	132,110
Government grant income (included in other income)	**(168,065)**	(80,578)
Fair value loss on financial assets measured at FVTPL (included in other gains or losses)	**88,932**	26,113
Fair value gain on structured bank deposits (included in other gains or losses)	**(69,400)**	(82,031)
Impairment losses recognised under expected credit loss model (included in other gains or losses)	**13,760**	14,791
Interest income on bank deposits and balances (included in other income)	**(199,693)**	(145,756)
Net foreign exchange gain (included in other gains or losses)	**(77,356)**	(125,359)

Note: (a) The amount mainly included employee share-based compensation expenses of RMB18,916,000 (first nine months of 2022: RMB6,984,000) in respect of share awards granted under the Share Award Scheme of the Company and RMB147,926,000 (first nine months of 2022: RMB121,472,000) in respect of share awards granted to selected employees of the Group by a shareholder of the Company in 2022 involving the existing shares of the Company held by the shareholder.

(b) For the nine months ended 30 September 2023 and 2022, cost of inventories recognised as expense approximated cost of sales as shown in the condensed consolidated statement of profit or loss and other comprehensive income.

REVIEW OF RESULTS

The financial data for the nine months ended 30 September 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, 30 November 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.