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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 2024

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 2024.

FINANCIAL HIGHLIGHTS (in RMB'000, unless otherwise stated)	Three months ended 31 March			
	2024 (unaudited)	2023 (unaudited)	Change	
Revenue by business units:	((
Finished drugs	7,561,303	6,421,510	+17.7%	
Bulk products	935,370	1,016,739	-8.0%	
Functional food and others	486,061	615,020	-21.0%	
Total revenue	8,982,734	8,053,269	+11.5%	
Profit attributable to shareholders				
Underlying profit (note)	1,724,052	1,544,901	+11.6%	
As reported	1,612,850	1,428,843	+12.9%	
Earnings per shares (<i>RMB cents</i>) Based on underlying profit attributable to shareholders				
– Basic	14.55	12.96	+12.3%	
– Diluted	14.55	12.96	+12.3%	
Based on reported profit attributable to shareholders				
– Basic	13.61	11.99	+13.5%	
– Diluted	13.61	11.99	+13.5%	

Note: Underlying profit attributable to shareholders, a non-HKFRS measure, represents profit before taking into account the fair value changes on financial assets measured at FVTPL and employee share-based compensation expense. Reconciliation between the reported and underlying profit is provided on page 8 of this announcement.

RESULTS OF FIRST QUARTER 2024

Revenue amounted to RMB8,983 million, an increase of 11.5% as compared to the same period last year.

Underlying profit attributable to shareholders amounted to RMB1,724 million, an increase of 11.6% as compared to the same period last year.

Reported profit attributable to shareholders amounted to RMB1,613 million, an increase of 12.9% as compared to the same period last year.

BUSINESS REVIEW

1. Finished Drugs Business

Revenue of the finished drugs business increased by 17.7% to RMB7,561 million for the period. Revenues in all therapeutic areas, except for the respiratory system, increased as compared to the same period last year, while new products launched in recent years continued to increase their contributions to the revenue.

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

Therapeutic Area	Sales (RMB'million)	Change	
Nervous system	2,707	+27.4%	
Oncology	1,611	+11.6%	
Anti-infectives	1,350	+9.8%	
Cardiovascular	720	+22.3%	
Respiratory system	467	-6.2%	
Digestion and metabolism	314	+60.0%	
Others	392	+28.5%	

2. Bulk Products Business

Revenue of the bulk products business decreased by 8.0% to RMB935 million for the period. Sales of vitamin C products decreased by 11.8% to RMB486 million due to weakened demand. Sales of antibiotic products remained stable, which decreased slightly by 3.6% to RMB449 million.

3. Functional Food and Others Business

Revenue of the functional food and others business decreased by 21.0% to RMB486 million, mainly affected by the decrease in price of caffeine products.

4. Research and Development

During the period, R&D expenses amounted to RMB1,169 million, an increase of 16.0% as compared to the same period last year and accounted for approximately 15.5% of the revenue of the finished drug business. Currently, more than 60 key drug candidates have entered clinical trial or registration stage, of which 7 candidates have filed marketing approval application and 20 candidates have entered pivotal clinical trial stage.

Regulatory Updates

Since the beginning of 2024, 1 innovative drug (new indication) has obtained marketing approval, 16 innovative drug candidates have obtained clinical trial approval and 2 generic drugs have obtained registration approval in China; and 2 innovative drug candidates have obtained clinical trial approval in North America.

China

- In February 2024, Mingfule (明復樂[®]) (recombinant human TNK tissue-type plasminogen activator for injection) (rhTNK-tPA) obtained marketing approval for the thrombolytic treatment in patients with acute ischemic stroke. It is the first approval for this indication of this product type in China, and the second approved indication of the product.
- 7 drug candidates have obtained clinical trial approval for their first indication, and 9 additional indications have obtained clinical trial approval:

Drug Candidate	Indication
JMT202 (mAb)	Lower triglyceride (TG) levels in patients with
	hypertriglyceridaemia
SYS6023 (ADC)	Advanced solid tumors
SYH2039 (MAT2A)	Advanced malignant tumors
Dexmedetomidine hydrochloride nasal spray	Sedation before invasive procedures
Pilocarpine hydrochloride eye drops	Presbyopia
Pregabalin extended-release tablets	Neuropathic pain associated with diabetic
	peripheral neuropathy
Semaglutide injection	Weight management

First Indication

Additional Indication

Drug Candidate	Indication
SYSA1801 injection	In combination with CAPOX and SG001 or with irinotecan hydrochloride liposome injection for first-line and second-line treatment of Claudin18.2-positive gastric cancer
JMT101 injection	In combination with docetaxel (albumin-bound) for treatment of second-line and above EGFR lung squamous cell carcinoma
Simmitnib hydrochloride tablets	In combination with irinotecan liposome for the treatment of second-line advanced esophageal cancer
Sirolimus for injection (albumin-bound)	In combination with endocrine therapy for the treatment of second-line and above HR-positive HER2-negative advanced breast cancer after failure of standard therapy
Sirolimus for injection (albumin-bound)	In combination with gumetinib for the treatment of locally advanced/recurrent or distant metastasis MET-overexpression non-small cell lung cancer
SYH2043 tablets	In combination with fulvestrant for the treatment of advanced breast cancer
Cisplatin micelle injection	In combination with paclitaxel for the treatment of advanced solid tumors
Octreotide long-acting injection	Gastroenteropancreatic neuroendocrine tumors
Irinotecan liposome injection	In combination with oxaliplatin and tegafur for adjuvant treatment of pancreatic cancer

• Since the beginning of 2024, the generic drugs dapagliflozin tablets and peramivir injection have obtained drug registration approval.

North America

- In January 2024, JMT106 injection (bispecific fusion protein targeting GPC3 and interferon receptors) obtained clinical trial approval in the US.
- In April 2024, SYH2039 tablets (MAT2A enzyme inhibitor) obtained clinical trial approval in the US.

Major Clinical Trials Progress

DP303c (recombinant humanised anti-HER2 monoclonal antibody–MMAE conjugate for injection)

• In February 2024, the first phase III trial for the treatment of second-line or above HER2positive advanced breast cancer was initiated in China. The study is currently in the enrollment stage.

Daunorubicin cytarabine liposome for injection

• In February 2024, the first phase III trial for the treatment of high-risk secondary acute myeloid leukemia (AML) in the elderly patients who have not been previously treated was initiated in China. The study is currently in the enrollment stage.

Docetaxel for injection (albumin-bound)

• In February 2024, the first phase III clinical study comparing to Taxotere[®] for the treatment of locally advanced or metastatic gastric adenocarcinoma or gastroesophageal junction adenocarcinoma that has previously failed first-line treatments was initiated in China. The study is currently in the enrollment stage.

Semaglutide injection

• In February 2024, the first phase III clinical study for the treatment of type 2 diabetes was initiated in China. The study is currently in the enrollment stage.

JMT103 (Narlumosbart for injection)

• In March 2024, the first phase III trial for the treatment of bone metastasis of malignant solid tumors was initiated in China.

Clevidipine butyrate emulsion injection

• In March 2024, the phase III trial for the treatment of hypertensive emergencies/subemergencies was initiated in China and fully enrolled.

SYHX2011 (Paclitaxel for injection (albumin-bound) II)

• In March 2024, the phase III trial for the treatment of advanced breast cancer was initiated in China and fully enrolled.

TG103 injection (GLP-1 receptor agonists)

- In January 2024, the phase III trial for the treatment of overweight and obesity was initiated in China and fully enrolled.
- In April 2024, the first phase III clinical study for the treatment of type 2 diabetes was initiated in China. The study is currently in the enrollment stage.

JMT101 (recombinant humanised anti-epidermal growth factor receptor monoclonal antibody for injection)

- In January 2024, the phase II clinical study for the treatment of second-line and above EGFR exon 20 insertion mutations in non-small cell lung cancer (NSCLC) in China met its predefined endpoint.
- In April 2024, the first phase III trial of JMT101 in combination with osimertinib comparing to cisplatin in combination with pemetrexed for the first-line treatment NSCLC patients with EGFR exon 20 insertion mutations was initiated in China. The trial is currently in the enrollment stage.

Publication of Major Clinical Trial Results

SYS6002 (Anti-Nectin-4 monoclonal antibody-drug conjugate for injection)

• In January 2024, the results of a phase I clinical study for the treatment of advanced solid tumors were presented at the 2024 ASCO-GU Conference (No. B622). Preliminary results indicated that SYS6002 demonstrates clear efficacy signals and good tolerability in advanced solid tumors such as cervical cancer and urothelial cancer.

DBPR108 (Prusogliptin Tablets)

• In January 2024, the results of a phase III clinical study of the monotherapy for the treatment of diabetes were published in the international journal *Diabetes, Obesity & Metabolism.* The results demonstrated that the hypoglycemic efficacy of DBPR108 tablets is significantly better than that of the placebo group and non-inferior to the active group of sitagliptin phosphate tablets. In addition, the safety profile of DBPR108 tablets is similar to that of the placebo group and that of the active group of sitagliptin phosphate tablets.

Duentai (度恩泰[®]) (SARS-CoV-2 mRNA vaccine)

- From February 2024 to March 2024, multiple clinical study results of the first-generation COVID-19 mRNA vaccine were published in international journals such as *Emerging Microbes & Infections, Vaccine* and *Journal of Medical Virology,* respectively, demonstrating that the vaccine has good protective efficacy and immunogenicity as well as a good safety profile, and that it has a certain protective effect against XBB mutant strains.
- In March 2024, the results of a phase I clinical study of the bivalent COVID-19 mRNA vaccine (XBB.1.5/BQ.1) (SYS6006.32) were published in the international journal *Vaccine*, demonstrating that the vaccine has a good safety profile and good immunogenicity, and can produce cross-immunity against multiple mutant strains.

JMT101(recombinant humanised anti-epidermal growth factor receptor monoclonal antibody for injection)

• In March 2024, the results of a phase II clinical trial (BECOME) of JMT101 in combination with osimertinib for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) carrying EGFR exon 20 insertion mutations were orally presented at the European Lung Cancer Congress 2024 (2024 ELCC), demonstrating the high potential efficacy of JMT101 in combination with osimertinib in NSCLC patients with EGFR exon 20 insertion mutations, and that the overall safety is controllable.

TG103 injection (GLP-1 receptor agonists)

• In April 2024, the results of a phase Ib clinical study of the monotherapy for overweight or obesity without type II diabetes were published in the international journal *BMC Medicine*. The results demonstrated that the weight-reducing efficacy of TG103 monotherapy is significantly better than that of the placebo group.

Patents

Since the beginning of 2024, 12 international PCT applications and 62 patent applications (46 domestic and 16 overseas) were filed, and 22 patents (13 domestic and 9 overseas) were granted. As of 30 April 2024, 174 international PCT applications and 1,856 patent applications (1,230 domestic and 626 overseas) were filed, and 921 patents (618 domestic and 303 overseas) were granted.

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 reported profit attributable to shareholders and the underlying profit attributable to shareholders:

	Three months ended 31 March		
	2024 (RMB'000)	2023 (RMB '000)	
Reported profit attributable to shareholders	1,612,850	1,428,843	
Adjustment for:			
– Fair value loss on financial assets measured at FVTPL (note a)	48,801	70,435	
– Employee share-based compensation expense (note b)	65,328	50,523	
– Effect of corresponding income tax	(2,927)	(4,900)	
Underlying profit attributable to shareholders	1,724,052	1,544,901	

Notes:

- (a) The fair value changes on financial assets measured at fair value through profit or loss ("FVTPL") arise 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 for the period, RMB47,634,000 was in respect of share awards granted to selected employees of the Group by Key Honesty Limited, a shareholder of the Company (first quarter 2023: RMB50,045,000).

CONDENSED CONSOLIDATED INCOME STATEMENT

For the three months ended 31 March 2024 – Unaudited

	Three months ended 31 March		
	2024 <i>RMB'000</i>	2023 <i>RMB</i> '000	
Revenue	8,982,734	8,053,269	
Cost of sales	(2,487,305)	(2,534,670)	
Gross profit	6,495,429	5,518,599	
Other income	122,701	117,770	
Other gains or losses, net	(52,147)	(59,269)	
Selling and distribution expenses	(2,959,541)	(2,487,600)	
Administrative expenses	(332,831)	(263,080)	
Research and development expenses	(1,169,277)	(1,007,649)	
Other expenses	(11,499)	(16,644)	
Share of results of associates	(15,009)	(12,045)	
Share of results of joint ventures	(13,484)	(4,692)	
Finance costs	(6,105)	(4,429)	
Profit before tax	2,058,237	1,780,961	
Income tax expense	(428,350)	(311,861)	
Profit for the period	1,629,887	1,469,100	
Profit for the period attributable to:			
Owners of the Company	1,612,850	1,428,843	
Non-controlling interests	17,037	40,257	
	1,629,887	1,469,100	
	RMB cents	RMB cents	
Earnings per share			
– Basic	13.61	11.99	
– Diluted	13.61	11.99	

CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

For the three months ended 31 March 2024 – Unaudited

	Three months ended 31 March		
	2024 <i>RMB</i> '000	2023 <i>RMB</i> '000	
Profit for the period	1,629,887	1,469,100	
Other comprehensive income/(expense) 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	203,965	1,890	
Item that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	(2,480)	(3,010)	
Other comprehensive income/(expense) for the period,			
net of income tax	201,485	(1,120)	
Total comprehensive income for the period	1,831,372	1,467,980	
Total comprehensive income for the period attributable to:			
Owners of the Company	1,814,335	1,427,723	
Non-controlling interests	17,037	40,257	
	1,831,372	1,467,980	

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 2024 are consistent with those followed in the preparation of the Group's financial statements for the year ended 31 December 2023.

2. Revenue and Segment Information

		Three months ended 31 March		
	2024	2023		
Sale of goods	<i>RMB</i> '000 8,982,734	<i>RMB</i> '000 8,018,569		
Licence fee income	0,702,75 4	34,700		
	8,982,734	8,053,269		

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 licence 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.

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

For the three months ended 31 March 2024

	Finished drugs RMB'000	shed Bulk products		Functional food and	Segment		
		Vitamin C <i>RMB'000</i>	Antibiotics <i>RMB'000</i>	others RMB'000	s total	Eliminations <i>RMB'000</i>	Consolidated <i>RMB'000</i>
SEGMENT REVENUE							
External sales	7,561,303	486,295	449,075	486,061	8,982,734	_	8,982,734
Inter-segment sales	—	8,958	48,251	28,120	85,329	(85,329)	_
TOTAL REVENUE	7,561,303	495,253	497,326	514,181	9,068,063	(85,329)	8,982,734
SEGMENT PROFIT	1,884,587	12,523	105,926	121,075	2,124,111		2,124,111
Unallocated income							71,788
Unallocated expenses							(103,064)
Share of results of associates							(15,009)
Share of results of joint ventures							(13,484)
Finance costs							(6,105)
Profit before tax							2,058,237

For the three months ended 31 March 2023

	Finished drugs <i>RMB</i> '000	ished Bulk products		Functional food and	Segment		
		Vitamin C RMB '000	Antibiotics RMB'000	others RMB'000	rs total	Eliminations RMB'000	Consolidated 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

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 FVTPL, central administrative expenses, share of results of associates and joint ventures, and finance costs. 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.

REVIEW OF RESULTS

The financial data for the three months ended 31 March 2024 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, 27 May 2024

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.