

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2616)

ANNOUNCEMENT OF INTERIM RESULTS FOR THE SIX MONTHS ENDED JUNE 30, 2025

The board (the “**Board**”) of directors (the “**Directors**”) of CStone Pharmaceuticals (the “**Company**” or “**CStone**”) is pleased to announce the unaudited condensed consolidated results of the Company and its subsidiaries (together, the “**Group**”, “**we**” or “**us**”) for the six months ended June 30, 2025 (the “**Reporting Period**”), together with comparative figures for the six months ended June 30, 2024. Unless otherwise defined herein, capitalized terms used in this announcement shall have the same meanings as those defined in the prospectus of our Company dated February 14, 2019 (the “**Prospectus**”) and our announcement of interim results for the six months ended June 30, 2024 dated August 23, 2024.

FINANCIAL HIGHLIGHTS

International Financial Reporting Standards (“IFRS”) Measures:

- **Revenue** was RMB49.4 million for the six months ended June 30, 2025, representing a decrease of RMB204.8 million or 80.5% compared to RMB254.2 million for the six months ended June 30, 2024. The revenue is composed of RMB20.2 million from sales of pharmaceutical products (avapritinib, pralsetinib), RMB17.9 million from license fee income and RMB11.3 million from royalty income of sugemalimab. (1) Revenue from sales of pralsetinib decreased substantially period-on-period, which is primarily due to price adjustments of pralsetinib in preparation for the National Reimbursement Drug List (“**NRDL**”) negotiation and related one-off channel compensation. If included in NRDL, benefit from sales ramp up of pralsetinib in 2026 and beyond is expected to outweigh short-term negative impact on revenue. (2) License fee income also decreased substantially period-on-period, primarily due to the fact that we received a strong contribution from a one-time milestone payment for sugemalimab gastric cancer approval in China in the first half of 2024. No material out-licensing arrangement was entered into during the first half of 2025, however, the major out-licensing agreement with Istituto Gentili (“**Gentili**”) in July 2025 is expected to contribute to license fee income for the second half of 2025.
- **Cost of revenue** was RMB142.2 million for the six months ended June 30, 2025, representing an increase of RMB60.1 million from RMB82.1 million for the six months ended June 30, 2024, primarily due to inventory write-downs charged to cost of revenue and cost associated with an early billing of pralsetinib supply under the Patient Assistance Program covering the period through the first half of 2026 to mitigate customs clearance risks amid trade uncertainties.

- **Research and development expenses** were RMB105.2 million for the six months ended June 30, 2025, representing an increase of RMB39.0 million from RMB66.2 million for the six months ended June 30, 2024, primarily due to increased costs for clinical trials.
- **Administrative expenses** were RMB43.5 million for the six months ended June 30, 2025, representing a decrease of RMB3.2 million from RMB46.7 million for the six months ended June 30, 2024, primarily due to a decrease in depreciation and amortization.
- **Selling and marketing expenses** were RMB35.7 million for the six months ended June 30, 2025, representing a decrease of RMB27.1 million from RMB62.8 million for the six months ended June 30, 2024, primarily due to a decrease in channel service fee and others.
- **Loss for the period** was RMB270.2 million for the six months ended June 30, 2025, representing an increase in loss of RMB285.9 million, from a profit of RMB15.7 million for the six months ended June 30, 2024, primarily due to a shift from gross profit to gross loss.
- **Cash and cash equivalents and time deposits** were RMB652.8 million as of June 30, 2025.

Non-International Financial Reporting Standards (“Non-IFRS”) Measures:

- **Research and development expenses** excluding the share-based payment expenses were RMB102.1 million for the six months ended June 30, 2025, representing an increase of RMB31.1 million from RMB71.0 million for the six months ended June 30, 2024, primarily due to increased costs for clinical trials.
- **Administrative and selling and marketing expenses** excluding the share-based payment expenses were RMB77.2 million for the six months ended June 30, 2025, representing a decrease of RMB32.4 million from RMB109.6 million for the six months ended June 30, 2024, primarily due to a decrease in channel service fee and others.
- **Loss for the period** excluding the share-based payment expenses was RMB265.1 million for the six months ended June 30, 2025, representing an increase in loss of RMB275.9 million, from a profit of RMB10.8 million for the six months ended June 30, 2024, primarily due to a shift from gross profit to gross loss.

BUSINESS HIGHLIGHTS

For the six months ended June 30, 2025 and up to the date of this results announcement, we accelerated our global expansion strategy, advanced our differentiated pipeline, and strengthened our commercial footprint through strategic partnerships. Key achievements during this period include regulatory approvals, clinical advancements, and strategic collaborations, collectively reinforcing our position in developing innovative therapeutics.

Commercial Products

- ***CEJEMLY® (sugemalimab), anti-PD-L1 antibody***

- *Global expansion and regulatory approvals*

Following sugemalimab's approvals for stage IV non-small cell lung cancer ("NSCLC") in the European Union ("EU") and United Kingdom ("U.K.") last year, we submitted a new indication application in March 2025 to the European Medicines Agency ("EMA") for the treatment of patients with unresectable stage III NSCLC who have not progressed following concurrent or sequential platinum-based chemoradiotherapy ("CRT"). If approved, sugemalimab would address a critical unmet need in stage III NSCLC, where only one anti-PD-(L)1 antibody is currently approved in Europe.

- *Global commercialization driven by strategic alliances*

In January 2025, we entered into a partnership with SteinCares to commercialize sugemalimab across ten countries in Latin America ("LATAM"). This was followed by a partnership with Gentili in July 2025 to commercialize sugemalimab in 23 countries in Western Europe and the United Kingdom. To date, four partnerships have been executed extending sugemalimab's international footprint to over 60 countries around the world. Additional partnerships in Southeast Asia, Canada, and other markets are expected in the near future.

- *Robust data reinforcing clinical impact*

- **Publications in top-tier journals:** In February 2025, the results of the final progression-free survival ("PFS") and overall survival ("OS") for the GEMSTONE-303 study (for first-line gastric cancer/gastroesophageal junction cancer [GC/GEJC]) were published in JAMA (Journal of the American Medical Association). In June 2025, long-term survival data from the GEMSTONE-302 study (for first-line stage IV NSCLC) were published in the Lancet Oncology, marking the trial's third publication in top-tier journals.
- **Global guideline adoption:** Sugemalimab has been incorporated into the Non-Oncogene-Addicted Metastatic NSCLC Living Guideline of the European Society for Medical Oncology ("ESMO") in February 2025 and is recommended as a Level [I, A] first-line combination therapy for both squamous and non-squamous NSCLC.

- ***GAVRETO® (pralsetinib), rearranged during transfection (RET) inhibitor***

- *Localized production approved*

In July 2025, the China National Medical Products Administration (“China NMPA”) approved the manufacturing localization application for GAVRETO® (pralsetinib, 100mg). Commencing in 2026, the Chinese market supply will transition gradually from imports to end to end domestic production, from active pharmaceutical ingredient to finished drug product, significantly enhancing cost efficiency and supply chain resilience.

- *NRDL negotiation*

In August 2025, pralsetinib has passed the formal review for the 2025 NRDL negotiation.

- ***AYVAKIT® (avapritinib), KIT/PDGFRα inhibitor***

- *Domestic supply launch*

Following the China NMPA approval for localization production of AYVAKIT® tablets (300 mg and 100 mg) in 2024, domestic supply of AYVAKIT® commenced in February 2025. This shift is projected to drive gross margin expansion.

Clinical Stage Core Assets

- ***CS5001, ROR1 ADC***

- *Global Phase Ib trial progress*

The global multicenter clinical trial of CS5001 is actively enrolling patients across Australia, China and the United States of America (“U.S.”). Recruitment efforts are prioritizing combination therapy cohorts, including CS5001 in combination with R-CHOP (Rituximab + Cyclophosphamide + Hydroxydaunorubicin + Vincristine + Prednisone) for the first-line diffuse large B-cell lymphoma (“DLBCL”), and CS5001 in combination with standard of cares (“SOC”) for front-line DLBCL. No dose-limiting toxicity (“DLT”) was observed to date. Additionally, enrollment is ongoing for monotherapy cohorts targeting aggressive and indolent advanced lymphomas with potential to be expanded into a Phase II single-arm registrational study. CS5001 is also being studied both as a monotherapy and in combination with sugemalimab for advanced solid tumors, underscoring its clinical potential across oncological indications.

- ***CS2009, PD-1/VEGF/CTLA-4 trispecific antibody***

- *Global multicenter Phase I/II trial progress*

The global multicenter Phase I/II study is rapidly enrolling patients in Australia and China, with planned expansion to the U.S. for Phase II enrollment. Phase Ia data including safety, pharmacokinetic (“PK”), pharmacodynamic (“PD”), and antitumor activity will be presented at ESMO Congress in October 2025.

- *First-in-class (“FIC”)/best-in-class (“BIC”) potential and next-generation I/O backbone*

The Phase Ia dose escalation study has evaluated five dose levels in patients with advanced and heavily pretreated solid tumors. Dose level 5 at 30 mg/kg, Q3W has just passed safety evaluation without identifying any DLT. The study is currently enrolling to establish a wide safety margin over potential recommended phase 2 dose (“RP2D”), while backfilling is ongoing for prior dose levels (1-30 mg/kg, Q3W). As of the date of this announcement, CS2009 is found to be well tolerated across all evaluated dose levels, with excellent PK profile supporting Q3W dosing, and with PD responses indicating both T cell activation and proliferation from PD-1 and CTLA-4 blockade and potent VEGFA neutralization. Anti-tumor activities have been observed from lower-dose cohorts in patients with “cold” tumors and PD-(L)1 pretreated tumors.

- ***Nofazinlimab, anti-PD-1 antibody***

- *Final analysis of CS1003-305*

In July 2025, the final analysis of the global multicenter Phase III CS1003-305 study demonstrated a clinical compelling trend in OS for the nofazinlimab-lenvatinib combination compared to placebo-lenvatinib, indicating meaningful patient benefit despite not reaching statistical significance. In addition, clinically meaningful improvements in PFS and objective response rate (“ORR”) were achieved and no new safety signals were observed. We will engage with regulatory authorities to explore the registration pathway for this combination therapy.

Preclinical/IND (Investigational New Drug)-enabling Stage Programs and Proprietary ADC Platform

CStone’s preclinical pipeline comprises over nine promising candidates across multispecific antibodies, antibody-drug conjugates (“ADC”) etc. These programs focus on FIC/BIC profiles covering various therapeutic fields such as oncology, autoimmune and inflammatory diseases. We are dedicated to delivering clinical value through the development of these Pipeline 2.0 candidates, which will undergo international, multi-center clinical trials to maximize their global potential.

Our innovative in-house ADC technology platform features optimized proprietary linkers improving tumor-selective payload release. This platform supports multiple ADC products in Pipeline 2.0, including CS5007 (dual targeting epidermal growth factor receptor [EGFR] and human epidermal growth factor receptor 3 [HER3] bispecific ADC), CS5005 (somatostatin receptor 2 [SSTR2] ADC), CS5008 (delta-like ligand 3 [DLL3] and SSTR2 bispecific ADC), CS5006 (integrin β4 [ITGB4] ADC), CS5009 (B7H3/PD-L1 bispecific ADC), etc.

In May 2025, we presented preclinical data for CS2009 (PD-1/VEGF/CTLA-4 trispecific antibody), CS2011 (EGFR/HER3 bispecific antibody), CS5007 (EGFR/HER3 bispecific ADC), CS5006 (ITGB4 ADC) and CS5005 (SSTR2 ADC) at the 2025 annual meeting of the American Association for Cancer Research (“AACR”).

In July 2025, we disclosed the targets of two autoimmune/inflammatory candidates, CS2013 (B-cell-Activating Factor [BAFF]/A Proliferation-Inducing Ligand [APRIL] bispecific antibody) and CS2015 (OX40 Ligand [OX40L]/Thymic Stromal Lymphopoietin [TSLP] bispecific antibody). Both have FIC/BIC potential, and IND-enabling studies with respect to both are expected to be initiated in the second half of 2025. These candidates reflect our strategic expansion into non-oncology therapeutic pipelines.

FUTURE AND OUTLOOK

Our mission is to deliver transformative therapies through scientific excellence and technological innovation, making high-quality treatments accessible worldwide to benefit patients and their families.

We reaffirm our commitment to advancing a robust and differentiated pipeline by prioritizing internal discovery capabilities and sustained R&D investments, while executing strategic partnerships to unlock the global value of our in-market products. Critical catalysts for the second half of 2025 include:

- Clinical milestones:
 - Progress CS5001 (ROR1 ADC) and CS2009 (PD-1/VEGF/CTLA-4 trispecific antibody) towards pivotal trials and in parallel pursue global partnerships to expedite development.
 - Advance early-stage candidates into clinical stages.
- Commercial excellence:
 - Maximize the value of AYVAKIT[®] and GAVRETO[®] through strategic collaborations and potential transactions.
 - Continue to accelerate ex-China commercialization of sugemalimab via regional partnerships.
- Innovation and technology:
 - Strengthen proprietary platforms (e.g., ADC technology) to sustain pipeline growth.
 - Present key clinical data at major conferences (e.g., ESMO, American Society of Hematology (“ASH”)).

CAUTIONARY STATEMENT REQUIRED BY RULE 18A.08(3) OF THE LISTING RULES: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP OR MARKET ANY OF OUR PIPELINE PRODUCTS SUCCESSFULLY.

MANAGEMENT DISCUSSION AND ANALYSIS

OUR VISION









To be a pioneer in enhancing global patient health through innovation.

OVERVIEW

CStone (HKEX: 2616), established in late 2015, is an innovation-driven biopharmaceutical company focused on the research and development of anti-cancer therapies. Dedicated to addressing patients' unmet medical needs in China and globally, the Company has made significant strides since its inception. To date, the Company has successfully launched 4 innovative drugs and secured approvals for 16 New Drug Application (“NDAs”) covering 9 indications. The Company's pipeline is balanced by 16 promising candidates, featuring potentially FIC or BIC ADCs, multispecific antibodies, immunotherapies and precision medicines. CStone also prides itself on a management team with comprehensive experiences and capabilities that span the entire drug development spectrum, from preclinical and translational research to clinical development, drug manufacturing, business development, and commercialization. For details of any of the foregoing, please refer to the rest of this announcement and, where applicable, the Prospectus and prior announcements published on the websites of The Stock Exchange of Hong Kong Limited (the “Stock Exchange”) and the Company.

Product Pipeline

The following pipeline chart demonstrates the milestone and development status of our selected assets as of the date of this results announcement:

Drug candidate	Indication	POC	Pivotal	NDA	Marketed	Approval						Partners	Partnering regions
						CN	TW	HK	US	EU	UK		
Pralsetinib (RET)	2L NSCLC					✓	✓	✓	✓			 	Mainland China
	1L NSCLC					✓		✓	✓				
	1L MTC/TC					✓	(TC)		(TC)				
	Multiple tumors												
Avapritinib (KIT/PDGFR)	PDGFRA exon 18 GIST					✓	✓	✓	✓				Mainland China
	SM ¹								✓				
Sugemalimab (PD-L1)	1L Stage IV NSCLC					✓							Mainland China
	1L Stage IV NSCLC									✓	✓		
	Stage III NSCLC					✓							Switzerland and Central Eastern Europe
	1L GC/GEJ					✓							
	1L ESCC					✓							Middle East and Africa
	R/R ENKTL					✓							
	R/R ENKTL												Latin America
CS1003 (PD-1)	1L HCC												West Europe and the UK
CS1002 (CTLA-4)	Solid tumors												Mainland China
													Greater China

Note: Assets status denotes progress in the region(s) noted in the column titled “Rights”; CN = Mainland China, TW = Taiwan, China, HK = Hong Kong SAR, China, US = United States, POC = Proof of Concept, NSCLC = Non-small Cell Lung Cancer, MTC = Medullary Thyroid Cancer, TC = Thyroid Cancer, GIST = Gastrointestinal Stromal Tumor, SM = Systemic Mastocytosis, GC/GEJ = gastric adenocarcinoma/gastroesophageal junction adenocarcinoma, ESCC = Esophageal Squamous Cell Carcinoma, R/R = Relapsed or Refractory, NKTL = Natural KILLER/T Cell Lymphoma, HCC = Hepatocellular Carcinoma; RoW = Rest of World
1. POC was conducted in the U.S. and no clinical trials have been conducted in China;

 Greater China
  Global Rights
 Expedited registration

Drug candidate	Right	Indication	Discovery	Preclinical Development	IND-Enabling	FIH	POC
CS5001 ¹ (ROR1 ADC)	●	Solid tumors hematologic malignancies					
CS2009 (PD-1/VEGF/CTLA-4 trispecific antibody)	●	Solid tumors					
CS5007 (EGFR/HER3 bispecific ADC)	●	Solid tumors					
CS2011 (EGFR/HER3 bispecific antibody)	●	Solid tumors					
CS5008 (SSTR2/DLL3 bispecific ADC)	●	Solid tumors					
CS5005 (SSTR2 ADC)	●	Solid tumors					
CS5005-R (SSTR2 RDC)	●	Solid tumors					
CS5006 (ITGB4 ADC)	●	Solid tumors					
CS5009 (B7H3/PD-L1 bispecific ADC)	●	Solid tumors					
CS2013 (BAFF/APRIL bispecific antibody)	●	Autoimmune Diseases					
CS2015 (OX40L/TSLP bispecific antibody)	●	Inflammatory Diseases					

Note: Assets status denotes progress in the region(s) noted in the column titled "Rights"; FIH – First in Human, POC – Proof of Concept.
¹ CStone obtains the exclusive global right from LigandChem Biosciences, Inc. (LCB) to lead development and commercialization of LCB71/CS5001 outside the Republic of Korea

Antibody ADC RDC ● Global Rights

BUSINESS REVIEW

Commercial Products

Our partnerships with pharmaceutical and biotech companies are cornerstones of our near-term commercial plans as well as our global aspirations. In order to further improve the commercialization efficiency, we have established commercial collaborations with multiple companies to leverage their strengths while enabling us to strategically focus on research and development going forward.

Details on our commercial portfolio are set out below:

- ***CEJEMLY® (sugemalimab, anti-PD-L1 antibody) approved in China, E.U. and the U.K., expanding global presence and commercial value***
 - Sugemalimab, developed by CStone using the OmniRat® transgenic animal platform, is a fully human, full-length anti-PD-L1 immunoglobulin G4 (IgG4) monoclonal antibody, which may reduce the risk of immunogenicity and toxicity for patients.
 - Approved indications in different territories.

The China NMPA has approved sugemalimab for five indications:

- **Stage IV NSCLC:** In combination with chemotherapy as first-line treatment of patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations and metastatic squamous NSCLC;
- **Stage III NSCLC:** For patients with unresectable Stage III NSCLC whose disease has not progressed following concurrent or sequential platinum-based chemoradiotherapy;
- **NK/T-cell lymphoma:** For patients with relapsed or refractory extranodal NK/T-cell lymphoma;
- **ESCC:** In combination with fluorouracil and platinum-based chemotherapy as first-line treatment of patients with unresectable locally advanced, recurrent or metastatic esophageal squamous cell carcinoma (“ESCC”); and
- **G/GEJ:** In combination with fluoropyrimidine- and platinum-containing chemotherapy as first-line treatment for unresectable locally advanced or metastatic gastric or gastroesophageal junction (“G/GEJ”) adenocarcinoma with PD-L1 combined positive score (“CPS”) ≥5.

The European Commission (“EC”) and the Medicines and Healthcare products Regulatory Agency (“MHRA”) in the U.K. have approved sugemalimab (brand name: CEJEMLY®) in combination with platinum-based chemotherapy for the first-line treatment of patients with metastatic NSCLC with no sensitizing EGFR mutations, or ALK, receptor tyrosine kinase-like orphan receptor 1 (“ROS1”) or rearrangement during transfection (“RET”) genomic tumor aberrations. We have completed the submission to EMA for the new indication application of Stage III NSCLC. If approved, sugemalimab’s dual utility in Stages III and IV NSCLC could solidify its role as a cornerstone immunotherapy in lung cancer. We continue to engage with health authorities in Europe and other regions for other indications of sugemalimab.

– Commercial collaborations

Building on our 2024 partnerships with Ewopharma and Pharmalink, we entered into a strategic agreement with SteinCares in January 2025 to commercialize sugemalimab across 10 LATAM countries. In July 2025, we signed an exclusive license agreement with Gentili covering 23 European countries, expanding sugemalimab’s global reach to over 60 countries and regions. Under the terms of the agreement with Gentili, CStone is eligible to receive up to US\$192.5 million in total consideration, including an upfront payment and milestone-based payments. CStone will supply the product and recognize approximately 50% of net sales from the licensed territories as revenue, while Gentili will lead all local regulatory and commercial activities in the covered regions.

– Guideline and academic recognition

- **ESMO Guideline recommendation:** In February 2025, CEJEMLY® (sugemalimab) has been included in the ESMO NSCLC Living Guideline. Sugemalimab is recommended as a Level [I, A] first-line combination therapy for both non-oncogene-addicted metastatic squamous and non-squamous NSCLC, with substantial clinical benefits. This is another significant milestone in sugemalimab’s global journey and provides critical support for our efforts to expand global market access and benefit patients.

- **Publications and presentations:** In February 2025, the results of the PFS and OS final analysis in the registrational GEMSTONE-303 study (first-line G/GEJ with CPS ≥ 5) were published in a top-tier medical journal – *Journal of the American Medical Association*. In June 2025, long-term survival data of the GEMSTONE-302 trial on sugemalimab was published in the *Lancet Oncology*. It is the trial’s third publication in prestigious journals.
- ***GAVRETO® (pralsetinib, RET inhibitor) commercial partnership with Allist execution on track and manufacturing localization approved by China NMPA***
 - GAVRETO® (pralsetinib), a FIC rearranged during transfection (“RET”) inhibitor in China, has been approved by the China NMPA for the first-line treatment of adults with locally advanced or metastatic RET fusion-positive NSCLC, the treatment of adults with locally advanced or metastatic RET fusion-positive NSCLC previously treated with platinum-based chemotherapy; and the treatment of patients with advanced or metastatic RET-mutant medullary thyroid cancer (“MTC”) and RET fusion-positive thyroid cancer (“TC”). In addition, this medicine has been approved by the Department of Health of the Government of Hong Kong (“HK DoH”) for the treatment of patients with RET fusion-positive locally advanced or metastatic NSCLC and it has been approved by the Taiwan Food and Drug Administration (“TFDA”) for the treatment of adult patients with locally advanced or metastatic RET fusion-positive NSCLC and advanced or metastatic RET fusion-positive TC.
 - In 2025, we continue to integrate GAVRETO® (pralsetinib) into Allist’s highly synergistic lung cancer franchise, enabling GAVRETO® (pralsetinib) to benefit from Allist’s mature commercial team and broad market coverage, while simultaneously allowing us to reduce operating costs associated with GAVRETO® (pralsetinib) commercialization and improving overall profitability.
 - In July 2025, the China NMPA approved the manufacturing localization application for GAVRETO® (pralsetinib, 100mg). Commencing in 2026, supply for the Chinese market will transition gradually from imported to locally manufactured product.
 - In August 2025, pralsetinib has passed the formal review for the 2025 NRDL negotiation.
 - GAVRETO® (pralsetinib) has been included in 11 of China’s national guidelines for testing and treatment in multiple therapeutic areas, such as NSCLC and TC. In 2023, GAVRETO® (pralsetinib) was recommended by the 2023 Chinese Society of Clinical Oncology (“CSCO”) NSCLC guideline, which recommended RET mutation gene testing and GAVRETO® (pralsetinib) in the treatment of RET positive NSCLC patients. In 2024, GAVRETO® (pralsetinib) as a treatment of stage IV RET fusion-positive NSCLC has been upgraded to a Level 1 recommendation in the 2024 CSCO NSCLC guideline.
- ***AYVAKIT® (avapritinib, KIT/PDGFRα inhibitor) advances commercialization with Hengrui’s commercial partnership with domestic supply fully operational since February 2025***
 - AYVAKIT® (avapritinib), a FIC KIT/PDGFRα inhibitor, has been approved by the China NMPA for the treatment of adults with unresectable or metastatic GIST harboring a PDGFRα exon 18 mutation, including PDGFRα D842V mutations. AYVAKIT® (avapritinib) has also been approved by the TFDA and the HK DoH for the treatment of patients with unresectable or metastatic PDGFRα D842V mutant GIST.

- In July 2024, we entered into a commercial partnership with Jiangsu Hengrui Pharmaceuticals Co., Ltd. (“**Hengrui**”) for the exclusive promotion rights of AYVAKIT® (avapritinib) in mainland China. The China NMPA has approved the manufacturing localization application in August 2024, and domestic supply has been launched in February 2025, with significant gross margin increase anticipated.
- We continued to improve the accessibility and affordability of AYVAKIT® (avapritinib). In 2023, AYVAKIT® (avapritinib) was included in the 2023 NRDL in China, for the treatment of adults with unresectable or metastatic GIST harboring the PDGFRA exon 18 mutation, including PDGFRA D842V mutations. The updated NRDL was implemented on January 1, 2025. The product has passed the formal review for the 2025 NRDL renewal negotiation.
- AYVAKIT® (avapritinib) is recommended by several authoritative guidelines, including the updated 2022 CSCO GIST guideline and the 2022 Chinese Guideline for Diagnosis and Treatment of Systemic Mastocytosis in Adults.

Clinical Stage Core Products

As of the date of this results announcement, significant progress has been made across our product pipeline.

CS5001 (LCB71, ROR1 ADC) advances to Phase Ib stage with encouraging efficacy and safety profile

- CS5001 is a clinical-stage ADC targeting ROR1, featured with proprietary tumor-cleavable linker and pyrrolobenzodiazepine (“**PBD**”) dimer prodrug. Only after reaching the tumor, the linker and prodrug are cleaved to release the PBD toxin, resulting in lethal DNA cross-links in cancer cells. The use of the linker plus PBD prodrug effectively helps address toxicity associated with traditional PBD payloads, leading to a better safety profile. CS5001 has demonstrated complete tumor suppression in several preclinical cancer models and demonstrated favorable serum half-life and pharmacokinetic characteristics. CS5001 is a promising candidate drug with precision treatment potential in both hematologic tumors and malignant solid tumors. Additionally, CS5001 utilizes site-specific conjugation for a precise drug antibody ratio of which enables homogeneous production and large-scale manufacturing. CS5001 is so far the first ROR1 ADC known to demonstrate clinical anti-tumor activity in both solid tumors and lymphomas.
- A global, multicenter, Phase Ia/Ib clinical trial of CS5001 is actively enrolling patients across the U.S., Australia and China. Phase Ib recruitment continues for monotherapy cohorts in aggressive and indolent advanced lymphomas with potential expansion into a Phase II single-arm registrational study. The Phase Ib study is also exploring therapeutic potential of CS5001 across different stages of DLBCL and solid tumors, including:
 - CS5001 + R-CHOP: First-line treatment for DLBCL patients who have not received prior systemic therapy.
 - CS5001 + SoC: For patients with relapsed or refractory DLBCL.
 - CS5001 Monotherapy: Targeting ROR1-expressing solid tumors.
 - CS5001 + Sugemalimab: Combination therapy for advanced solid tumors.

CS2009 (PD-1/VEGF/CTLA-4 trispecific antibody): potential next-generation I/O backbone with smooth global Phase I/II clinical trial progress

- CS2009, a leading asset from the Company's Pipeline 2.0, is a potential FIC/BIC PD-1/VEGF/CTLA-4 trispecific antibody independently developed by CStone. It features balanced and monovalent PD-1 and CTLA-4 arms and a bivalent anti-VEGFA arm, which leads to potent multi-target synergy in the TME and preferential targeting of tumor tissue to reduce systemic toxicity. CS2009 preferentially blocks PD-1 and CTLA-4 on double-positive tumor-infiltrating T cells via avidity-driven engagement, while minimizing interference with CTLA-4 signaling in peripheral T cells, thus potentially offering enhanced efficacy with minimized systemic toxicity. In the tumor micro-environment ("TME"), CS2009's anti-PD-1 and anti-CTLA-4 activities are further enhanced significantly by crosslinking with VEGFA dimers that are upregulated in the TME.
- The global multicenter Phase I/II study is actively enrolling patients in Australia and China, with planned Phase II expansion into the U.S. The trial is progressing smoothly and is expected to exceed 100 patients by year-end. We also updated key clinical progress in July 2025:
 - The Phase Ia dose escalation study has evaluated five dose levels in patients with advanced and heavily pretreated solid tumors. Dose level 5 at 30 mg/kg, Q3W has just passed safety evaluation by the SMC without identifying any DLT. The study is currently enrolling to establish a wide safety margin over potential RP2D, while backfilling is ongoing for prior dose levels (1-30 mg/kg, Q3W). Phase Ib/II dose expansion/pivotal extension studies are anticipated to commence in the second half of 2025.
 - To date, CS2009 is found to be well tolerated across all evaluated dose levels, with excellent PK profile supporting Q3W dosing, with PD responses indicating both T cell activation and proliferation from PD-1 and CTLA-4 blockade and potent VEGFA neutralization. Anti-tumor activities have been observed from lower-dose cohorts in patients with "cold" tumors and PD-(L)1 pretreated tumors.
 - Phase Ia data including safety, PK, PD, and antitumor activity will be presented at ESMO Congress in October 2025.

CS1002 (SHR-8068, anti-CTLA-4 antibody): strategic partnership with Hengrui in Greater China and active Phase III trial progress

- In November 2021, we entered an exclusive licensing agreement with Hengrui, which obtained the exclusive rights to research, development, registration, manufacturing, and commercialization of CS1002/SHR-8068 in Greater China. CStone retained all rights to develop and commercialize CS1002 outside of Greater China.

- Hengrui is actively advancing two major late-stage clinical trials for CS1002/SHR-8068. In March 2024, Hengrui initiated a Phase II/III trial evaluating CS1002/SHR-8068 in combination with adebrelimab and chemotherapy as a first-line treatment for advanced or metastatic non-squamous NSCLC. In September 2024, Hengrui commenced another Phase III trial comparing CS1002/SHR-8068 combined with adebrelimab and bevacizumab versus sintilimab combined with bevacizumab for the first-line treatment of advanced hepatocellular carcinoma (“**HCC**”). Both registrational trials are actively recruiting patients and progressing as planned.
- Additionally, Hengrui has planned several other clinical trials to evaluate CS1002/SHR-8068 combination therapy in multiple solid tumor types. In July 2025, Hengrui received IND acceptance for a Phase II study of CS1002/SHR-8068 in combination with adebrelimab, bevacizumab and apatinib for colorectal cancer (“**CRC**”).

Nofazinlimab (CS1003, anti-PD-1 antibody) final analysis readout

- CS1003-305 study is a global, multicenter, randomized, double-blind Phase III registrational trial conducted across 74 sites worldwide. The study evaluates the efficacy and safety of the anti-PD-1 monoclonal antibody nofazinlimab (CS1003) in combination with LENVIMA® (lenvatinib) versus placebo in combination with lenvatinib as first-line treatment for patients with unresectable or metastatic HCC. The primary endpoint was OS. Key secondary endpoints included PFS and ORR as assessed by Blinded Independent Central Review (“**BICR**”).
- In July 2025, we updated the final analysis which demonstrated a clinical compelling trend in OS for the nofazinlimab-lenvatinib combination compared to placebo-lenvatinib, indicating meaningful patient benefit despite not reaching statistical significance. In addition, clinically meaningful improvements in PFS and ORR were achieved, with outcomes numerically competitive against established therapeutic benchmarks. Nofazinlimab demonstrated a manageable safety profile, consistent with prior research findings and marketed PD-(L)1 antibodies, and no new safety signals were observed. We will engage with regulatory authorities to explore the registration pathway for this combination therapy.

Preclinical/IND-enabling candidates

We maintains our commitment to pioneering next-generation anti-cancer therapeutics, including multispecific antibodies, ADCs and more. Meanwhile, our early research portfolio has been expanded to encompass autoimmune and inflammatory diseases.

Key pipeline advancements include:

- **In-house proprietary ADC technology platform:** CStone is actively advancing next-generation linker technology to improve systematic stability and tumor selectivity of ADCs. Our proprietary tandem-cleavable β -glucuronide linker demonstrates:
 - Enhanced hydrophilicity improving circulating stability of the entire molecule.
 - Tumor selective payload release through tandem cleavage mechanism.
 - Clinical validated semi-stochastic conjugation with maleimide function group for manufacturability.

This in-house proprietary ADC technology platform optimizes ADC safety/efficacy profiles, broadens target compatibility, and supports multiple ADC candidates in CStone's Pipeline 2.0, including CS5005 (SSTR2 ADC), CS5008 (DLL3&SSTR2 bispecific ADC), CS5006 (ITGB4 ADC), CS5007 (EGFR&HER3 bispecific ADC), CS5009 (B7H3/PD-L1 bispecific ADC), etc.

- **Core ADC pipeline:**

- **CS5007 (EGFR/HER3 bispecific ADC):** CS5007 is composed of EGFR/HER3 bispecific antibody backbone (CS2011), a hydrophilic β -glucuronide linker, and exatecan. It is designed to address tumor heterogeneity by simultaneously targeting EGFR and HER3, with strong affinities to EGFR+ and/or HER3+ tumor cells. It demonstrates potent antitumor efficacy and favorable safety/PK profiles. CS5007 is positioned as a best-in-class candidate for precision oncology across multiple solid tumors, including NSCLC, SCCHN, CRC, etc.
- **CS5005 (SSTR2 ADC) and CS5008 (SSTR2/DLL3 bispecific ADC):** CS5005 is composed of CStone's proprietary anti-SSTR2 antibody (high affinity and selectivity), hydrophilic β -glucuronide linker, and exatecan (clinically validated topoisomerase I inhibitor). It represents a promising therapeutic approach for SSTR2+ solid tumors including neuroendocrine neoplasms ("NENs") and small cell lung cancer ("SCLC"), and demonstrates potent antigen-dependent tumor growth inhibition. CS5008 is a novel DLL3/SSTR2 bispecific ADC using CStone's proprietary antibody and linker payload. Through dual targeting of SSTR2 and DLL3, which are frequently co-expressed in NENs, SCLC and other malignancies, CS5008 aims to overcome tumor heterogeneity, a challenge inherent to mono-targeting therapies.
- **CS5006 (ITGB4 ADC):** CS5006 is a FIC ADC against novel pan-tumor target ITGB4, a transmembrane protein that exclusively pairs with integrin $\alpha 6$ (ITGA6) to form $\alpha 6\beta 4$ heterodimer. Robust in vitro and in vivo evidence supports its clinical development. This molecule targets diverse indications including NSCLC, squamous cell carcinoma of head and neck ("SCCHN"), CRC, etc.

- **Autoimmune and inflammatory multi-specific antibodies:**

- **CS2013 (BAFF/APRIL bispecific antibody):** CS2013 features a differentiated molecular design to simultaneously block BAFF and APRIL, which are two essential ligands for B cell/plasma cell development and survival. Preclinical studies have demonstrated synergistic effects and exceptional stability that supports the development of subcutaneous formulations. Furthermore, it exhibits superior PK profiles to fusion proteins, including an extended half-life that potentially enables reduced dosing frequency. CS2013 targets B-cell-mediated autoimmune diseases, such as systemic lupus erythematosus ("SLE"), rheumatoid arthritis ("RA"), IgA nephropathy ("IgAN"), etc.
- **CS2015 (OX40L/TSLP bispecific antibody):** CS2015, a potential FIC bispecific antibody targeting both OX40L (a key ligand on immune effector cells) and TSLP (a critical alarmin secreted by epithelial cells), potently blocks these two key ligands in Th2-mediated inflammatory diseases, such as atopic dermatitis ("AD"), asthma and chronic obstructive pulmonary disease ("COPD"). Robust preclinical PK data have further confirmed an extended half-life and feasibility for subcutaneous administration.

**CAUTIONARY STATEMENT REQUIRED BY RULE 18A.08(3) OF THE LISTING RULES:
WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ANY OF OUR
PIPELINE PRODUCTS, SUCCESSFULLY.**

Business Development and Strategic Partnerships

Our business development team plays a pivotal role in driving strategic growth for our organization. This encompasses expanding the commercialization of our in-market drugs, strengthening our clinical-stage pipeline with potential FIC and BIC molecules, and acquiring innovative technologies that enhance our research and development efforts. As of the date of this results announcement, we have established strong strategic partnerships with leading companies, including Pfizer, Sanofi, Hengrui, 3SBio Inc., Allist, Ewopharma, Pharmalink, SteinCares and Gentili, etc.

Regarding our in-market products in mainland China, we executed an exclusive commercialization agreement with Allist for GAVRETO® in November 2023. Subsequently, we entered into a strategic partnership with Hengrui in July 2024 to commercialize AYVAKIT®. Under both agreements, CStone retains all other rights including development, registration, manufacturing and distribution, etc.

For the global commercialization of our anti-PD-L1 antibody sugemalimab (CEJEMLY®), we continue to establish strategic partnerships across key regions. In May 2024, we secured a commercial collaboration with Ewopharma, covering Switzerland and 18 Central Eastern European countries (“CEE”) countries. In November 2024, we further expanded our global footprint through a strategic alliance with Pharmalink for Middle East and North Africa (“MENA”) region and South Africa. In January 2025, we formed a commercialization partnership with SteinCares for LATAM region. In July 2025, we signed an exclusive license agreement with Gentili for Western Europe and the U.K..

Beyond these initiatives, we remain actively engaged with potential partners to explore a range of opportunities aimed at accelerating value creation. These include in-licensing, out-licensing, and strategic partnerships.

Note: AYVAKIT® and associated logos are trademarks of Blueprint Medicines Corporation. GAVRETO® and associated logos are trademarks of Blueprint Medicines Corporation outside of the U.S. In July 2025, Sanofi publicly announced the successful completion of its US\$9.5 billion acquisition of Blueprint Medicines Corporation.

FINANCIAL INFORMATION

CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE SIX MONTHS ENDED JUNE 30, 2025

		For the six months ended June 30,	
	NOTES	2025 RMB'000 (Unaudited)	2024 RMB'000 (Unaudited)
Revenue	3	49,451	254,165
Cost of revenue		(142,241)	(82,136)
Gross (loss) profit		(92,790)	172,029
Other income	4	9,315	14,824
Other gains and losses	4	4,566	12,884
Research and development expenses		(105,166)	(66,248)
Selling and marketing expenses		(35,654)	(62,769)
Administrative expenses		(43,546)	(46,672)
Finance costs		(6,908)	(8,349)
(Loss) profit for the period	6	(270,183)	15,699
Other comprehensive income (expense):			
<i>Item that may be reclassified subsequently to profit or loss:</i>			
Exchange differences arising on translation of foreign operations		269	(11)
Total comprehensive (expense) income for the period		(269,914)	15,688
(Loss) earnings per share			
– Basic (RMB)	8	(0.21)	0.01
– Diluted (RMB)		(0.21)	0.01

CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION
AT JUNE 30, 2025

		June 30, 2025	December 31, 2024
	<i>NOTES</i>	RMB'000	RMB'000
		(Unaudited)	(Audited)
Non-current assets			
Property, plant and equipment		88,624	93,218
Right-of-use assets		21,361	37,325
Intangible assets		155,526	161,366
Financial assets measured at fair value through profit or loss (“FVTPL”)		4,847	9,032
Other receivables		20,058	2,617
		290,416	303,558
Current assets			
Account receivables	9	62,536	83,929
Deposits, prepayments and other receivables		37,336	46,946
Inventories		148,851	286,096
Time deposits with original maturity over three months		195,000	285,000
Cash and cash equivalents		457,766	387,937
		901,489	1,089,908
Current liabilities			
Account and other payables and accrued expenses	10	387,690	576,181
Refund liabilities		7,774	2,224
Bank borrowings		194,000	60,800
Contract liabilities		10,385	10,385
Lease liabilities		25,947	32,416
		625,796	682,006
Net current assets		275,693	407,902
Total assets less current liabilities		566,109	711,460

	June 30, 2025	December 31, 2024
<i>NOTES</i>	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Audited)
Non-current liabilities		
Bank borrowings	169,200	257,400
Contract liabilities	79,639	84,832
Lease liabilities	2,226	5,357
	<u>251,065</u>	<u>347,589</u>
Net assets	<u><u>315,044</u></u>	<u><u>363,871</u></u>
Capital and reserves		
Share capital	918	860
Treasury shares held in the trusts	(4)	(7)
Reserves	<u>314,130</u>	<u>363,018</u>
Total equity	<u><u>315,044</u></u>	<u><u>363,871</u></u>

NOTES

1. GENERAL AND BASIS OF PREPARATION

The Company is a public limited company incorporated in the Cayman Islands and its shares are listed on the Main Board of The Stock Exchange since February 26, 2019.

The Company is an investment holding company. The Company's subsidiaries are principally engaged in research and development of highly complex biopharmaceutical products and sale of pharmaceutical products.

The condensed consolidated financial statements have been prepared in accordance with International Accounting Standard 34 *Interim Financial Reporting* issued by the International Accounting Standards Board ("IASB") as well as the applicable disclosure requirements of the Rules Governing the Listing of Securities on the Stock Exchange.

The directors of the Company have, at the time of approving the condensed consolidated financial statements, a reasonable expectation that the Group has adequate resources to continue in operational existence for the foreseeable future. Thus they continue to adopt the going concern basis of accounting in preparing the condensed consolidated financial statements.

2. ACCOUNTING POLICIES

The condensed consolidated financial statements have been prepared on the historical cost basis except for certain financial instruments, which are measured at fair values, as appropriate.

Other than additional accounting policies resulting from application of amendments to IFRS Accounting Standards issued by IASB, the accounting policies and methods of computation used in the condensed consolidated financial statements for the six months ended June 30, 2025 are the same as those presented in the Group's annual consolidated financial statements for the year ended December 31, 2024.

Application of amendments to IFRS Accounting Standard

In the current interim period, the Group has applied the following amendments to IFRS Accounting Standard issued by the IASB, for the first time, which are mandatory effective for the Group's annual period beginning on January 1, 2025 for the preparation of the Group's condensed consolidated financial statements:

Amendments to IAS 21	Lack of Exchangeability
----------------------	-------------------------

The application of the amendment to IFRS Accounting Standards in the current interim period has had no material impact on the Group's financial positions and performance for the current and prior periods and/or on the disclosures set out in these condensed consolidated financial statements.

3. REVENUE

Disaggregation of revenue from contracts with customers

	For the six months ended June 30,	
	2025	2024
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Type of goods or services		
Sales of pharmaceutical products	20,216	118,279
License fee income	17,934	122,567
Royalty income	11,301	13,319
	<u>49,451</u>	<u>254,165</u>
Timing of revenue recognition		
A point in time	<u>49,451</u>	<u>254,165</u>

Segment Information

The Group has been operating in one reportable segment, being the research and development of highly complex biopharmaceutical products, sale of pharmaceutical products and provide license of its patented intellectual property or commercialisation license to customers.

The Group's chief operating decision maker ("CODM") has been identified as the chief executive of the Group. For the purpose of resource allocation and performance assessment, the CODM reviews the overall results and financial position of the Group prepared based on the same accounting policies.

Geographical information

Substantially, majority of the Group's operation and non-current assets are located in the People's Republic of China (the "PRC"). The geographical information of the Group's revenue, determined based on the geographical location of the registered office of the customers, during the reporting period is as follows:

	For the six months ended June 30,	
	2025	2024
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Mainland China	26,942	232,106
Outside Mainland China	22,509	22,059
	<u>49,451</u>	<u>254,165</u>

4. OTHER INCOME AND OTHER GAINS AND LOSSES

Other income

	For the six months ended June 30,	
	2025	2024
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Bank and other interest income	1,087	7,439
Government grants income	2,712	525
Amortisation of payments received for exclusive promotion rights granted	5,193	3,443
Income from sales of scrap materials	–	2,723
Others	323	694
	<u>9,315</u>	<u>14,824</u>

Other gains and losses

	For the six months ended June 30,	
	2025	2024
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Net foreign exchange gains	7,021	3,235
Net gain on fair value changes of money market funds	136	196
Net (loss) gain on fair value changes of financial assets measured at FVTPL	(2,617)	9,132
Gain on disposal of property, plant and equipment	–	340
Others	26	(19)
	<u>4,566</u>	<u>12,884</u>

5. INCOME TAX EXPENSE

No income tax expense for the six months ended June 30, 2025 and 2024 as the Group had no assessable profits derived from the operating entities of the Group.

6. (LOSS) PROFIT FOR THE PERIOD

	For the six months ended June 30,	
	2025	2024
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
(Loss) profit for the period has been arrived at after charging (crediting):		
Depreciation of:		
Property, plant and equipment	291	1,043
Right-of-use assets	15,964	17,125
Amortisation of intangible assets	5,840	5,839
	<hr/>	<hr/>
Total depreciation and amortisation	22,095	24,007
	<hr/>	<hr/>
Directors' emoluments	10,909	15,423
Other staff costs:		
Salaries and other allowances	34,523	52,501
Performance related bonus	11,249	3,986
Retirement benefit scheme contributions	7,475	12,370
Share-based payment expenses	(1,525)	(16,927)
	<hr/>	<hr/>
	51,722	51,930
	<hr/>	<hr/>
	62,631	67,353
	<hr/>	<hr/>
Impairment losses recognised on construction in progress (included in research and development expenses)	4,303	4,161
Write-down (reversal) of inventories (included in cost of revenue)	64,901	(2,710)
Cost of inventories recognised as cost of revenue	53,181	43,529
	<hr/>	<hr/>

7. DIVIDENDS

No dividends were paid, declared or proposed for ordinary shareholders of the Company during the interim period, nor has any dividend been proposed since the end of the reporting period.

8. (LOSS) EARNINGS PER SHARE

The calculation of the basic and diluted (loss) earnings per share for the period is as follows:

	For the six months ended June 30,	
	2025	2024
	(Unaudited)	(Unaudited)
(Loss) Earnings (RMB' 000)		
(Loss) earnings for the period attributable to owners of the Company for the purpose of basic and diluted (loss) earnings per share	(270,183)	15,699
Number of shares (' 000)		
Weighted average number of ordinary shares for the purpose of basic and diluted (loss) earnings per share	1,314,139	1,275,512

The calculation of basic and diluted (loss) earnings per share for both periods has excluded the treasury shares held in trust of the Company.

Diluted (loss) earnings per share for both periods did not assume the exercise of share options awarded under the employee stock option and the vesting of unvested restricted stock units as their inclusion would be anti-dilutive.

9. ACCOUNT RECEIVABLES

The Group generally allows an average credit period of 60 days for its customers.

The following is an aged analysis of account receivables presented based on invoice dates at the end of the reporting period.

	June 30, 2025	December 31, 2024
	RMB' 000	RMB' 000
	(Unaudited)	(Audited)
0 – 60 days	24,923	48,688
61 – 90 days	1,827	–
Over 90 days	35,786	35,241
	62,536	83,929

10. ACCOUNT AND OTHER PAYABLES AND ACCRUED EXPENSES

	June 30, 2025 RMB'000 (Unaudited)	December 31, 2024 RMB'000 (Audited)
Account payables	212,085	338,029
Other payables and accruals	175,605	238,152
	387,690	576,181

The credit period on account payables is ranged from 0 to 90 days. The following is an aged analysis of account payables presented based on invoice dates at the end of the reporting period.

	June 30, 2025 RMB'000 (Unaudited)	December 31, 2024 RMB'000 (Audited)
0 – 30 days	47,336	74,545
31 – 60 days	16,635	142,635
61 – 90 days	6,227	24,848
Over 90 days	141,887	96,001
	212,085	338,029

11. EVENTS AFTER THE REPORTING PERIOD

On July 16, 2025, the Company completed the placing of 100,000,000 placing shares by a placing agent to not less than six placees at the placing price of HK\$4.72 per placing share, representing 6.83% of the issued share capital of the Company as enlarged by the allotment and issue of the placing shares immediately upon completion of the placing. The Company received net proceeds from the placing, after deducting the placing commission and other related expenses and professional fees, of approximately HK\$467.28 million (equivalent to RMB425.79 million).

Financial Review

CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

Six months ended June 30, 2025 Compared to Six months ended June 30, 2024

	For the six months ended June 30,	
	2025	2024
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Revenue	49,451	254,165
Cost of revenue	(142,241)	(82,136)
Gross (loss) profit	(92,790)	172,029
Other income	9,315	14,824
Other gains and losses	4,566	12,884
Research and development expenses	(105,166)	(66,248)
Selling and marketing expenses	(35,654)	(62,769)
Administrative expenses	(43,546)	(46,672)
Finance costs	(6,908)	(8,349)
(Loss) profit for the period	(270,183)	15,699
Other comprehensive income (expense):		
<i>Item that may be reclassified subsequently to profit or loss:</i>		
Exchange differences arising on translation of foreign operations	269	(11)
Total comprehensive (expense) income for the period	(269,914)	15,688
Non-IFRS measures:		
Adjusted (loss) profit for the period	(265,099)	10,810

Revenue. Our revenue was RMB49.4 million for the six months ended June 30, 2025, representing a decrease of RMB204.8 million or 80.5% compared to RMB254.2 million for the six months ended June 30, 2024. The revenue is composed of RMB20.2 million from sales of pharmaceutical products (avapritinib, pralsetinib), RMB17.9 million from license fee income and RMB11.3 million from royalty income of sugemalimab. (1) Revenue from sales of pralsetinib decreased substantially period-on-period, which is primarily due to price adjustments of pralsetinib in preparation for the NRDL negotiation and related one-off channel compensation. If included in NRDL, benefit from sales ramp up of pralsetinib in 2026 and beyond is expected to outweigh short-term negative impact on revenue. (2) License fee income also decreased substantially period-on-period, primarily due to the fact that we received a strong contribution from a one-time milestone payment for sugemalimab gastric cancer approval in China in the first half of 2024. No material out-licensing arrangement was entered into during the first half of 2025, however, the major out-licensing agreement with Gentili in July 2025 is expected to contribute to license fee income for the second half of 2025.

Cost of Revenue. Our cost of revenue was RMB142.2 million for the six months ended June 30, 2025, representing an increase of RMB60.1 million from RMB82.1 million for the six months ended June 30, 2024, primarily due to inventory write-downs charged to cost of revenue and cost associated with an early billing of pralsetinib supply under the Patient Assistance Program covering the period through the first half of 2026 to mitigate customs clearance risks amid trade uncertainties.

Other Income. Our other income decreased by RMB5.5 million from RMB14.8 million for the six months ended June 30, 2024 to RMB9.3 million for the six months ended June 30, 2025. This was primarily due to less bank and other interest income.

Other Gains and Losses. Our other gains and losses decreased by RMB8.3 million from RMB12.9 million for the six months ended June 30, 2024 to RMB4.6 million for the six months ended June 30, 2025. This decrease was primarily due to a net loss on fair value changes of financial assets measured at FVTPL.

Research and Development Expenses. Our research and development expenses increased by RMB39.0 million from RMB66.2 million for the six months ended June 30, 2024 to RMB105.2 million for the six months ended June 30, 2025. This increase was primarily attributable to an increase of RMB35.9 million in milestone fee and third party contracting cost for different phases of our clinical trials from RMB15.4 million for the six months ended June 30, 2024 to RMB51.3 million for the six months ended June 30, 2025.

	For the six months ended June 30,	
	2025	2024
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Milestone fee and third party contracting cost	51,315	15,363
Employee cost	35,895	34,173
Depreciation and others	17,956	16,712
	<hr/>	<hr/>
Total	<u>105,166</u>	<u>66,248</u>

Administrative Expenses. Our administrative expenses decreased by RMB3.2 million from RMB46.7 million for the six months ended June 30, 2024 to RMB43.5 million for the six months ended June 30, 2025. This decrease was primarily attributable to a decrease of RMB2.7 million in depreciation and amortization from RMB5.3 million for the six months ended June 30, 2024 to RMB2.6 million for the six months ended June 30, 2025.

	For the six months ended June 30,	
	2025	2024
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Employee cost	24,359	23,860
Professional fees	13,345	13,351
Depreciation and amortization	2,636	5,278
Rental expenses	484	1,500
Others	2,722	2,683
Total	43,546	46,672

Selling and Marketing Expenses. Our selling and marketing expenses decreased by RMB27.1 million from RMB62.8 million for the six months ended June 30, 2024 to RMB35.7 million for the six months ended June 30, 2025. This decrease was primarily attributable to a decrease of RMB19.6 million in channel service fee and others from RMB53.5 million for the six months ended June 30, 2024 to RMB33.9 million for the six months ended June 30, 2025.

	For the six months ended June 30,	
	2025	2024
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Employee cost	1,713	9,318
Channel service fee and others	33,941	53,451
Total	35,654	62,769

Finance Costs. The finance costs decreased by RMB1.4 million from RMB8.3 million for the six months ended June 30, 2024 to RMB6.9 million for the six months ended June 30, 2025, primarily due to a decrease in interest on bank borrowings.

Non-IFRS Measures

To supplement the Group's condensed consolidated financial statements, which are presented in accordance with the IFRS, the Company also uses adjusted (loss) profit for the period and other adjusted figures as additional financial measures, which are not required by, or presented in accordance with, the IFRS. The Company believes that these adjusted measures provide useful information to shareholders and potential investors in understanding and evaluating the Group's consolidated results of operations in the same manner as they help the Company's management.

Adjusted (loss) profit for the period represents the (loss) profit for the period excluding the effect of certain noncash items and one-time events, namely the share-based payment expenses. The term adjusted (loss) profit for the period is not defined under the IFRS. The use of this non-IFRS measure has limitations as an analytical tool, and you should not consider it in isolation from, or as substitute for analysis of, the Group's results of operations or financial condition as reported under IFRS. The Company's presentation of such adjusted figure may not be comparable to a similarly titled measure presented by other companies. However, the Company believes that this and other non-IFRS measures are reflections of the Group's normal operating results by eliminating potential impacts of items that the management do not consider to be indicative of the Group's operating performance, and thus facilitate comparisons of operating performance from period to period and company to company to the extent applicable.

The table below sets forth a reconciliation of the (loss) profit to adjusted (loss) profit during the periods indicated:

	For the six months ended June 30,	
	2025	2024
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
(Loss) profit for the period	(270,183)	15,699
Added:		
Share-based payment expenses	<u>5,084</u>	<u>(4,889)</u>
Adjusted (loss) profit for the period	<u>(265,099)</u>	<u>10,810</u>

The table below sets forth a reconciliation of the research and development expenses to adjusted research and development expenses during the periods indicated:

	For the six months ended June 30,	
	2025	2024
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Research and development expenses for the period	(105,166)	(66,248)
Added:		
Share-based payment expenses	<u>3,077</u>	<u>(4,770)</u>
Adjusted research and development expenses for the period	<u>(102,089)</u>	<u>(71,018)</u>

The table below sets forth a reconciliation of the administrative and selling and marketing expenses to adjusted administrative and selling and marketing expenses during the periods indicated:

	For the six months ended June 30,	
	2025 RMB'000 (Unaudited)	2024 RMB'000 (Unaudited)
Administrative and selling and marketing expenses for the period	(79,200)	(109,441)
Added:		
Share-based payment expenses	<u>2,007</u>	<u>(119)</u>
Adjusted administrative and selling and marketing expenses for the period	<u><u>(77,193)</u></u>	<u><u>(109,560)</u></u>

Employees and Remuneration Policies

The following table sets forth a breakdown of our employees as of June 30, 2025 by function:

Function	Number of employees	% of total number of employees
Research and Development	83	63.36
Sales, General and Administrative	<u>48</u>	<u>36.64</u>
Total	<u><u>131</u></u>	<u><u>100.0</u></u>

As of June 30, 2025, we had 93 employees in Shanghai, 9 employees in Beijing, 21 employees in Suzhou and 8 employees in other regions of the PRC and overseas. Our employees' remuneration comprises salaries, bonuses, employee provident fund, social security contributions and other welfare payments. In accordance with applicable Chinese laws, we have made contributions to social security insurance funds (including pension plans, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance) and housing funds for our employees.

Liquidity and Financial Resources

The Group has always adopted a prudent treasury management policy. The Group has taken a multi-source approach to fund our operations and meet development demands for capital, including service and milestone and upfront payments from our collaboration partners, bank borrowings, investments from other third parties and proceeds from our listing on the Stock Exchange.

On February 26, 2019, 186,396,000 Shares of US\$0.0001 each were issued at a price of HK\$12.00 per Share in connection with the Company's initial public offering ("IPO") on the Stock Exchange. The proceeds of HK\$146,294.76 representing the par value, were credited to the Company's share capital. The remaining proceeds of RMB2,090.16 million (before deduction of the expenses relating to the Company's IPO) were credited to the share premium account. The translation from US\$ to HK\$ is made at the exchange rate set forth in the H.10 weekly statistical release of the Federal Reserve System of the United States as of February 26, 2019.

On September 30, 2020 (before trading hours), the Company entered into the share subscription agreement with Pfizer, pursuant to which Pfizer has conditionally agreed to subscribe for an aggregate of 115,928,803 subscription shares at the subscription price of approximately HK\$13.37 per Share. The gross proceeds from the allotment and issue of the subscription shares were approximately US\$200.0 million (equivalent to approximately RMB1,355.9 million).

On February 15, 2023, the Company completed the placing of 84,800,000 placing shares by a placing agent to not less than six placees at the placing price of HK\$4.633 per placing share, representing 6.61% of the issued share capital of the Company as enlarged by the allotment and issue of the placing shares immediately upon completion of the placing. The Company received net proceeds from the placing, after deducting the placing commission and other related expenses and professional fees, of approximately HK\$389.07 million (equivalent to approximately RMB338.12 million).

On April 10, 2025, the Company completed the placing of 80,000,000 placing shares by a placing agent to not less than six placees at the placing price of HK\$2.933 per placing share, representing 5.86% of the issued share capital of the Company as enlarged by the allotment and issue of the placing shares immediately upon completion of the placing. The Company received net proceeds from the placing, after deducting the placing commission and other related expenses and professional fees, of approximately HK\$232.29 million (equivalent to RMB215.82 million).

At June 30, 2025, our cash and cash equivalents and time deposits were RMB652.8 million, as compared to RMB672.9 million as of December 31, 2024. The decrease was mainly due to the payment of research and development expenses, payroll and purchase of inventories. The cash and cash equivalents were mainly denominated in RMB, USD and HKD.

Gearing Ratio

Gearing ratio is calculated using total liabilities divided by total assets and multiplied by 100%. At June 30, 2025, our gearing ratio was 73.6% (December 31, 2024: 73.9%).

Charge on Assets

At June 30, 2025, the Group did not pledge any assets (December 31, 2024: Nil).

OTHER FINANCIAL INFORMATION

Significant Investments, Material Acquisitions and Disposals

As at June 30, 2025, we did not hold any significant investments and there had been no material acquisitions and disposals by the Group. As at the date of this announcement, we have no specific future plan for material investments or capital assets, as well as material acquisitions or disposals of subsidiaries, associates and joint ventures.

Foreign Exchange Risk

Our financial statements are expressed in RMB, but certain of our cash and cash equivalents, restricted bank deposits, time deposits, other receivables, financial assets measured at FVTPL and trade and other payables are denominated in foreign currencies, and are exposed to foreign currency risk. We currently do not have a foreign currency hedging policy. However, the management of the Group monitors foreign exchange exposure and will consider hedging significant foreign currency exposure should the need arise.

Bank Loans and Other Borrowings

As at June 30, 2025, the Group's bank borrowings were RMB363,200,000, all bank borrowings denominated in RMB.

Contingent Liabilities

As at June 30, 2025, the Group did not have any material contingent liabilities (December 31, 2024: Nil).

CORPORATE GOVERNANCE AND OTHER INFORMATION

The Company was incorporated in the Cayman Islands with limited liability on December 2, 2015, and the shares of the Company (the “**Shares**”) were listed on the Stock Exchange on February 26, 2019.

Compliance with the Corporate Governance Code

The Board is committed to achieving high corporate governance standards. During the Reporting Period, the Company has complied with all the code provisions as set out in Part 2 of the Corporate Governance Code (the “**CG Code**”) contained in Appendix C1 to the Rules Governing the Listing of Securities on the Stock Exchange (“**Listing Rules**”).

We will continue to regularly review and monitor its corporate governance practices to ensure compliance with the CG Code, and maintain a high standard of corporate governance practices of the Company.

Model Code for Securities Transactions by Directors of Listed Issuers

We have adopted our own code of conduct regarding Directors' securities transactions, namely the policy on management of securities transactions by directors (the “**Securities Transactions Code**”), which applies to all Directors on terms not less exacting than the required standard indicated by the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix C3 to the Listing Rules (the “**Model Code**”).

Specific enquiries have been made to all the Directors and they have confirmed that they have complied with the Securities Transactions Code during the Reporting Period. The Company's employees, who are likely to be in possession of our unpublished inside information, are subject to the Model Code. No incident of non-compliance of the Model Code by the employees was noted by the Company as of the date of this announcement.

Purchase, Sale or Redemption of Listed Securities

Neither the Company nor any of its subsidiaries purchased, sold or redeemed any of the Company's listed securities (including any sale of treasury Shares (as defined under the Listing Rules)) during the Reporting Period. As at June 30, 2025, the Company did not hold any treasury Shares (as defined under the Listing Rules).

Material Litigation

The Company was not involved in any material litigation or arbitration during the Reporting Period. The Directors are also not aware of any material litigation or claims that were pending or threatened against the Group during the Reporting Period.

Material Events after the Reporting Period

On July 16, 2025, the Company completed the placing of 100,000,000 placing shares by a placing agent to not less than six placees at the placing price of HK\$4.72 per placing share, representing 6.83% of the issued share capital of the Company as enlarged by the allotment and issue of the placing shares immediately upon completion of the placing. The Company received net proceeds from the placing, after deducting the placing commission and other related expenses and professional fees, of approximately HK\$467.28 million. Please refer to the announcements of the Company dated July 9, 2025 and July 16, 2025 for more details.

Use of Net Proceeds

On September 30, 2020 (before trading hours), the Company entered into the share subscription agreement with Pfizer, pursuant to which Pfizer has conditionally agreed to subscribe for an aggregate of 115,928,803 subscription shares (being ordinary shares of the Company) at the subscription price of approximately HK\$13.37 per Share (the closing price of the Company as quoted on the Stock Exchange on September 29, 2020 was HK\$9.30 per Share) (the “**Share Subscription**”). Pfizer applies science and its global resources to improve health and well-being at every stage of life, and was a third party independent of the Company or any of its connected person at the time of the Share Subscription. The gross proceeds from the allotment and issue of the subscription shares were approximately US\$200.0 million (equivalent to approximately RMB1,355.9 million), which will be used for the funding of the development activities under the collaboration agreement dated September 30, 2020 (the “**Collaboration Agreement**”). The Company entered into the Share Subscription and the Collaboration Agreement to advance the Company's strategic, commercial and financial objectives as it transitions into a fully integrated biopharma company. All the conditions of the subscription have been fulfilled and the closing of the subscription took place on October 9, 2020. The use of these proceeds is in line with the planned use and there is no significant change.

The table below sets out the planned applications of the proceeds and actual usage up to June 30, 2025:

	% of use of proceeds	Proceeds from the subscription (RMB million)	Unutilized net proceeds as of December 31, 2024 (RMB million)	Actual usage during the Reporting Period (RMB million)	Unutilized net proceeds as of June 30, 2025 (RMB million)
Fund the development activities under the collaboration agreement	100%	1,355.9	409.3	40.6	368.7

Note: The unutilized net proceeds are planned to be put into use by December 31, 2025. Please refer to the 2023 annual report of the Company for details.

On April 2, 2025 (before trading hours), the Company entered into a placing agreement with Morgan Stanley Asia Limited (the “**Placing Agent**”), pursuant to which the Company agreed to place, through the Placing Agent, an aggregate of 80,000,000 placing shares (being ordinary shares of the Company) to not less than six placees at a price of HK\$2.933 per placing share (the closing price of the Company as quoted on the Stock Exchange on April 1, 2025 was HK\$3.45 per Share). The net placing price (after deducting related costs and expenses to be borne by the Company) is approximately HK\$2.904 per Share. The aggregate nominal value of the placing shares under the placing is US\$8,000. The placees are professional, institutional or other investors, and together with their ultimate beneficial owners, are third parties independent of the Company and any of its connected persons. The placing would enlarge the Shareholder base and the capital base of the Company, and strengthen the Group’s financial position for its future development. The net proceeds from the placing, after deducting the placing commission and other related expenses and professional fees, were approximately HK\$232.29 million (equivalent to approximately RMB215.82 million). The Company intends to use the net proceeds for purposes as stated below. All the conditions of the placing were fulfilled and the closing of the placing took place on April 10, 2025. The use of these proceeds is in line with the planned use and there is no significant change or delay.

The table below sets out the planned applications of the proceeds and actual usage up to June 30, 2025:

	% of use of proceeds	Proceeds from the placing (RMB million)	Actual usage during the Reporting Period (RMB million)	Unutilized net proceeds as of June 30, 2025 (RMB million)
Research and development of Pipeline “2.0”, including in particular CS5001, a clinical stage ROR1 ADC (a potentially best-in-class ROR1 ADC), and CS2009, a trispecific antibody targeting PD-1, VEGFA and CTLA-4 (a potentially first-in-class/best-in-class next-generation immuno-oncology backbone)	90%	194.24	25.97	168.27
General corporate purposes	10%	21.58	4.28	17.30
Total	100%	215.82	30.25	185.57

Note: The unutilized net proceeds are planned to be put into use by December 31, 2026.

Audit Committee

The Company has established an audit committee (the “**Audit Committee**”) with written terms of reference in accordance with the Listing Rules. The Audit Committee currently comprises two independent non-executive Directors, namely, Ms. Yip Betty Ho (Chairperson) and Mr. Ting Yuk Anthony Wu.

The Audit Committee has considered and reviewed the accounting principles and practices adopted by the Group and discussed matters in relation to internal control and financial reporting with the management. The Audit Committee reviewed and considered that the interim financial results for the six months ended June 30, 2025 are in compliance with the relevant accounting standards, rules and regulations and appropriate disclosures have been duly made.

Review of Interim Results

The independent auditors of the Company, namely Deloitte Touche Tohmatsu, have conducted a review of the interim financial information in accordance with the International Standard on Review Engagement 2410 *Review of Interim Financial Information Performed by the Independent Auditor of the Entity* issued by the International Auditing and Assurance Standards Board. The Audit Committee has jointly reviewed with the management of the Company, the accounting principles and policies adopted by the Company and discussed internal control and financial reporting matters (including the review of the unaudited interim results for the six months ended June 30, 2025) of the Group.

INTERIM DIVIDEND

The Board does not recommend the payment of an interim dividend for the six months ended June 30, 2025 (2024: Nil).

PUBLICATION OF INTERIM RESULTS ANNOUNCEMENT AND INTERIM REPORT

This announcement is published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.cstonepharma.com).

The interim report for the six months ended June 30, 2025 containing all the information required by Appendix D2 to the Listing Rules will be published on the websites of the Stock Exchange and the Company in due course.

APPRECIATION

The Board would like to express its sincere gratitude to the shareholders, management team, employees, business partners and customers of the Group for their support and contribution to the Group.

By order of the Board
CStone Pharmaceuticals
Dr. Wei Li
Chairman and Non-executive Director

Suzhou, the PRC, August 14, 2025

As at the date of this announcement, the board of directors of the Company comprises Dr. Wei Li as Chairman and non-executive director, Dr. Jianxin Yang as executive director, Mr. Kenneth Walton Hitchner III and Mr. Edward Hu as non-executive directors, and Mr. Ting Yuk Anthony Wu and Ms. Yip Betty Ho as independent non-executive directors.