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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, 2024

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, 2024 (the “**Reporting Period**”), together with comparative figures for the six months ended June 30, 2023. 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, 2023 dated August 15, 2023.

FINANCIAL HIGHLIGHTS

International Financial Reporting Standards (“IFRS”) Measures:

- **Revenue** was RMB254.2 million for the six months ended June 30, 2024, composed of RMB118.3 million in sales of pharmaceutical products (avapritinib and pralsetinib), RMB122.6 million in license fee income and RMB13.3 million in royalty income of sugemalimab, representing an increase of RMB122.6 million in license fee income which largely offset a decrease of RMB128.6 million in revenue from sales of pharmaceutical products, such that total revenue decreased by RMB7.3 million, or 2.8%, period-on-period.
- **Research and development expenses** were RMB66.2 million for the six months ended June 30, 2024, representing a decrease of RMB120.6 million from RMB186.8 million for the six months ended June 30, 2023, primarily due to a decrease in milestone fee and third party contracting costs and a decrease in employee costs.
- **Administrative expenses** were RMB46.7 million for the six months ended June 30, 2024, representing a decrease of RMB42.5 million from RMB89.2 million for the six months ended June 30, 2023, primarily due to a decrease in employee costs.

- **Selling and marketing expenses** were RMB62.8 million for the six months ended June 30, 2024, representing a decrease of RMB68.6 million from RMB131.4 million for the six months ended June 30, 2023, primarily attributable to a decrease in employee costs.
- **Profit for the period** was RMB15.7 million for the six months ended June 30, 2024, representing a turnaround from a loss of RMB209.2 million for the six months ended June 30, 2023, primarily attributable to a substantial decrease in operating expenses and an increase in gross profit.

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

- **Research and development expenses** excluding the share-based payment expenses were RMB71.0 million for the six months ended June 30, 2024, representing a decrease of RMB127.1 million from RMB198.1 million for the six months ended June 30, 2023, primarily due to a decrease in milestone fee and third party contracting costs and a decrease in employee costs.
- **Administrative and selling and marketing expenses** excluding the share-based payment expenses were RMB109.6 million for the six months ended June 30, 2024, representing a decrease of RMB73.5 million from RMB183.1 million for the six months ended June 30, 2023, primarily attributable to a decrease in employee costs.
- **Profit for the period** excluding the share-based payment expenses was RMB10.8 million for the six months ended June 30, 2024, representing a turnaround from the loss of RMB183.0 million for the six months ended June 30, 2023, primarily attributable to a substantial decrease in operating expenses and an increase in gross profit.

BUSINESS HIGHLIGHTS

For the six months ended June 30, 2024 and as of the date of this announcement, tremendous progress has been made with respect to our product pipeline and business operations. Key achievements over this period include:

Key Pipeline Highlights:

Immunotherapy

- ***Sugemalimab (anti-PD-L1 antibody)***
 - **EU Approval:** In July 2024, the European Commission (“EC”) approved sugemalimab (Brand name: CEJEMLY®) in combination with platinum-based chemotherapy for the first-line treatment of adults with metastatic non-small cell lung cancer (“NSCLC”) with no sensitizing epidermal growth factor receptor (“EGFR”) mutations, or anaplastic lymphoma kinase (“ALK”), c-ros oncogene 1 (“ROS1”) or rearranged during transfection (“RET”) genomic tumor aberrations. This marks the first successful international approval of a China domestic anti-PD-L1 monoclonal antibody. Sugemalimab’s marketing authorization application (“MAA”) for first-line Stage IV NSCLC is currently under review by the Medicines and Healthcare Products Regulatory Agency (“MHRA”) in the United Kingdom (“U.K.”).
 - **Strategic Partnership:** In May 2024, we entered into a strategic collaboration with Ewopharma AG (“Ewopharma”) to commercialize sugemalimab in Switzerland and 18 Central and Eastern European (“CEE”) countries. CStone will receive up to US\$51.3 million consisting of an upfront payment and additional payables upon regulatory and sales milestones.
 - **Fifth Indication Approved in China:** In March 2024, sugemalimab was approved in China for its fifth indication – sugemalimab in combination with fluoropyrimidine – and platinum-containing chemotherapy as a first-line treatment for unresectable locally advanced or metastatic gastric adenocarcinoma or gastroesophageal junction adenocarcinoma (“GC/GEJC”) with a Programmed death-ligand 1 (“PD-L1”) expression (Combined Positive Score (“CPS”) ≥5).
 - **Publication in *Nature Medicine*:** In February 2024, the progression-free survival (“PFS”) final analysis and overall survival (“OS”) interim analysis of the GEMSTONE-304 study (first-line ESCC) were published in a top-tier medical journal – *Nature Medicine*.
 - **Long-Term OS Data at ESMO:** In July 2024, the long-term OS analysis of the GEMSTONE-302 study (first-line Stage IV NSCLC) was accepted for poster presentation at the 2024 Congress of the European Society for Medical Oncology (“ESMO”).

- **Guideline Inclusion:** In 2024, CEJEMLY® (sugemalimab) is recommended as a Tier-1 treatment based on Class-1A evidence in multiple Chinese clinical guidelines, including the 2024 CSCO guideline for gastric cancer, the 2024 CSCO guideline for esophageal cancer and the 2024 CSCO Immune Checkpoint Inhibitor Clinical Practice Guidelines, and further including the 2024 Chinese Expert Consensus on Immunotherapy for Lymphoma.
- ***Nofazinlimab (PD-1)***
 - **Global Phase III Study:** In March 2024, we completed a prespecified interim analysis for the global phase III trial of nofazinlimab in combination with LENVIMA® (lenvatinib) for the first-line treatment of patients with unresectable or metastatic hepatocellular carcinoma (“HCC”). No new or unexpected safety signals were observed, and the independent Data Monitoring Committee (“iDMC”) recommended continuing the trial without protocol modifications until the final overall survival (“OS”) analysis.

Pipeline 2.0 Highlights

- ***CS5001, a receptor tyrosine kinase-like orphan receptor 1 (ROR1) antibody-drug conjugate (“ADC”)***
 - **First-in-Human Study:** The global first-in-human (“FIH”) trial is ongoing in the United States of America (“U.S.”), Australia and China. As of the date of this announcement, the dose has been escalated to the 10th level without observing any dose-limiting toxicities (“DLTs”) or reaching the maximum tolerated dose (“MTD”).
 - **Promising Antitumor Activity:** CS5001 has been well tolerated and safe and has exhibited encouraging anti-tumor activities in various solid tumors and hematologic malignancies. CS5001 is so far the first ROR1 ADC known to demonstrate clinical anti-tumor activity in both solid tumors and lymphomas.
 - **ASCO 2024 Presentation:** On June 1, 2024, we presented the latest FIH data at a poster session of the 2024 American Society of Clinical Oncology (“ASCO”) Annual Meeting. We also plan to disclose more lymphoma data at the 2024 annual meeting of the American Society of Hematology (“ASH”).
 - **Phase 1b with Registrational Potential:** We plan to initiate phase 1b dose-expansion studies with registrational potential in multiple indications for dose optimization by the end of 2024.
 - **ROR1 Antibody Development:** We have identified a promising candidate ROR1 antibody clone for immunohistochemistry (“IHC”) and plan to evaluate the relationship between ROR1 expression and efficacy in phase 1b.

- **CS2009 (PD-1, CTLA4 and VEGFa Tri-specific Antibody)**
 - **Potential FIC/BIC:** CS2009 is a potentially first-in-class (“**FIC**”)/best-in-class (“**BIC**”) next-generation I/O backbone that targets three critical immune suppressive pathways in the tumor microenvironment and has the potential to enhance the efficacy of PD-(L)1 therapies in high-prevalence cancers, including NSCLC and HCC.
 - **IND Submission:** Currently under investigational new drug application (“**IND**”)-enabling process; IND submissions expected in 2024 or 2025.
- **FIC/BIC ADCs and Antibody**
 - **CS5006 (Novel Target) & CS5005 (SSTR2):** Two FIC ADC programs are advancing toward preclinical candidate (“**PCC**”) nomination. CS5006, targeting high-prevalence tumors with a novel tumor-associated antigen identified using an in-house machine-learning bioinformatic algorithm, is expected to submit IND in 2025. CS5005 (SSTR2 ADC) has demonstrated encouraging *in vitro* and *in vivo* efficacy with its conjugated lead molecules; IND submission expected in 2025.
 - **CS5007 (EGFRxHER3 Bispecific ADC) & CS2011 (EGFRxHER3 Bispecific Antibody)** are progressing towards PCC nomination. CS5007 (CS2011) targets EGFR and human epidermal growth factor receptor 3 (“**HER3**”), and both are well-validated targets with proven syngeneic antitumor activity. IND submissions are expected in 2025.
- **Autoimmune Multi-specific Antibody**
 - **CS2013**, which is a bispecific molecule targeting two key pathways critical for B-cell development, is in discovery stage, with selection of lead molecule expected by the end of 2024.
 - CS2013 is designed to address unmet needs in treating systemic lupus erythematosus (“**SLE**”), IgA nephropathy (“**IgAN**”), and other B-cell mediated autoimmune diseases.

Precision Medicine Highlights

- **GAVRETO[®] (pralsetinib)**
 - **Manufacturing Localization in Process:** In April 2024, the application of manufacturing localization for GAVRETO[®] has been accepted by the Center for Drug Evaluation (“CDE”) of the National Medical Products Administration (“NMPA”) in China and is currently under review.
 - **Commercial Transition:** Following the exclusive commercialization agreement for GAVRETO[®] in November 2023, we transitioned commercial activities to Allist in the first half of 2024 and are in close collaboration.
- **AYVAKIT[®] (avapritinib)**
 - **Manufacturing Localization Approved:** The manufacturing localization applications of AYVAKIT[®] (300mg and 100mg) were approved by the NMPA in June and August 2024.
 - **Partnership with Hengrui:** In July 2024, we entered into an exclusive partnership with Jiangsu Hengrui Pharmaceuticals Co., Ltd. (“Hengrui”) to commercialize AYVAKIT[®] in mainland China. CStone received an upfront payment of RMB35 million and will continue to book sales revenue from AYVAKIT[®] in mainland China in our financial reports, with service fees payable to Hengrui.
 - **Inclusion in National Reimbursement Drug List:** AYVAKIT[®] was included in the National Reimbursement Drug List for National Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (2023) (the “NRDL”) in China for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (“GIST”) harboring the PDGFRA exon 18 mutation, including PDGFRA D842V mutations. The updated NRDL has been implemented from January 1, 2024.
- **Guideline Inclusions:** GAVRETO[®] and AYVAKIT[®] were included in 15 national guidelines in China, covering multiple therapeutic areas such as NSCLC, thyroid cancer (“TC”), GIST, systemic mastocytosis (“SM”), etc.

FUTURE AND OUTLOOK

Looking forward, we remain committed to advancing our innovative pipeline and maximizing commercial value of our marketed products. Anticipated near-term catalysts include

- **Sugemalimab:** MAA approval for the first-line treatment of Stage IV NSCLC in the U.K. expected in the second half of 2024, and more global partnerships expected in 2024, and expect to launch in global markets in early 2025.
- **CS5001:** Presentation of the latest clinical safety and efficacy data at international academic conferences (e.g. ASH in the second half of 2024), initiation of phase 1b trial with registrational potential in 2024, and global business development (“**BD**”) partnerships expected in 2024 or 2025.
- **CS2009:** IND submissions expected in 2024 or 2025.
- **CS5006:** IND submission expected in 2025.
- **CS5005:** IND submission expected in 2025.
- **CS2011/CS5007:** IND submission expected in 2025.
- **GAVRETO® (pralsetinib):** Approval for manufacturing localization expected in the first half of 2025.
- **Nofazinlimab:** Final OS analysis expected in the first half of 2025; seeking ex-China partnership opportunities.

INTERIM RESULTS CALL

The Company will host a 2024 interim results conference call at 10:00 a.m. to 11:00 a.m. (Hong Kong time) on Monday, August 26, 2024. Please attend the conference call through the link: <https://s.comein.cn/AHDiL> (Password:564723). To ensure that all Shareholders and potential investors of the Company have equal and timely access to the information pertaining to the Company as well as its business and operations, details of the conference call and a copy of the presentation materials will also be available on the Company’s website (www.cstonepharma.com) under the section headed “Investor Relations – Information Disclosure and IR Events” before the hosting of the conference call.

Drug candidate	Rights	Indication	Discovery	Preclinical Development	IND	FIH	POC	Partner
CS5001 ¹ (ROR1 ADC)		Solid tumors hematologic malignancies						
CS2009 (PD-1xCTLA4xVEGFa trispecific antibody)		Solid tumors						
CS5006 (Undisclosed ADC)		Solid tumors						
CS2011 (EGFRxHER3 bispecific antibody)		Solid tumors						
CS5005 (SSTR2 ADC)		Solid tumors						
CS5007 (EGFRxHER3 bispecific ADC)		Solid tumors						
CS2012 (SSTR2 T-cell engager)		Solid tumors						
CS2013 (Bispecific antibody)		Autoimmune						
EX012 (Bispecific antibody)		Solid tumors						
EX018 (Bispecific antibody)		Autoimmune						

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 to lead development and commercialization of LCB71/CS5001 outside the Republic of Korea

Antibody Global Rights
 ADC

BUSINESS REVIEW

Commercial Operations

Marching into the fourth year since we launched our first product, we are committed to establishing leadership in precision medicine and to benefiting more patients.

Our partnerships with pharmaceutical and biotech companies are cornerstones of our near-term commercial plans as well as our global aspirations. Through our successful collaboration with Pfizer, we are demonstrating the merits of our unique clinical development capabilities, and our attractiveness to multinational players who may potentially partner with us. In order to further improve the commercialization efficiency, we have established commercial collaborations with multiple companies during the Reporting Period to leverage their strengths while enabling us to strategically focus on research and development going forward.

Details on our commercial activities are set out below:

- ***GAVRETO[®] (pralsetinib)***
 - GAVRETO[®] (pralsetinib), a FIC RET inhibitor in China, has been approved by the 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 MTC and RET fusion-positive 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 2024, we continue to integrate GAVRETO[®] (pralsetinib) into Allist’s highly synergistic lung cancer franchise, enabling GAVRETO[®] (pralsetinib) to benefit from Allist’s more mature commercial team and significantly broader market coverage, while concurrently allowing us to reduce operating costs associated with GAVRETO[®] (pralsetinib) commercialization, thereby improving overall profitability.
 - GAVRETO[®] (pralsetinib) was 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 CSCO NSCLC guidelines, 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 Category 1 recommendation in the 2024 CSCO NSCLC guideline.

- **AYVAKIT® (avapritinib)**
 - AYVAKIT® (avapritinib), a first-in-class KIT/PDGFRα inhibitor, has been approved by the 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 FDA 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 Hengrui to grant the exclusive promotion rights of precision therapy AYVAKIT® (avapritinib) in mainland China to Hengrui. Except for promotion, CStone retains all rights to AYVAKIT® (avapritinib) in mainland China under its exclusive license agreement with Blueprint Medicines, including rights to development, registration, manufacturing and distribution, etc. This deal integrates AYVAKIT® (avapritinib) into Hengrui's extensive and robust commercial infrastructure with 97% geographic coverage, covering all 32 provinces and over 20,000 hospitals.
 - We continued to improve the accessibility and affordability of AYVAKIT® (avapritinib). In 2023, AYVAKIT® (avapritinib) has been added to the 2023 NRDL in China, for the treatment of adults with unresectable or metastatic GIST harboring the PDGFRα exon 18 mutation, including PDGFRα D842V mutations. The updated NRDL has been implemented from January 1, 2024.
 - AYVAKIT® (avapritinib) is recommended by several authoritative guidelines. AYVAKIT® (avapritinib) was recommended by the updated 2022 CSCO GIST guideline and the 2022 Chinese Guideline for Diagnosis and Treatment of Systemic Mastocytosis in Adults.
- **CEJEMLY® (sugemalimab)**
 - In May 2024, we successfully entered into a strategic commercial collaboration with Ewopharma. Under the terms of the licensing and commercialization agreement, Ewopharma will gain the commercial rights for sugemalimab in Switzerland and 18 CEE countries. CStone will receive up to US\$51.3 million consisting of an upfront payment and additional consideration payable upon the achievement of certain regulatory and sales milestones. In addition, CStone will book revenues from sales of drug supply to Ewopharma and its affiliates. Ewopharma will be in charge of pricing, reimbursement, sales & marketing, and distribution, whilst CStone will be responsible for product supply and providing necessary training and support for the brand.
 - A new indication was successfully launched in mainland China in combination with chemotherapy for the first-line treatment of patients with locally advanced or metastatic GC/GEJC in 2024.
 - We continue to work closely with Pfizer to support the commercialization of CEJEMLY® (sugemalimab) in mainland China.

- In 2024, CEJEMLY® (sugemalimab) as a treatment of HER2-negative advanced gastric cancer (CPS ≥ 5) has been included in the 2024 CSCO guideline for gastric cancer as a Category 1 (1A evidence) recommendation, as a treatment of advanced ESCC in the 2024 CSCO guideline for esophageal cancer as a Category 1 (1A evidence) recommendation and as a treatment of HER2-negative esophageal adenocarcinoma in the 2024 CSCO guideline for esophageal cancer as a Category 1 (1A evidence) recommendation in China. In addition, CEJEMLY® (sugemalimab) as a treatment of R/R ENKTL has been included in the 2024 CSCO Immune Checkpoint Inhibitor Clinical Practice Guidelines as a Category 1 (1A evidence) recommendation and the 2024 Chinese Expert Consensus on Immunotherapy of Lymphoma in China.

Clinical Development

As of the date of this announcement, we have made significant progress with respect to our product pipeline.

CS5001 (LCB71, ROR1 ADC)

- The phase 1a dose escalation in the global FIH study of this potential BIC ROR1 ADC has been ongoing in the U.S., Australia and China, with in-parallel patient backfilling at tentative RP2Ds.
- On June 1, 2024, we presented the latest FIH data at the ASCO annual meeting in a poster session:
 - As of the data cut-off date in our poster, DLT evaluation for the first nine dose levels (7 to 156 $\mu\text{g}/\text{kg}$) in Phase 1a has been completed. No DLTs were observed, and the MTD was not reached.
 - Most treatment-related adverse events observed were Grade 1 or 2 (per NCI-CTCAE v5.0), indicating that CS5001 was well tolerated by heavily pretreated patients with advanced solid tumors and lymphomas.
 - PK data suggested dose-proportional exposure of CS5001, with similar exposure for ADC and total antibody, demonstrating excellent stability of CS5001 ADC in circulation.
 - Encouraging anti-tumor activity has been observed in various solid tumors (per RECIST v1.1) and hematologic malignancies (per Lugano 2014):
 - Hodgkin Lymphoma: Objective responses were observed from dose level 5 (50 $\mu\text{g}/\text{kg}$) and above, including 1 CR and 4 PR among 9 evaluable patients at dose levels 5-9, achieving an ORR of 55.6%.
 - DLBCL: Objective responses were observed from dose level 7 (100 $\mu\text{g}/\text{kg}$) and above, including 1 CR and 2 PRs among 6 evaluable patients at dose levels 7-9, achieving an ORR of 50.0%.

- In solid tumors, multiple PRs and SDs with reduced tumor burden were emerging from dose level 7 (100 µg/kg) and above, notably in NSCLC (1 PR and 3 SDs), pancreatic cancer (1 PR), TNBC (1 SD), and ovarian cancer (1 SD). Based on the efficacy trends observed, more potent anti-tumor activity is expected in solid tumors as the dose increases.
- CS5001 is so far the first ROR1 ADC known to demonstrate clinical anti-tumor activity in both solid tumors and lymphomas.
- As of the date of this announcement, we have escalated to dose level 10; no DLT was observed; and the MTD has not been reached. We expect to determine the tentative RP2Ds of CS5001 in the second half of 2024 and plan to initiate phase Ib dose-expansion studies in multiple indications for dose optimization by the end of 2024, followed by initiation of registrational trials in 2025. We also plan to present more data from lymphoma patients accumulated during phase 1a at the 2024 ASH conference.
- CS5001 has many distinctive features, including proprietary site-specific conjugation, tumor-cleavable linker, and prodrug technology. CS5001 demonstrated a BIC potential in MCL and TNBC xenograft models compared to a benchmark ROR1 ADC with MMAE payload. In addition, CS5001 demonstrated a bystander effect in *in vitro* co-culture systems, suggesting that solid tumors with heterogeneous/low expression of ROR1 may also benefit.
- In addition, we have identified a promising candidate ROR1 antibody clone for IHC to enable biomarker-driven patient selection based on tumor ROR1 expression, and we plan to evaluate the relationship between ROR1 expression and efficacy in phase 1b dose expansion.

Sugemalimab (CS1001, PD-L1 antibody)

- Sugemalimab is a monoclonal antibody directed against PD-L1 that has been approved by the NMPA in China for stage IV NSCLC, stage III NSCLC, R/R ENKTL, ESCC and GC/GEJC indications. As a fully-human, full-length anti-PD-L1 monoclonal antibody, sugemalimab mirrors the natural G-type IgG4 human antibody, which may potentially reduce the risk of immunogenicity and toxicity in patients, a potential unique advantage and differentiation factor compared to similar drugs.
- **Stage IV NSCLC:**
 - The MAAs for sugemalimab in combination with chemotherapy as the first-line treatment for patients with metastatic NSCLC were accepted by the EMA in the E.U. and the MHRA in the U.K., respectively, before 2024.
 - For the E.U., we completed GCP inspections from the EMA at two study centers and at a CRO in February 2024. In May 2024, the CHMP of the EMA issued a positive opinion recommending approval of sugemalimab in combination with chemotherapy as a first-line treatment for metastatic NSCLC. The official approval was granted by the EC in July 2024.
 - For the U.K., the MAA for sugemalimab in combination with chemotherapy as first-line treatment of patients with metastatic NSCLC is under review by the MHRA.

- In July 2024, the results of the long-term OS analysis in the GEMSTONE-302 study were accepted as a poster and will be showcased at the 2024 ESMO Congress.
- **GC/GEJC:**
 - In March 2024, we received the NDA approval from the NMPA for the first-line treatment of patients with locally advanced or metastatic GC/GEJC (CPS \geq 5).
- **ESCC:**
 - In February 2024, the results of the PFS final analysis and the OS interim analysis in the registrational GEMSTONE-304 study were published in a top-tier medical journal – *Nature Medicine*.

CAUTIONARY STATEMENT REQUIRED BY RULE 18A.05 OF THE LISTING RULES: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET SUGEMALIMAB, OR ANY OF OUR PIPELINE PRODUCTS, SUCCESSFULLY.

Nofazinlimab (CS1003, PD-1 antibody)

- In March 2024, we completed a prespecified interim analysis for the global phase III trial of nofazinlimab in combination with LENVIMA[®] (lenvatinib) for the first-line treatment of patients with unresectable or metastatic HCC; no new or unexpected safety signals were observed; and the iDMC recommended a continued follow-up, without protocol modification, until the final assessment of OS.

Lorlatinib (ALK/ROS-1 inhibitor)

- In February 2024, the pivotal study in patients with ROS1-positive advanced NSCLC who have been previously treated with crizotinib and platinum-based chemotherapy met the primary endpoint, and CStone and Pfizer are in discussion with the CDE regarding the pre-NDA/NDA in mainland China for ROS1-positive advanced NSCLC in 2024.
- In June 2024, the results of the pivotal study in patients with ROS1-positive advanced NSCLC who have been previously treated with crizotinib and platinum-based chemotherapy were accepted as an oral presentation and will be showcased at the 2024 WCLC conference.

Pralsetinib (CS3009, RET inhibitor)

- In February 2024, we published the results from the phase I/II ARROW trial in Chinese patients with RET-mutant MTC in *Endocrine-Related Cancer*. Pralsetinib demonstrated broad, deep, and durable efficacy, as well as a manageable safety profile in Chinese patients with advanced RET-mutant MTC.

Ivosidenib (CS3010, IDH1 inhibitor)

- In June 2024, we completed GCP inspection from the NMPA for regular approval of ivosidenib as a treatment for R/R AML.
- In June 2024, we published the results from the registrational phase I trial in Chinese patients with IDH1-mutated R/R AML in *Blood Science*. Ivosidenib demonstrated sustained efficacy and a manageable safety profile in Chinese patients with IDH1-mutated R/R AML.

Research

ADCs which deliver cytotoxic agents to tumors with precision, and multi-specific biologics which can create new biology and combinations represent two near-term modalities for early development.

We have made significant progress in the first half of 2024 with several initiatives:

- **I/O multi-specifics:** CS2009, which is a tri-specific molecule against PD-1, CTLA4 and VEGFa, is under IND enabling process, and IND submissions expected in 2024 or 2025. This is potentially FIC/BIC next-generation I/O backbone that targets three critical immune-suppressive pathways in the tumor microenvironment and may deepen response of a PD-(L)1 based therapy in large tumor types including NSCLC and HCC.
- **FIC/BIC ADCs:** Two FIC ADC programs are progressing toward PCC nomination. The first ADC project, CS5006, which targets a novel tumor-associated antigen expressed in multiple large tumor indications and identified using an in-house machine-learning bioinformatic algorithm, is expected to file IND in 2025. In addition, the lead antibodies of the other FIC SSTR2 ADC, CS5005, have been selected. The conjugated lead molecules have demonstrated encouraging *in vitro* and *in vivo* efficacy. The IND is expected to be filed in 2025. Moreover, CS5007, which is expected to be the BIC bispecific ADC together with its corresponding bispecific antibody CS2011, is progressing towards PCC nomination. CS5007 (CS2011) is targeting EGFR and HER3, both are well validated targets with proven syngeneic effectiveness. The INDs are expected to be filed in 2025.
- **Autoimmune multi-specifics:** CS2013, which is a bispecific molecule targeting two targets critical to B cell development, is under discovery, and we currently expect to identify the lead molecule by the end of 2024. This is a molecule designed to tackle the Achilles heel of the current treatments for SLE, IgAN and B-cell mediated autoimmune diseases.

Trademarks

Blueprint Medicines, AYVAKIT® and associated logos are trademarks of Blueprint Medicines Corporation. GAVRETO® and associated logos are trademarks of Blueprint Medicines Corporation outside of the United States.

Business Development and Strategic Partnerships

Our business development team plays a vital strategic role in the growth of our business. They will pursue partnerships to expand commercialization of our in-market and late-stage drugs, bolster our early-stage pipeline of potential FIC/BIC molecules, and access technologies that complement our research and development efforts. In addition, they are supporting the development of our existing strategic partnerships including Pfizer, Hengrui, 3SBio, Allist and Ewopharma.

As of the date of this announcement, we have made significant progress with respect to our existing partnerships.

- ***Ewopharma***

- In May 2024, we successfully entered into a strategic commercial collaboration with Ewopharma. Under the terms of the licensing and commercialization agreement, Ewopharma will gain the commercial rights for sugemalimab in Switzerland and 18 CEE countries, including EU member countries Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, and Slovenia, as well as non-EU countries Albania, Bosnia & Herzegovina, Kosovo, North Macedonia, Moldova, Montenegro, and Serbia. CStone will receive up to US\$51.3 million consisting of an upfront payment and additional consideration payable upon the achievement of certain regulatory and sales milestones. In addition, CStone will book revenues from sales of drug supply to Ewopharma and its affiliates. Ewopharma will be in charge of pricing, reimbursement, sales & marketing, and distribution, whilst CStone will be responsible for product supply and providing necessary training and support for the brand.

- ***Hengrui***

- In July 2024, we established a strategic partnership with Hengrui to grant the exclusive promotion rights of avapritinib in mainland China to Hengrui. Except for promotion, CStone retains all rights to avapritinib in mainland China under its exclusive license agreement with Blueprint Medicines, including rights to development, registration, manufacturing and distribution, etc. Under the terms of the agreement, CStone will receive an upfront payment of RMB35 million and will continue to book sales revenue from avapritinib in mainland China in its financial reports, and Hengrui will charge CStone a service fee.
- In November 2021, we established a strategic partnership with Hengrui by signing an exclusive licensing agreement on the Greater China rights to the anti-CTLA-4 mAb (CS1002). Under the terms of the agreement, CStone received an upfront payment and will be eligible for additional milestone payments up to US\$200 million in addition to double-digit royalties. Hengrui obtained the exclusive rights for research, development, registration, manufacturing, and commercialization of CS1002 in Greater China. CStone retained the rights to develop and commercialize CS1002 outside of Greater China. In 2022, Hengrui received the IND clearance from NMPA for a phase Ib/II trial of CS1002 combination therapy for the treatment of advanced solid tumors and has initiated two studies in HCC and NSCLC respectively. Currently, the patient recruitment process for this trial is running smoothly. In January 2024, Hengrui received an IND approval from the NMPA for evaluating CS1002 (SHR-8068) in combination with adabrelimab and chemotherapy as the first-line treatment of patients with advanced or metastatic non-squamous NSCLC.

- ***3SBio***
 - In November 2023, we entered into a strategic partnership and exclusive licensing agreement with 3SBio for nofazinlimab in mainland China. 3SBio is a leading biopharmaceutical company in China with more than 40 products in market and also owns five production bases which are Good Manufacturing Practice (“GMP”)-compliant. Under the terms of the agreement, CStone has received an upfront payment of RMB60 million and will be eligible to receive development and registration milestone payments reaching approximately RMB100 million, and additional payments for future sales-based milestones and tiered sales royalties. 3SBio has obtained the exclusive rights for the development, registration, manufacturing, and commercialization of nofazinlimab in mainland China. This partnership will combine the strengths of CStone and 3SBio in research and development, manufacturing, and commercialization, accelerating the CMC development and commercialization of nofazinlimab. In the first half of 2024, 3SBio reported good progress of the manufacturing technology transfer for nofazinlimab.

- ***Allist***
 - In November 2023, we entered into a commercial partnership with Allist, pursuant to which Allist has obtained the exclusive right to promote pralsetinib in mainland China, while CStone retains the rights in mainland China for research, development and registration. This deal integrates pralsetinib into Allist’s highly synergistic lung cancer franchise and enables pralsetinib to benefit from Allist’s more mature commercial team and a significantly broader market coverage, while concurrently allowing us to reduce overhead and operating costs associated with pralsetinib’s commercialization, thereby improving overall profitability. In the first half of 2024, we transitioned our commercial activities to Allist and we are currently working with Allist on the commercialization of pralsetinib in mainland China.

- ***Servier***
 - In December 2023, through the execution of an asset purchase agreement, we transferred the Greater China and Singapore rights of ivosidenib to the global license holder Servier for up to US\$50 million including US\$44 million upfront (transfer of ivosidenib business). This highly accretive transaction allowed us to recoup our initial investment on this asset and monetize future potential cash flow from the business. Simultaneously under a transition plan agreement, we are working with Servier to ensure an orderly transition of the ivosidenib business. As of the date of this announcement, the transition of ivosidenib has been progressing smoothly and we expect to receive the transition completion milestone payment in late 2024 or early 2025.

- ***Pfizer***

- In December 2021, we received the first approval of sugemalimab for stage IV NSCLC including both squamous and non-squamous patients in China. CStone and Pfizer have worked closely together to successfully launch and commercialize sugemalimab by leveraging Pfizer’s leading commercial infrastructure and deep expertise in China. In May 2022, we received the second indication approval of sugemalimab for the treatment of patients with unresectable stage III NSCLC in China. Sugemalimab is the world’s first anti-PD-1/PD-L1 monoclonal antibody successfully approved as a consolidation therapy to improve PFS in patients with stage III NSCLC, after concurrent or sequential platinum-based chemoradiotherapy. In October 2023, we received the third indication approval of sugemalimab as a monotherapy for the treatment of patients with R/R ENKTL in China. In December 2023, we received the fourth indication approval for sugemalimab as the first-line treatment of patients with unresectable locally advanced, recurrent, or metastatic ESCC in China. In March 2024, we also received the fifth indication approval for sugemalimab as the first-line treatment of patients with unresectable locally advanced or metastatic G/GEJ adenocarcinoma with a PD-L1 expression (CPS ≥ 5) in China.
- In June 2021, CStone and Pfizer jointly announced that they had selected the first late-stage oncology asset for co-development under the strategic collaboration agreement formed in 2020. The two companies initiated a pivotal clinical trial of lorlatinib for ROS1-positive advanced NSCLC. In May 2022, the first patient was enrolled in the pivotal study of lorlatinib as a monotherapy for the treatment of ROS1-positive advanced NSCLC under the joint efforts of CStone and Pfizer. In June 2023, we completed the patient enrolment for this study. In February 2024, the pivotal study met the primary endpoint.

- ***Blueprint Medicines***

- In 2022, we entered into a new partnership with Roche Pharmaceuticals Co., Ltd (“**Roche**”) which became the global marketing authorization holder (“**MAH**”) for pralsetinib. Through this partnership, we acquired full manufacturing technology transfer rights to pralsetinib in Greater China. Locally manufactured supply is expected to provide significant cost savings and improve CStone’s overall profitability as a result. In the meantime, Roche, as the global MAH, will be responsible for the manufacturing and supply of pralsetinib for China until our successful technology transfer. In February 2023, Blueprint Medicines announced that it would regain global commercialization and development rights to pralsetinib from Roche, excluding Greater China. Rigel Pharmaceuticals, Inc. has purchased the U.S. rights to research, develop, manufacture, and commercialize pralsetinib from Blueprint Medicines. CStone is currently working with all involved parties to take necessary steps to ensure continuity of supply of pralsetinib for patients in Greater China.

- ***DotBio***

- In 2024, we continued our productive collaboration with DotBio, a biotech company specializing in next generation antibody therapies. Several bi and tri-specific prototype molecules are under testing.

In addition to the above, we continue to engage potential partners for multiple partnership opportunities that will accelerate our value creation, including in-licensing, out-licensing and strategic partnerships.

FINANCIAL INFORMATION

CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE SIX MONTHS ENDED JUNE 30, 2024

	NOTES	For the six months ended June 30,	
		2024 RMB'000 (Unaudited)	2023 RMB'000 (Unaudited)
Revenue	3	254,165	261,474
Cost of revenue		<u>(82,136)</u>	<u>(108,037)</u>
Gross profit		172,029	153,437
Other income	4	14,824	25,843
Other gains and losses	4	12,884	24,772
Research and development expenses		(66,248)	(186,770)
Selling and marketing expenses		(62,769)	(131,445)
Administrative expenses		(46,672)	(89,189)
Finance costs		<u>(8,349)</u>	<u>(5,874)</u>
Profit (loss) for the period	6	<u>15,699</u>	<u>(209,226)</u>
Other comprehensive expense:			
<i>Item that may be reclassified subsequently to profit or loss:</i>			
Exchange differences arising on translation of foreign operations		<u>(11)</u>	<u>(840)</u>
Total comprehensive income (expense) for the period		<u><u>15,688</u></u>	<u><u>(210,066)</u></u>
Earning (loss) per share			
– Basic (RMB)	8	<u><u>0.01</u></u>	<u><u>(0.17)</u></u>
– Diluted (RMB)		<u><u>0.01</u></u>	<u><u>(0.17)</u></u>

CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION
AT JUNE 30, 2024

		June 30, 2024	December 31,
	<i>NOTES</i>	RMB'000 (Unaudited)	RMB'000 (Audited)
Non-current assets			
Property, plant and equipment		100,428	105,664
Right-of-use assets		30,579	47,704
Intangible assets		167,206	173,045
Financial assets measured at fair value through profit or loss (“FVTPL”)		12,673	3,541
Other receivables		2,939	2,258
		<u>313,825</u>	<u>332,212</u>
Current assets			
Account receivables	<i>9</i>	179,094	172,438
Deposits, prepayments and other receivables		43,794	21,850
Inventories		181,530	108,828
Time deposits with original maturity over three months		135,000	30,000
Cash and cash equivalents		678,856	996,671
		<u>1,218,274</u>	<u>1,329,787</u>
Current liabilities			
Account and other payables and accrued expenses	<i>10</i>	604,466	681,442
Refund liabilities		3,522	22,698
Bank borrowings		78,122	105,986
Contract liabilities		6,885	6,885
Lease liabilities		20,202	33,327
		<u>713,197</u>	<u>850,338</u>
Net current assets		<u>505,077</u>	<u>479,449</u>
Total assets less current liabilities		<u>818,902</u>	<u>811,661</u>

		June 30, 2024	December 31, 2023
	<i>NOTES</i>	RMB'000 (Unaudited)	RMB'000 (Audited)
Non-current liabilities			
Account payables	<i>10</i>	56,377	68,729
Bank borrowings		228,300	213,000
Contract liabilities		58,525	61,967
Lease liabilities		8,044	11,135
		<u>351,246</u>	<u>354,831</u>
Net assets		<u>467,656</u>	<u>456,830</u>
Capital and reserves			
Share capital		860	860
Treasury shares held in the trust		(7)	(8)
Reserves		466,803	455,978
Total equity		<u>467,656</u>	<u>456,830</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 to 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. PRINCIPAL 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 International Financial Reporting Standards ("IFRSs"), the accounting policies and methods of computation used in the condensed consolidated financial statements for the six months ended June 30, 2024 are the same as those presented in the Group's annual consolidated financial statements for the year ended December 31, 2023.

Application of amendments to IFRSs

In the current period, the Group has applied the following amendments to IFRSs issued by the IASB, for the first time, which are mandatory effective for the Group's interim period beginning on January 1, 2024 for the preparation of the Group's condensed consolidated financial statements:

Amendments to IFRS 16	Lease Liability in a Sale and Leaseback
Amendments to IAS 1	Classification of Liabilities as Current or Non-current
Amendments to IAS 1	Non-current Liabilities with Covenants
Amendments to IAS 7 and IFRS 7	Supplier Finance Arrangements

The application of all these amendments to IFRSs 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 AND SEGMENT INFORMATION

Disaggregation of revenue from contracts with customers

	For the six months ended June 30,	
	2024 <i>RMB'000</i> (Unaudited)	2023 <i>RMB'000</i> (Unaudited)
Type of goods or services		
Sales of pharmaceutical products	118,279	246,855
License fee income	122,567	–
Royalty income	13,319	14,619
	254,165	261,474
	254,165	261,474
Timing of revenue recognition		
A point in time	254,165	261,474
	254,165	261,474
	254,165	261,474

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 as a whole.

Geographical information

Substantially, majority of 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 geographical location of the registered office of the customers, during the reporting period is as follows:

	For the six months ended June 30,	
	2024 <i>RMB'000</i> (Unaudited)	2023 <i>RMB'000</i> (Unaudited)
The PRC (excluding Hong Kong and Taiwan)	232,106	258,145
Switzerland	16,036	–
Others	6,023	3,329
	254,165	261,474
	254,165	261,474

4. OTHER INCOME AND OTHER GAINS AND LOSSES

Other income

	For the six months ended June 30,	
	2024 <i>RMB'000</i> (Unaudited)	2023 <i>RMB'000</i> (Unaudited)
Bank and other interest income	7,439	15,387
Government grants income	525	5,825
Income from sales of scrap materials	2,723	4,574
Amortisation of payments received for exclusive promotion rights granted	3,443	–
Others	694	57
	<u>14,824</u>	<u>25,843</u>

Other gains and losses

	For the six months ended June 30,	
	2024 <i>RMB'000</i> (Unaudited)	2023 <i>RMB'000</i> (Unaudited)
Net foreign exchange gains	3,235	24,613
Net gain on fair value of money market funds	196	84
Net gain on fair value changes of financial assets measured at FVTPL	9,132	–
Net gain on disposal of property, plant and equipment	340	–
Others	(19)	75
	<u>12,884</u>	<u>24,772</u>

5. INCOME TAX EXPENSE

No income tax expense for the six months ended June 30, 2024 and 2023 as the Group had no assessable profits derived from the operating entities of the Group.

6. PROFIT (LOSS) FOR THE PERIOD

	For the six months ended June 30,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Profit (loss) for the period has been arrived at after charging (crediting):		
Depreciation of:		
Property, plant and equipment	1,043	2,450
Right-of-use assets	17,125	18,922
Amortisation of intangible assets	5,839	7,257
	<hr/>	<hr/>
Total depreciation and amortisation	24,007	28,629
	<hr/>	<hr/>
Directors' emoluments	15,423	40,803
Other staff costs:		
Salaries and other allowances	52,501	110,453
Performance related bonus	3,986	12,097
Retirement benefit scheme contributions	12,370	23,878
Share-based payment expenses	(16,927)	(11,037)
	<hr/>	<hr/>
	51,930	135,391
	<hr/>	<hr/>
	67,353	176,194
	<hr/>	<hr/>
Impairment losses recognised on construction in progress (included in research and development expenses)	4,161	5,775
(Reversal) write-down of inventories (included in cost of revenue)	(2,710)	1,791
Cost of inventories recognised as cost of revenue	43,529	55,169
	<hr/>	<hr/>

7. DIVIDENDS

No dividend was paid or declared by the Company during the interim period. The directors of Company have determined that no dividend will be paid in respect of the interim period.

8. EARNING (LOSS) PER SHARE

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

	For the six months ended June 30,	
	2024	2023
	(Unaudited)	(Unaudited)
Earning (loss) (RMB' 000)		
Earning (loss) for the period attributable to owners of the Company for the purpose of basic and diluted earning (loss) per share	<u><u>15,699</u></u>	<u><u>(209,226)</u></u>
Number of shares (' 000)		
Weighted average number of ordinary shares for the purpose of basic and diluted earning (loss) per share	<u><u>1,275,512</u></u>	<u><u>1,251,793</u></u>

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

Diluted earning (loss) per share for both periods did not assume the exercise of share options awarded under the employee stock option and the vesting of unvested RSUs 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, 2024	December 31, 2023
	RMB' 000	RMB' 000
	(Unaudited)	(Audited)
0 – 60 days	108,685	28,447
61 – 90 days	1,922	20
Over 90 days	<u><u>68,487</u></u>	<u>143,971</u>
	<u><u>179,094</u></u>	<u><u>172,438</u></u>

10. ACCOUNT AND OTHER PAYABLES AND ACCRUED EXPENSES

	June 30, 2024 RMB'000 (Unaudited)	December 31, 2023 RMB'000 (Audited)
Account payables	301,419	315,106
Other payables and accruals	<u>359,424</u>	<u>435,065</u>
	<u>660,843</u>	<u>750,171</u>
Analysed as:		
– Non-current	56,377	68,729
– Current	<u>604,466</u>	<u>681,442</u>
	<u>660,843</u>	<u>750,171</u>

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

	June 30, 2024 RMB'000 (Unaudited)	December 31, 2023 RMB'000 (Audited)
0 – 30 days	27,330	171,216
31 – 60 days	148,265	24,520
61 – 90 days	7,760	39,850
Over 90 days	<u>118,064</u>	<u>79,520</u>
	<u>301,419</u>	<u>315,106</u>

Financial Review

CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

Six months ended June 30, 2024 Compared to six months ended June 30, 2023

	For the six months ended June 30,	
	2024 RMB'000 (Unaudited)	2023 RMB'000 (Unaudited)
Revenue	254,165	261,474
Cost of revenue	<u>(82,136)</u>	<u>(108,037)</u>
Gross profit	172,029	153,437
Other income	14,824	25,843
Other gains and losses	12,884	24,772
Research and development expenses	(66,248)	(186,770)
Selling and marketing expenses	(62,769)	(131,445)
Administrative expenses	(46,672)	(89,189)
Finance costs	<u>(8,349)</u>	<u>(5,874)</u>
Profit (loss) for the period	<u>15,699</u>	<u>(209,226)</u>
Other comprehensive expense:		
<i>Item that may be reclassified subsequently to profit or loss:</i>		
Exchange differences arising on translation of foreign operations	<u>(11)</u>	<u>(840)</u>
Total comprehensive income (expense) for the period	<u>15,688</u>	<u>(210,066)</u>
Non-IFRS measures:		
Adjusted profit (loss) for the period	<u>10,810</u>	<u>(183,038)</u>

Revenue. Our revenue was RMB254.2 million for the six months ended June 30, 2024, composed of RMB118.3 million in sales of pharmaceutical products (avapritinib and pralsetinib), RMB122.6 million in license fee income and RMB13.3 million in royalty income of sugemalimab, representing an increase of RMB122.6 million in license fee income which largely offset a decrease of RMB128.6 million in revenue from sales of pharmaceutical products, such that total revenue decreased by RMB7.3 million, or 2.8%, period-on-period.

Other Income. Our other income decreased by RMB11.0 million from RMB25.8 million for the six months ended June 30, 2023 to RMB14.8 million for the six months ended June 30, 2024. This was primarily due to less bank and other interest income and government grants income.

Other Gains and Losses. Our other gains and losses decreased by RMB11.9 million from gains of RMB24.8 million for the six months ended June 30, 2023 to gains of RMB12.9 million for the six months ended June 30, 2024. This decrease was primarily due to decrease in net foreign exchange gains with the relatively stable exchange rate during the six months ended June 30, 2024.

Research and Development Expenses. Our research and development expenses decreased by RMB120.6 million from RMB186.8 million for the six months ended June 30, 2023 to RMB66.2 million for the six months ended June 30, 2024. This decrease was primarily attributable to (i) a decrease of RMB106.6 million in milestone fee and third party contracting cost for different phases of our clinical trials from RMB122.0 million for the six months ended June 30, 2023 to RMB15.4 million for the six months ended June 30, 2024; and (ii) a decrease of RMB12.3 million in employee cost from RMB46.5 million for the six months ended June 30, 2023 to RMB34.2 million for the six months ended June 30, 2024.

	For the six months ended June 30,	
	2024	2023
	RMB'000	RMB'000
Milestone fee and third party contracting cost	15,363	121,987
Employee cost	34,173	46,457
Depreciation and others	16,712	18,326
	<hr/>	<hr/>
Total	66,248	186,770
	<hr/> <hr/>	<hr/> <hr/>

Administrative Expenses. Our administrative expenses decreased by RMB42.5 million from RMB89.2 million for the six months ended June 30, 2023 to RMB46.7 million for the six months ended June 30, 2024. This decrease was primarily attributable to a decrease of RMB37.8 million in employee cost from RMB61.7 million for the six months ended June 30, 2023 to RMB23.9 million for the six months ended June 30, 2024.

	For the six months ended June 30,	
	2024	2023
	RMB'000	RMB'000
Employee cost	23,860	61,654
Professional fees	13,351	13,482
Depreciation and amortization	5,278	9,511
Rental expenses	1,500	1,492
Others	2,683	3,050
	<u>46,672</u>	<u>89,189</u>
Total	<u>46,672</u>	<u>89,189</u>

Selling and Marketing Expenses. Our selling and marketing expenses decreased by RMB68.6 million from RMB131.4 million for the six months ended June 30, 2023 to RMB62.8 million for the six months ended June 30, 2024. This decrease was primarily attributable to a decrease of RMB58.8 million in employee cost from RMB68.1 million for the six months ended June 30, 2023 to RMB9.3 million for the six months ended June 30, 2024.

	For the six months ended June 30,	
	2024	2023
	RMB'000	RMB'000
Employee cost	9,318	68,083
Professional fees	1,348	15,331
Channel service fee	50,338	–
Others	1,765	48,031
	<u>62,769</u>	<u>131,445</u>
Total	<u>62,769</u>	<u>131,445</u>

Finance Costs. The finance costs increased by RMB2.4 million from RMB5.9 million for the six months ended June 30, 2023 to RMB8.3 million for the six months ended June 30, 2024, primarily due to an increase 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 profit (loss) 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 profit (loss) for the period represents the profit (loss) for the period excluding the effect of certain non-cash items and onetime events, namely the share-based payment expenses. The term adjusted profit (loss) 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 profit (loss) to adjusted profit (loss) during the periods indicated:

	For the six months ended June 30,	
	2024	2023
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Profit (loss) for the period	15,699	(209,226)
Added:		
Share-based payment expenses	(4,889)	26,188
Adjusted profit (loss) for the period	<u>10,810</u>	<u>(183,038)</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,	
	2024	2023
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Research and development expenses for the period	(66,248)	(186,770)
Added:		
Share-based payment expenses	(4,770)	(11,377)
Adjusted research and development expenses for the period	<u>(71,018)</u>	<u>(198,147)</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,	
	2024	2023
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Administrative and selling and marketing expenses for the period	(109,441)	(220,634)
Added:		
Share-based payment expenses	(119)	37,565
	<u>(109,560)</u>	<u>(183,069)</u>

Employees and Remuneration Policies

The following table sets forth a breakdown of our employees as of June 30, 2024 by function:

Function	Number of employees	% of total number of employees
Research and Development	88	53.66
Sales, General and Administrative	76	46.34
Total	<u>164</u>	<u>100.0</u>

As of June 30, 2024, we had 104 employees in Shanghai, 19 employees in Beijing, 20 employees in Suzhou and 21 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).

At June 30, 2024, our cash and cash equivalents and time deposits with original maturity over three months were RMB813.9 million, as compared to RMB1,026.7 million as of December 31, 2023. The decrease was mainly due to the payment of inventory purchase and research and development expenses. The cash and cash equivalents were mainly denominated in RMB and USD.

Gearing Ratio

Gearing ratio is calculated using total liabilities divided by total assets and multiplied by 100%. At June 30, 2024, our gearing ratio was 69.5% (December 31, 2023: 72.5%).

Charge on Assets

At June 30, 2024, the amount of assets pledged by the Group to bank to secure bank loan facilities granted to the Group was RMB63,321,000 (December 31, 2023: RMB101,936,000).

OTHER FINANCIAL INFORMATION

Significant Investments, Material Acquisitions and Disposals

As at June 30, 2024, 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, 2024, the Group's bank borrowings were RMB306,422,000, all bank borrowings denominated in RMB.

Contingent Liabilities

As of June 30, 2024, the Group did not have any material contingent liabilities (as of December 31, 2023: 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**”), save for the deviation as disclosed herein. Pursuant to code provision C.6.2 of the CG Code, a board meeting should be held to discuss the appointment of the company secretary and the matter should be dealt with by a physical board meeting rather than a written resolution. The appointment of the new joint company secretary was dealt with by a written resolution of the Board. Prior to the execution of the written resolution, all Directors were well informed of the new joint company secretary's educational background and working experiences and were satisfied that she possesses the required qualifications and expertise of the position without any dissenting opinion, and as such it was considered that a physical board meeting was not necessary for approving the said appointment.

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) during the Reporting Period. As at June 30, 2024, the Company did not hold any treasury Shares.

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

Save as disclosed in this announcement and as at the date of this announcement, there were no material events after the Reporting Period.

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 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), which will be used for the funding of the development activities under the collaboration agreement dated September 30, 2020 (the "**Collaboration Agreement**"). 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, 2024:

	% of use of proceeds	Proceeds from the subscription (RMB million)	Unutilized net proceeds as of December 31, 2023 (RMB million)	Actual usage during the Reporting Period (RMB million)	Unutilized net proceeds as of June 30, 2024 (RMB million)
Fund the development activities under the collaboration agreement	100%	1,355.9	409.3	-	409.3

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 February 8, 2023 (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 84,800,000 placing shares to not less than six places at a price of HK\$4.633 per placing share. The net proceeds from the placing, after deducting the placing commission and other related expenses and professional fees, were approximately HK\$389.07 million (equivalent to approximately RMB338.12 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 February 15, 2023. 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, 2024:

	% of use of proceeds	Proceeds from the placing (RMB million)	Unutilized net proceeds as of December 31, 2023 (RMB million)	Actual usage during the Reporting Period (RMB million)	Unutilized net proceeds as of June 30, 2024 (RMB million)
Commercialization and indication expansion of marketed products such as pralsetinib, avapritinib, and ivosidenib, as well as technology transfer to reduce drug supply cost and improve profitability	20%	67.62	-	-	-
Development of pipeline products including but not limited to CS5001 (a potentially best-in-class ROR1 ADC)	50%	169.06	53.47	22.14	31.33
Business development activities to enrich the Company’s pipeline and fully utilize the Company’s proven clinical capabilities	20%	67.62	52.31	6.18	46.13
General corporate purposes	10%	33.82	19.11	4.48	14.63
Total	100%	338.12	124.89	32.80	92.09

Note: The unutilized net proceeds are planned to be put into use by December 31, 2024.

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 three independent non-executive Directors, namely, Mr. Hongbin Sun (Chairman), Dr. Paul Herbert Chew 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, 2024 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 carried out 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, 2024) of the Group.

INTERIM DIVIDEND

The Board does not recommend the payment of an interim dividend for the six months ended June 30, 2024 (2023: 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, 2024 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 23, 2024

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, Mr. Xianghong Lin and Mr. Edward Hu as non-executive directors, and Dr. Paul Herbert Chew, Mr. Ting Yuk Anthony Wu and Mr. Hongbin Sun as independent non-executive directors.