CStone Pharmaceuticals
基石藥業
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 2616)

ANNOUNCEMENT OF ANNUAL RESULTS FOR THE YEAR ENDED DECEMBER 31, 2023

The board (the "**Board**") of directors (the "**Directors**") of CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce the audited consolidated results of the Company and its subsidiaries (together, the "**Group**", "**we**" or "**us**") for the year ended December 31, 2023 (the "**Reporting Period**"), together with comparative figures for the year ended December 31, 2022. 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 annual results for the year ended December 31, 2022 dated March 15, 2023.

FINANCIAL HIGHLIGHTS

International Financial Reporting Standards ("IFRS") Measures:

- **Revenue** was RMB463.8 million for the year ended December 31, 2023, composed of RMB336.7 million in sales of pharmaceutical products (avapritinib, pralsetinib and ivosidenib), RMB95.7 million in license fee income and RMB31.4 million in royalty income of sugemalimab, representing a year-on-year increase of RMB10.1 million, or 8.6%, in license fee and royalty income which largely offset a decrease in revenue from sales of pharmaceutical products, such that total revenue decreased by RMB17.5 million, or 3.6%, year on year.

- **Research and development expenses** were RMB527.8 million for the year ended December 31, 2023, representing a decrease of RMB86.4 million from RMB614.2 million for the year ended December 31, 2022, primarily due to the decrease in milestone fee and third party contracting costs and the decrease in employee costs.

- **Administrative expenses** were RMB182.7 million for the year ended December 31, 2023, representing a decrease of RMB66.4 million from RMB249.1 million for the year ended December 31, 2022, primarily due to the decrease in employee costs.

- **Selling and marketing expenses** were RMB199.3 million for the year ended December 31, 2023, representing a decrease of RMB128.0 million from RMB327.3 million for the year ended December 31, 2022, primarily attributable to the decrease in employee costs and professional fees.

- **Loss for the year** was RMB367.2 million for the year ended December 31, 2023, representing a decrease of RMB535.5 million, or 59.3%, from RMB902.7 million for the year ended December 31, 2022, primarily attributable to a substantial decrease in employee costs and the net gain related to the transfer of ivosidenib business.

Non-International Financial Reporting Standards ("Non-IFRS") Measures:

- **Research and development expenses** excluding the share-based payment expenses were RMB534.7 million for the year ended December 31, 2023, representing a decrease of RMB24.4 million from RMB559.1 million for the year ended December 31, 2022, primarily due to the decrease in milestone fee and third party contracting costs and the decrease in employee costs.

- **Administrative and selling and marketing expenses** excluding the share-based payment expenses were RMB338.2 million for the year ended December 31, 2023, representing a decrease of RMB151.1 million from RMB489.3 million for the year ended December 31, 2022, primarily attributable to the decrease in employee costs and professional fees.

- **Loss for the year** excluding the share-based payment expenses was RMB330.2 million for the year ended December 31, 2023, representing a decrease of RMB430.4 million, or 56.6%, from RMB760.6 million for the year ended December 31, 2022, primarily attributable to a substantial decrease in employee costs and the net gain related to the transfer of ivosidenib business.

BUSINESS HIGHLIGHTS

For the year ended December 31, 2023 and as of the date of this announcement, significant progress has been made with respect to our product pipeline and business operations. A shortlist of our achievements over this period includes:

– RMB463.8 million in total revenue, including RMB368.1 million in commercial revenue which is composed of RMB336.7 million in sales of our precision medicines and RMB31.4 million in royalty income of sugemalimab. RMB199.5 million in other gains and loss, which was primarily due to net gain of RMB179.5 million related to the transfer of license for the ivosidenib business to Les Laboratoires Servier ("**Servier**")

– Five new drug application ("**NDA**") approvals obtained for pralsetinib and sugemalimab: for pralsetinib, first-line treatment of rearranged during transfection ("**RET**") fusion-positive non-small cell lung cancer ("**NSCLC**") in mainland China which leads to a broader coverage of pralsetinib in both first-line and second-line NSCLC; RET fusion-positive NSCLC, RET-mutant medullary thyroid cancer ("**MTC**") & RET fusion-positive thyroid cancer ("**TC**") in Taiwan, China. For sugemalimab, monotherapy for relapsed or refractory ("**R/R**") extranodal natural killer/T-cell lymphoma ("**ENKTL**") in mainland China; in combination with chemotherapy for first-line esophageal squamous cell carcinoma ("**ESCC**") in mainland China and in combination with chemotherapy for first-line gastric adenocarcinoma/gastroesophageal junction adenocarcinoma ("**GC/GEJ**") in mainland China

– Two NDAs currently under review: sugemalimab in combination with chemotherapy for first-line stage IV NSCLC in the United Kingdom ("**U.K.**") and sugemalimab in combination with chemotherapy for first-line stage IV NSCLC in the European Union ("**E.U.**"). The Good Clinical Practice ("**GCP**") inspections from the European Medicines Agency (the "**EMA**") for first-line stage IV NSCLC have been completed at two study centers and at Contract Research Organization ("**CRO**")

– Global multi-regional clinical trial of CS5001 making rapid progress: the first-in-human ("**FIH**") global study of CS5001, a receptor tyrosine kinase-like orphan receptor 1 ("**ROR1**") antibody-drug conjugate ("**ADC**"), being conducted in the United States of America ("**U.S.**"), Australia and China; CS5001 appears well tolerated and safe and has demonstrated promising antitumor activities in both solid tumor and lymphoma. CS5001 is so far the first ROR1 ADC which demonstrates clinical anti-tumor activity in solid tumor

– Other key clinical programs proceeding smoothly: the pivotal study of lorlatinib for c-ros oncogene 1 ("**ROS1**")-positive advanced NSCLC in mainland China met the primary endpoint; the global phase III trial of nofazinlimab in combination with LENVIMA® (lenvatinib) in first-line unresectable or metastatic hepatocellular carcinoma ("**HCC**") is ongoing with continued follow-up

– Ten data presentations/publications at/in global academic conferences/top-tier medical journals, such as the American Society of Clinical Oncology ("**ASCO**") Annual Meeting, European Society for Medical Oncology ("**ESMO**") Congress, ESMO World Congress on Gastrointestinal Cancer ("**ESMO GI Congress**"), *Journal of Clinical Oncology, Nature Medicine, Nature Cancer,* etc.

– Over ten discovery projects in progress, including multi-specifics, ADCs, and a proprietary cell penetrating therapeutic ("**CPT**") platform for drugging intractable intracellular targets; Preclinical candidates ("**PCCs**") have been achieved by one multi-specific project and one ADC project

– Three commercial collaborations have been established to leverage multiple companies' strengths while enabling CStone to strategically focus on research and development going forward: a new partnership with 3SBio Inc. ("**3SBio**") in China for nofazinlimab to accelerate the Chemistry, Manufacturing and Controls ("**CMC**") development and commercialization of nofazinlimab; a new partnership with Allist Pharmaceuticals ("**Allist**") in China for GAVRETO® (pralsetinib) to significantly expand commercial support and improve overall profitability of the business; we transferred the Greater China & Singapore rights to TIBSOVO® (ivosidenib) to the global license holder Servier for up to US$50 million including US$44 million upfront to recoup the historical investments on this asset and monetize potential future cash flow

– The application of technology transfer for avapritinib is under review by the Center for Drug Evaluation ("**CDE**") of the National Medical Products Administration ("**NMPA**"). The technology transfer for pralsetinib, including manufacturing and clinical bio-equivalence ("**BE**") study, has been completed and the application dossier have been submitted to CDE. These will help to reduce costs and improve the long-term profitability of the products

I. Maximizing Commercial Value through Partnerships

Highlights and details on our commercial activities as of the date of this announcement are as follows:

- ***Commercial collaborations with multiple companies in China***

  In order to further improve the commercialization efficiency, we have established commercial collaborations with multiple companies during the year to leverage their strengths while enabling CStone to strategically focus on research and development going forward.

  – In November 2023, we granted the exclusive commercial rights for GAVRETO® (pralsetinib), a RET inhibitor, to Allist in mainland China. This deal integrates GAVRETO® (pralsetinib) into Allist's highly synergistic lung cancer franchise and enables GAVRETO® (pralsetinib) to benefit from Allist's more mature commercial team and significantly broader market coverage, while concurrently allowing CStone to reduce operating costs associated with GAVRETO® (pralsetinib) commercialization thereby improving overall profitability.

  – In December 2023, we transferred the exclusive rights to develop, manufacture and commercialize TIBSOVO® (ivosidenib) in the Greater China region (including mainland China, Hong Kong, Macau and Taiwan) and Singapore to Servier and will receive up to US$50 million in exchange. The transaction will help to expand indication and improve accessibility of TIBSOVO® (ivosidenib) for patients in Greater China and Singapore while monetizing potential future cash flow for CStone and recouping historical investment on the asset.

- ***Achieved successful launches of new indications***

  We expanded the indications for our in-market products and positioned them to become meaningful future contributors to our revenue.

  – GAVRETO® (pralsetinib): A new indication for the first-line treatment of patients with locally advanced or metastatic RET fusion-positive NSCLC was launched in mainland China.

  – GAVRETO® (pralsetinib): The indications for the treatment of patients with RET fusion-positive locally advanced or metastatic NSCLC, and advanced or metastatic RET-mutant MTC and RET fusion-positive TC were launched in Taiwan, China.

  – CEJEMLY® (sugemalimab): A new indication was successfully launched in mainland China for the first-line treatment of patients with unresectable locally advanced, recurrent, or metastatic ESCC in combination with fluorouracil and platinum-based chemotherapy.

  – CEJEMLY® (sugemalimab): A new indication was successfully launched in mainland China for the treatment of patients with R/R ENKTL as a monotherapy.

  – CEJEMLY® (sugemalimab): 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.

- ***Developing a range of approaches to promote accessibility and affordability of our drugs***

  – We have updated our pricing strategy for our in-market products. Specifically, AYVAKIT® (avapritinib) has been added to 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 patient assistance program ("**PAP**") scheme for GAVRETO® (pralsetinib) and TIBSOVO® (ivosidenib) were updated to lower the barrier for some patients with low affordability and improve price competitiveness.

- ***Established broad industry and academic awareness of our brand and scientific leadership***

  – GAVRETO® (pralsetinib), AYVAKIT® (avapritinib) and TIBSOVO® (ivosidenib) were included in 21 of China's national guidelines for testing and treatment in multiple therapeutic areas, such as NSCLC, TC, GIST, systemic mastocytosis ("**SM**"), and acute myeloid leukemia ("**AML**"), etc. In particular, the 2023 Chinese Society of Clinical Oncology ("**CSCO**") NSCLC guideline, the 2022 CSCO GIST Guidelines, the 2022 Chinese Guideline for Diagnosis and Treatment of Systemic Mastocytosis in Adults, and the 2022 China Anti-Cancer Association ("**CACA**") Hematological Oncology Guideline, etc.

  – We continued working with investigators in post-market clinical projects, such as investigator-initiated trials ("**IIT**") and real-world studies ("**RWS**"), to generate additional data in multiple cancer indications. For example, a multi-centered RWS evaluated the safety and efficacy of AYVAKIT® (avapritinib) in Chinese patients with GIST; another IIT aims to study the efficacy and safety profile of AYVAKIT® (avapritinib) for the treatment of R/R Core Binding Factor ("**CBF**")-AML with KIT D816 or N822 mutations.

- ***Collaborating with Pfizer on the commercialization of sugemalimab in China***

  – We are closely collaborating with our partner Pfizer on the commercialization of CEJEMLY® (sugemalimab) in mainland China.

  – In 2023, CEJEMLY® (sugemalimab) as a treatment of stage III NSCLC has been upgraded to a Level 1 recommendation in the 2023 CSCO NSCLC guideline and the 2023 CSCO Immunotherapy guideline. In addition, CEJEMLY® (sugemalimab) as a treatment of stage III NSCLC has also been included in the 2023 Chinese Medical Association clinical practice guideline in China.

II. Clinical Advancements across an Evolving Pipeline

Details are as follows:

- **CS5001** (LCB71, ROR1 ADC)

  – The global FIH study of this potential best-in-class ("**BIC**") ROR1 ADC has shown swift recruitment to the dose-escalation part in the U.S., Australia and China.

  – On December 20, 2023, we reported preliminary findings from the early phase of the ongoing FIH study, at which time the safety evaluation of dose level 7 had been completed and efficacy evaluation was ongoing. CS5001 appears to be well tolerated and safe and has demonstrated promising antitumor activities in both solid tumor and lymphoma. CS5001 is so far the first ROR1 ADC which has reported clinical anti-tumor activity in solid tumor.

  – As of the date of this announcement, we have escalated to dose level 9; no dose limiting toxicity ("**DLT**") was observed; and maximum tolerated dose ("**MTD**") has not been reached. In heavily pretreated patients with lymphoma or solid tumor who were enrolled regardless of ROR1 status, CS5001 has been well tolerated as the dose level increases; no grade 4-5 treatment-related adverse events were observed. The pharmacokinetics ("**PK**") profile of CS5001 was as expected and indicated excellent stability of the ADC. Encouraging antitumor activities were observed starting from dose level 5, including partial and complete responses in both advanced solid tumor (e.g. lung cancer and pancreatic cancer) and lymphoma (e.g. Hodgkin lymphoma and diffuse large B-cell lymphoma ("**DLBCL**")). We expect to determine the preliminary recommended phase 2 dose ("**RP2D**") of CS5001 in the first half of 2024 and plan to initiate a registrational phase Ib/II trial by the end of 2024. With more data being accumulated during dose escalation, multiple presentations at international academic conferences are being planned for in 2024, including ASCO, ESMO, American Society of Hematology Annual Meeting ("**ASH**"), etc.

  – CS5001 has many distinctive features, including proprietary site-specific conjugation, tumor-cleavable linker, and prodrug technology. CS5001 demonstrated BIC potential in mantle cell lymphoma and triple negative breast cancer xenograft models compared to a benchmark ROR1 ADC with Monomethyl auristatin E ("**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 March 2023, we presented the translational data of CS5001 in an oral session at the 13th world ADC London conference ("**World ADC London**").

  – In addition, we have identified a promising candidate ROR1 antibody clone for immuno-histochemistry ("**IHC**") to enable biomarker-driven patient selection based on tumor ROR1 expression, supporting precision medicine efforts in the future.

- **Sugemalimab** (CS1001, PD-L1 antibody), new indications under review and expanding to Europe and the U.K.

  – **Stage IV NSCLC:**

    - For the markets outside of Greater China, the marketing authorization application ("**MAA**") for stage IV NSCLC indication is under review by the regulatory agencies in multiple countries and regions. In February 2023 and December 2022, the MAA filing for sugemalimab in combination with chemotherapy as the first-line treatment for patients with metastatic NSCLC was accepted by the EMA in the E.U. and the Medicines and Healthcare products Regulatory Agency ("**MHRA**") in the U.K. respectively. Currently, this indication is under review by both parties. In July 2023, we received the GCP inspection notification from EMA for this indication in the E.U. In October 2023, we received the Day-80 Request for Further Information ("**RFI**") from MHRA which did not contain any unsolvable questions. In December 2023, we received the Day-180 List of Outstanding Issues ("**LoOI**") from EMA which indicated that all questions had been properly addressed during previous rounds of communications. In February 2024, we completed GCP inspections from the EMA at two study centers and at CRO.

    - In June 2023, we announced that the results of Overall Survival ("**OS**") interim analysis in the registrational GEMSTONE-302 study in patients with stage IV NSCLC had been published in a world-renowned oncology journal – *Nature Cancer*.

  – **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 (Combined Positive Score("**CPS**"))≥5).

    - In February 2023, we received the NDA acceptance from the NMPA for the first-line treatment of patients with locally advanced or metastatic GC/GEJC (CPS≥5).

    - In October 2023, the results of the pre-specified progression-free survival ("**PFS**") and OS final analyses in the GEMSTONE-303 study were accepted as a late-breaking abstract ("**LBA**") and showcased in an oral session at the ESMO Congress 2023. Sugemalimab in combination with chemotherapy demonstrated statistically significant and clinically meaningful improvement in PFS and OS compared with placebo plus chemotherapy.

– **ESCC:**

- In December 2023, we received the NDA approval from the NMPA for the first-line treatment of patients with unresectable locally advanced, recurrent, or metastatic ESCC.

- In April 2023, we received the NDA acceptance from the NMPA for the first-line treatment of patients with unresectable locally advanced, recurrent, or metastatic ESCC.

- In January 2023, we announced that the GEMSTONE-304 study for the first-line treatment of unresectable locally advanced, recurrent, or metastatic ESCC had met its primary endpoints. Sugemalimab in combination with chemotherapy demonstrated a statistically significant and clinically meaningful improvement in PFS and OS compared with placebo in combination with chemotherapy. We presented the detailed results at the ESMO GI Congress in June 2023.

- 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*.

– **R/R ENKTL:**

- In October 2023, we received the NDA approval from the NMPA for the treatment of the patients with R/R ENKTL as a monotherapy.

- In March 2023, we announced that the results of the registrational GEMSTONE-201 study in patients with R/R ENKTL were published in a top-tier oncology journal – *Journal of Clinical Oncology*.

- In December 2023, we reached an agreement with the U.S. FDA in a Type B consultation regarding the registration pathway for R/R ENKTL indication.

- **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; independent Data Monitoring Committee ("**iDMC**") recommended a continued follow-up, without protocol modification, until the final assessment of OS.

  - In September 2023, we announced that the results of the FIH trial (CS1003-101) of nofazinlimab in patients with advanced solid tumors had been published in a highly-cited journal – *British Journal of Cancer*.

- **Pralsetinib** (CS3009, RET inhibitor)

  – In January 2023, we received the NDA approval from the Taiwan Food and Drug Administration ("**TFDA**") for the treatment of patients with RET fusion-positive locally advanced or metastatic NSCLC, and advanced or metastatic RET-mutant MTC and RET fusion-positive TC.

  – In June 2023, we received the NDA approval from the NMPA for the first-line treatment of patients with RET fusion-positive locally advanced or metastatic NSCLC who have not been previously treated with systemic therapy.

  – In June 2023, we published updated results from the phase I/II ARROW trial in Chinese patients with RET fusion-positive NSCLC in *Cancer*.

- **Avapritinib** (CS3007, KIT/PDGFRA inhibitor)

  – In May 2023, our partner, Blueprint Medicines Corporation ("**Blueprint Medicines**"), received approval from the U.S. Food and Drug Administration ("**FDA**") for the treatment of adults with indolent systemic mastocytosis ("**ISM**") in the U.S..

  – In December 2023, our partner, Blueprint Medicines, received approval from the EMA for the treatment of adult patients with ISM with moderate to severe symptoms inadequately controlled on symptomatic treatment. To date, avapritinib is the first and only approved therapy for patients with ISM in Europe.

  – In June 2023, we presented new data of avapritinib in patients with advanced GIST at the ASCO Annual Meeting 2023.

  – In November 2023, we announced that a post hoc data analysis of the global Phase 1 NAVIGATOR and Phase 1/2 China bridging (CS3007-101) studies of avapritinib in advanced GIST were published in a reputable oncology journal – *Clinical Cancer Research*.

- **Ivosidenib** (CS3010, IDH1 inhibitor)

  – In December 2023, we received the acceptance from the NMPA to the supplemental submission for regular approval of ivosidenib as a treatment for R/R AML.

  – In May 2023, we reached alignment with CDE on the regulatory pathway toward regular approval of ivosidenib as a treatment for R/R AML.

  – In January 2023, we completed the China bridging study of ivosidenib in R/R AML patients.

- **Lorlatinib** (ALK/ROS-1 inhibitor)

  – We are conducting a pivotal study in patients with ROS1-positive advanced NSCLC who have been previously treated with crizotinib and platinum-based chemotherapy. In June 2023, we completed the patient enrollment for this study. In February 2024, the pivotal study met the primary endpoint, and we are in discussion with the CDE and Pfizer regarding the pre-NDA/NDA in mainland China for ROS1-positive advanced NSCLC in 2024.

III. Building out Research Pipeline Leveraging Multiple Sources of Innovation

Precision medicines and immuno-oncology ("**I/O**") combinations remain our strategic focus. 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 2023 with several initiatives:

- **First/Best-in-Class ("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 have the PCC nominee announced in the first half of 2024. In addition, the lead antibodies of the other FIC GPCR-x ADC, CS5005, have been selected. The conjugated lead molecules have demonstrated encouraging *in vitro* and *in vivo* efficacy. Investigational new drug applications ("**INDs**") with respect to these two FIC ADCs are 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 well validated targets with proven syngeneic effectiveness. The leading bispecific antibody candidate is expected to be nominated in the first half of 2024, and the PCC of this bispecific ADC is expected to be announced by the end of 2024.

- **I/O multi-specifics:** CS2009, which is a tri-specific molecule against PD-1, VEGFa and CTLA-4 target, is under cell line development, and the related IND is expected to be filed in 2024. This is a potential FIC 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.

- **Cell penetrating therapeutic platform:** Numerous well-known oncology targets are intracellular proteins deemed undruggable by current therapeutic approaches. We are developing a proprietary CPT platform against these otherwise intractable targets. Significant progress has been made in the development of this platform with broad therapeutic potential for oncology and beyond.

IV. Strategic Relationships Advance Commercialization Activities and Pipeline Development

We continue to grow and deepen relationships with key global strategic partners, including partners in China, 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.

We entered into a strategic collaboration for nofazinlimab in mainland China with 3SBio and granted 3SBio exclusive rights for the development, registration, manufacturing, and commercialization of nofazinlimab in mainland China in November 2023. This partnership will accelerate the CMC development and commercialization of nofazinlimab.

We entered into a commercial partnership with Allist in China for the promotion and marketing of pralsetinib in November 2023. 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 larger market coverage, while concurrently allowing CStone to reduce overhead and operating costs associated with pralsetinib commercialization thereby improving overall profitability.

We transferred the Greater China and Singapore rights to ivosidenib to the global license holder Servier for up to US$50 million including US$44 million upfront (transfer of ivosidenib business) in December 2023. This highly accretive transaction allowed CStone to recoup its initial investment on this asset and monetize future potential cash flow from the business.

Under our partnership with Jiangsu Hengrui Pharmaceuticals Co., Ltd. ("**Hengrui**") for anti-CTLA-4 mAb (CS1002), a phase Ib/II trial of CS1002 combination therapy for the treatment of advanced solid tumors including HCC and NSCLC is being conducted by Hengrui. Currently, the trial is recruiting patients smoothly. In January 2024, Hengrui received an IND approval from the NMPA for evaluating CS1002 (SHR-8068) in combination with adebrelimab and chemotherapy as the first-line treatment of patients with advanced or metastatic non-squamous NSCLC.

We regained rights for the development and commercialization of sugemalimab and nofazinlimab outside of Greater China, with the termination of the license agreement for sugemalimab and nofazinlimab between CStone and EQRx on May 9, 2023. The transition was completed in August 2023. Currently, we are leading the regulatory process for sugemalimab MAA reviews by the EMA and the U.K. MHRA. The termination of this License Agreement will not affect the upfront and milestone payments previously received from EQRx. We are currently exploring potential partnership opportunities for both sugemalimab and nofazinlimab outside of Greater China.

V. Other Business Updates

Manufacturing: We are also in the process of technology transfer for multiple imported products, which is expected to reduce costs and improve the long-term profitability of our products. Specifically, the application relating to technology transfer for avapritinib is under review by the CDE. At the same time, the technology transfer for pralsetinib, including manufacturing and clinical BE study, has been successfully completed and the application dossier have been submitted to CDE.

FUTURE AND OUTLOOK

Looking forward, we will continue to advance innovative pipeline and maximize commercial value of mature products.

A detailed breakdown of expected catalysts in the near term is set forth as below.

- Sugemalimab: opinion from the Committee for Medicinal Products for Human Use ("**CHMP**") to the MAA for the first-line treatment in stage IV NSCLC in the E.U. in the first half of 2024 and MAA approval in the second half of 2024; MAA approval for the first-line treatment in stage IV NSCLC in the U.K. in the second half of 2024; ex-China partnership exploration

- Lorlatinib: pre-NDA/NDA in mainland China for ROS1-positive advanced NSCLC in 2024

- Avapritinib: expect the abbreviated NDA ("**ANDA**") approval for manufacturing localization in the second half of 2024

- Pralsetinib: expect the ANDA acceptance for manufacturing localization in the first half of 2024

- Nofazinlimab: final assessment of OS and ex-China partnership exploration in 2025

- CS5001: to disclose the latest clinical safety and efficacy data at international academic conferences (e.g. ASCO in the first half of 2024, and ESMO/ASH in the second half of 2024); initiate registrational study in 2024; expected to reach global business development ("**BD**") partnership in 2024 or 2025

- CS2009: submit clinical trial notification ("**CTN**") to Australian Human Research Ethics Committee ("**HREC**") by the end of 2024, and apply for China IND in the first quarter of 2025

- CS5006: nominate PCC in the first half of 2024, and expect to file IND in 2025

- CS5005: nominate PCC in 2024, and expect to file IND in 2025

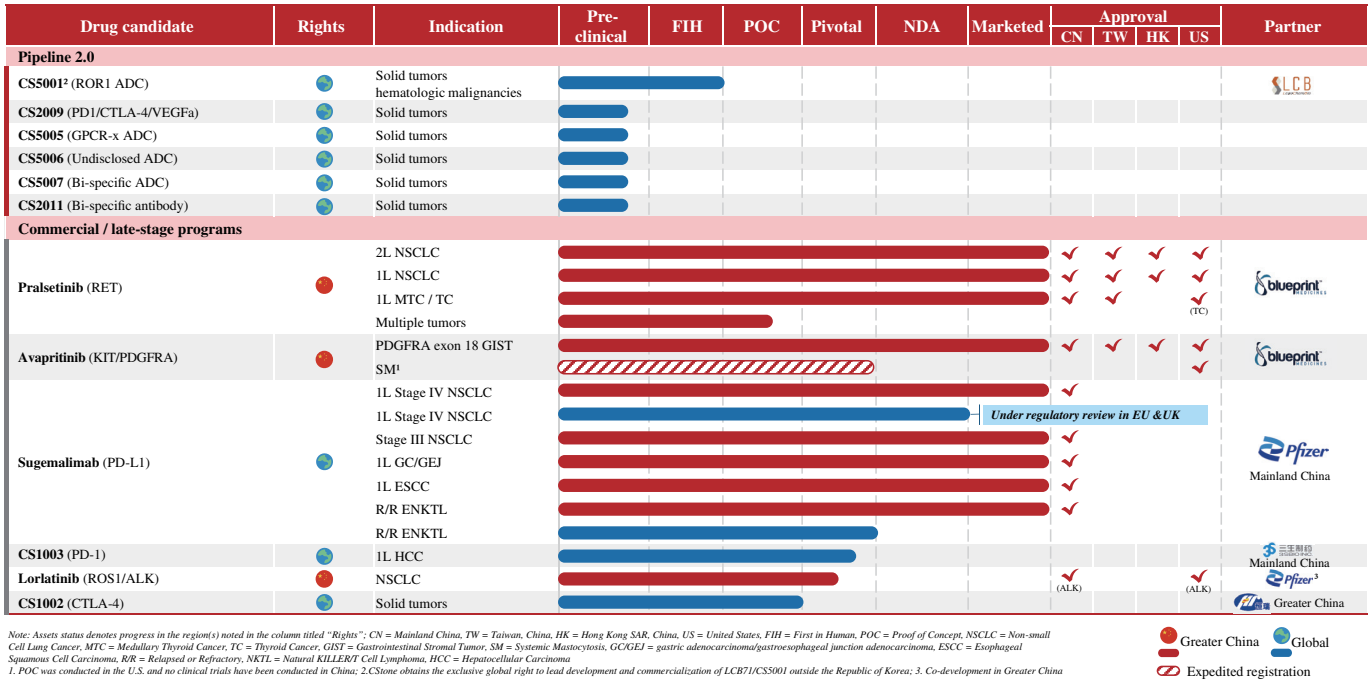
OUR VISION

Our vision is to become a world-renowned biopharmaceutical company leading the way to conquering cancer.

OVERVIEW

CStone is a biopharmaceutical company focused on researching, developing, and commercializing innovative immuno-oncology and precision medicines to address the unmet medical needs of cancer patients in China and worldwide. Established in 2015, CStone has assembled a management team with extensive experience in innovative drug development, clinical research, and commercialization. The Company has built an oncology-focused pipeline of 12 drug candidates with a strategic emphasis on precision medicines and immuno-oncology combination therapies. Since inception, CStone has obtained 14 NDA approvals for various drugs (including ivosidenib). For details of any of the foregoing, please refer to the rest of this announcement and, where applicable, the prospectus of the Company and prior announcements published on the websites of The Stock Exchange of Hong Kong Limited (the "**Stock Exchange**") and the Company.

Product Pipeline



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, FIH = First in Human, 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

1. POC was conducted in the U.S. and no clinical trials have been conducted in China; 2.CStone obtains the exclusive global right to lead development and commercialization of LCB71/CS5001 outside the Republic of Korea; 3. Co-development in Greater China

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 year to leverage their strengths while enabling CStone 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 TFDA for the treatment of adult patients with locally advanced or metastatic RET fusion-positive NSCLC, advanced or metastatic RET-mutant MTC, and RET fusion-positive TC.

  – In November 2023, we granted the exclusive commercial rights for GAVRETO® (pralsetinib), a RET inhibitor, to Allist in mainland China. This deal integrates GAVRETO® (pralsetinib) into Allist's highly synergistic lung cancer franchise and enables GAVRETO® (pralsetinib) to benefit from Allist's more mature commercial team and a significantly broader market coverage, while concurrently allowing CStone 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. During the Reporting Period, GAVRETO® (pralsetinib) was recommended by the newly updated 2023 CSCO NSCLC Guidelines, which recommended RET mutation gene testing and GAVRETO® (pralsetinib) in the treatment of RET positive NSCLC patients.

  – We continued to improve the accessibility and affordability of GAVRETO® (pralsetinib). The PAP scheme for GAVRETO® (pralsetinib) was updated in May 2023 to support the long-term treatment of patients.

- ***AYVAKIT® (avapritinib)***

  – AYVAKIT® (avapritinib), a FIC KIT/PDGFRA inhibitor, has been approved by the NMPA for the treatment of adults with unresectable or metastatic GIST harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutations. AYVAKIT® (avapritinib) has also been approved by the TFDA and the HK DoH for the treatment of patients with unresectable or metastatic PDGFRA D842V mutant GIST.

  – We continued to improve the accessibility and affordability of AYVAKIT® (avapritinib). As of the date of this announcement, AYVAKIT® (avapritinib) has been added to 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.

  – AYVAKIT® (avapritinib) is recommended by four authoritative guidelines. During the Reporting Period, AYVAKIT® (avapritinib) was recommended by the newly updated 2022 CSCO GIST guideline and the 2022 Chinese Guideline for Diagnosis and Treatment of Systemic Mastocytosis in Adults.

  – We initiated or supported investigators in post-approval clinical projects, such as IIT and RWS, to generate additional data in multiple cancer indications. For example, a multi-centered RWS evaluated the safety and efficacy of AYVAKIT® (avapritinib) in Chinese patients with GIST; another IIT aims to study the efficacy and safety profile of AYVAKIT® (avapritinib) for the treatment of R/R CBF-AML with KIT D816 or N822 mutations.

- ***TIBSOVO® (ivosidenib)***

  – TIBSOVO® (ivosidenib), a FIC IDH1 inhibitor, has been approved by the NMPA for the treatment of adult patients with R/R AML who have an IDH1 mutation.

  – In December 2023, we transferred the exclusive rights to develop, manufacture and commercialize TIBSOVO® (ivosidenib) in the Greater China region (including mainland China, Hong Kong, Macau and Taiwan) and Singapore to Servier and will receive up to US$50 million in exchange. The transaction will help to expand indication and improve accessibility of TIBSOVO® (ivosidenib) for patients in Greater China and Singapore while monetizing potential future cash flow for CStone and recouping historical investment on the asset.

  – TIBSOVO® (ivosidenib) is recommended by six authoritative guidelines, and it has become the first choice for treatment of AML with IDH1 mutation.

  – We adjusted the PAP scheme for TIBSOVO® (ivosidenib) to increase affordability and Duration of Therapy ("**DOT**").

- ***CEJEMLY® (sugemalimab)***

  – We continued to work closely with Pfizer to support the commercialization of CEJEMLY® (sugemalimab) in mainland China.

  – In 2023, CEJEMLY® (sugemalimab) as a treatment of stage III NSCLC has been upgraded to a Level 1 recommendation in the 2023 CSCO NSCLC guideline and the 2023 CSCO Immunotherapy guideline. In addition, CEJEMLY® (sugemalimab) as a treatment of stage III NSCLC has also been included in the 2023 Chinese Medical Association clinical practice guideline 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 global FIH study of this potential BIC ROR1 ADC has shown swift recruitment to the dose-escalation part in the U.S., Australia and China.

- On December 20, 2023, we reported preliminary findings from the early phase of the ongoing FIH study, at which time the safety evaluation of dose level 7 had been completed and efficacy evaluation was ongoing. CS5001 appears to be well tolerated and safe and has demonstrated promising anti-tumor activities in both solid tumor and lymphoma. CS5001 is so far the first ROR1 ADC which has reported clinical anti-tumor activity in solid tumor.

- As of the date of this announcement, we have escalated to dose level 9; no DLT was observed; and MTD has not been reached. In heavily pretreated patients with lymphoma or solid tumor who were enrolled regardless of ROR1 status, CS5001 has been well tolerated as the dose level increases; no grade 4-5 treatment-related adverse events were observed. The PK profile of CS5001 was as expected and indicated excellent stability of the ADC. Encouraging anti-tumor activities were observed starting from dose level 5, including partial and complete responses in both advanced solid tumor (e.g. lung cancer and pancreatic cancer) and lymphoma (e.g. Hodgkin lymphoma and DLBCL). We expect to determine the preliminary RP2D of CS5001 in the first half of 2024 and plan to initiate a registrational phase Ib/II trial by the end of 2024. With more data being accumulated during dose escalation, multiple presentations at international academic conferences are being planned for in 2024, including ASCO, ESMO, ASH, etc.

- CS5001 has many distinctive features, including proprietary site-specific conjugation, tumor-cleavable linker, and prodrug technology. CS5001 demonstrated a BIC potential in mantle cell lymphoma and triple negative breast cancer 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 March 2023, we presented the translational data of CS5001 in an oral session at the 13th World ADC London.

- In addition, we have identified a promising candidate ROR1 antibody clone for IHC to enable biomarker-driven patient selection based on tumor ROR1 expression, supporting precision medicine efforts in the future.

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/GEJ 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:**

  – For the markets outside of Greater China, the MAA for stage IV NSCLC indication is under review by the regulatory agencies in multiple countries and regions. In February 2023 and December 2022, the MAA filing for sugemalimab in combination with chemotherapy as the first-line treatment for patients with metastatic NSCLC was accepted by the EMA in the E.U. and the MHRA in the U.K., respectively. Currently, this indication is under review by both parties. In July 2023, we received the GCP inspection notification from the EMA for this indication in the E.U. In October 2023, we received the Day-80 RFI from MHRA which did not contain any unsolvable questions. In December 2023, we received the Day-180 LoOI from EMA which indicated that all questions had been properly addressed during previous rounds of communications. In February 2024, we completed GCP inspections from the EMA at two study centers and at CRO.

  – In June 2023, we announced that the results of OS interim analysis in the registrational GEMSTONE-302 study in patients with stage IV NSCLC had been published in a world-renowned oncology journal – *Nature Cancer*.

- **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≥5).

  – In February 2023, we received the NDA acceptance from the NMPA for the first-line treatment of patients with locally advanced or metastatic GC/GEJC (CPS≥5).

  – In October 2023, the results of the pre-specified PFS and OS final analyses in the GEMSTONE-303 study were accepted as a LBA and showcased in an oral session at the ESMO Congress 2023. Sugemalimab in combination with chemotherapy demonstrated statistically significant and clinically meaningful improvement in PFS and OS compared with placebo plus chemotherapy.

- **ESCC:**

  – In December 2023, we received the NDA approval from the NMPA for the first-line treatment of patients with unresectable locally advanced, recurrent, or metastatic ESCC.

  – In April 2023, we received the NDA acceptance from the NMPA for the first-line treatment of patients with unresectable locally advanced, recurrent, or metastatic ESCC.

  – In January 2023, we announced that the GEMSTONE-304 study for the first-line treatment of unresectable locally advanced, recurrent, or metastatic ESCC had met its primary endpoints. Sugemalimab in combination with chemotherapy demonstrated a statistically significant and clinically meaningful improvement in PFS and OS compared with placebo in combination with chemotherapy. We presented the detailed results at ESMO GI Congress in June 2023.

  – 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*.

- **R/R ENKTL:**

  – In October 2023, we received the NDA approval from the NMPA for the treatment of the patients with R/R ENKTL as a monotherapy.

  – In March 2023, we announced that the results of the registrational GEMSTONE-201 study in patients with R/R ENKTL were published in a top-tier oncology journal – *Journal of Clinical Oncology*.

  – In December 2023, we reached an agreement with the U.S. FDA in a Type B consultation regarding the registration pathway for R/R ENKTL indication.

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; iDMC recommended a continued follow-up, without protocol modification, until the final assessment of OS.

– In September 2023, we announced that the result of the FIH trial (CS1003-101) of nofazinlimab in patients with advanced solid tumors had been published in a highly-cited journal – *British Journal of Cancer*.

Pralsetinib (CS3009, RET inhibitor)

- In January 2023, we received the NDA approval from the TFDA for the treatment of patients with RET fusion-positive locally advanced or metastatic NSCLC, and advanced or metastatic RET-mutant MTC and RET fusion-positive TC.

- In June 2023, we received the NDA approval from the NMPA for the first-line treatment of patients with RET fusion-positive locally advanced or metastatic NSCLC who have not been previously treated with systemic therapy.

- In June 2023, we published updated results from the phase I/II ARROW trial in Chinese patients with RET fusion-positive NSCLC in *Cancer*. The data showed durable and long-term clinical benefits of pralsetinib in both treatment-naïve and previously treated Chinese patients with advanced RET fusion-positive NSCLC, and a generally well-tolerated safety profile.

Avapritinib (CS3007, KIT/PDGFRA inhibitor)

- In May 2023, our partner, Blueprint Medicines, received approval from the U.S. FDA for the treatment of adults with ISM in the U.S..

- In December 2023, our partner, Blueprint Medicines, received approval from the EMA for the treatment of adult patients with ISM with moderate to severe symptoms inadequately controlled on symptomatic treatment. To date, avapritinib is the first and only approved therapy for patients with ISM in Europe.

- In June 2023, we presented new data of avapritinib in patients with advanced GIST at ASCO Annual Meeting 2023. These results showed robust antitumor activity of avapritinib in patients with KIT activation loop-positive, adenosine triphosphate ("**ATP**") binding pocket-negative GIST versus patients whose tumors harbored other KIT mutational profiles.

- In November 2023, we announced that a post hoc data analysis of the global Phase 1 NAVIGATOR and Phase 1/2 China bridging (CS3007-101) studies of avapritinib in advanced GIST were published in a reputable oncology journal – *Clinical Cancer Research*.

Ivosidenib (CS3010, IDH1 inhibitor)

- In December 2023, we received the acceptance from the NMPA to the supplemental submission for regular approval of ivosidenib as a treatment for R/R AML.

- In May 2023, we reached alignment with the CDE on the regulatory pathway toward regular approval of ivosidenib as a treatment for R/R AML.

- In January 2023, we completed the China bridging study of ivosidenib in R/R AML patients.

Lorlatinib (ALK/ROS-1 inhibitor)

- We are conducting a pivotal study in patients with ROS1-positive advanced NSCLC who have been previously treated with crizotinib and platinum-based chemotherapy. In May 2022, we enrolled the first patient in this study. This is the first pivotal trial of lorlatinib for the treatment of ROS1-positive NSCLC who have been previously treated with crizotinib and platinum-based chemotherapy in the world. In June 2023, we completed the patient recruitment for this study. In February 2024, the pivotal study met the primary endpoint, and we are in discussion with the CDE and Pfizer regarding the pre-NDA/NDA in mainland China for ROS1-positive advanced NSCLC in 2024.

Research

Precision medicines and immuno-oncology combinations remain our strategic focus. 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 2023 with several initiatives:

- **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 have a PCC nominee announced in the first half of 2024. In addition, the lead antibodies of the other FIC GPCR-x ADC, CS5005, have been selected. The conjugated lead molecules have demonstrated encouraging *in vitro* and *in vivo* efficacy, and INDs relating to these two FIC ADCs are 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 well validated targets with proven syngeneic effectiveness. The leading bispecific antibody candidate is expected to be nominated in the first half of 2024, and the PCC of this bispecific ADC is expected to be announced by the end of 2024.

- **I/O multi-specifics:** CS2009, which is a tri-specific molecule against PD-1, VEGFa and CTLA-4 target, is under cell line development, and the related IND is expected to be filed in 2024. This is a potential FIC 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.

- **Cell penetrating therapeutic platform:** Numerous well-known oncology targets are intracellular proteins deemed undruggable by current therapeutic approaches. We are developing a proprietary CPT platform against these otherwise intractable targets. Significant progress has been made in the development of this platform with broad therapeutic potential for oncology and beyond.

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 and Allist.

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

- ***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.

- ***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 CStone to reduce overhead and operating costs associated with pralsetinib's commercialization, thereby improving overall profitability.

- ***Servier***

  – In December 2023, through the execution of an asset purchase agreement, we transferred the Greater China and Singapore rights to 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 CStone to recoup its 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.

- ***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. It 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 also 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 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. This step marks another milestone for CStone and Pfizer in their growing strategic partnership, which includes joint efforts to selectively introduce oncology therapies into the Greater China region. Additionally, it bolsters CStone's growing pipeline. 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.

- ***Blueprint Medicines***

  – In 2022, we entered into a new partnership with Roche which became the global marketing authorization holder ("**MAH**") for pralsetinib. We acquired full manufacturing technology transfer rights to pralsetinib. Locally manufactured supply is expected to provide significant cost savings and improve CStone's overall profitability as a result. In the meantime, the global MAH will be responsible for the manufacturing and supply of pralsetinib for China before our successful technology transfer. In February 2023, Blueprint Medicines announced that they will regain global commercialization and development rights to pralsetinib from Roche, excluding Greater China. A transition agreement was completed in February 2024. In February 2024, Blueprint Medicines announced that they have identified an alternate partner for pralsetinib in the U.S.. CStone is currently working with all involved parties to take necessary steps to ensure continuity of supply of pralsetinib for patients in Greater China.

- ***Hengrui***

  – 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. In 2023, the trial is recruiting patients smoothly. In January 2024, Hengrui received an IND approval from the NMPA for evaluating CS1002 (SHR-8068) in combination with adebrelimab and chemotherapy as the first-line treatment of patients with advanced or metastatic non-squamous NSCLC.

- ***EQRx***

  – We regained rights for the development and commercialization of sugemalimab and nofazinlimab outside of Greater China, with the termination of the license agreement for sugemalimab and nofazinlimab between CStone and EQRx on May 9th, 2023. The transition was completed in August 2023. Currently, we are leading the regulatory process for sugemalimab MAA reviews by the EMA and the U.K. MHRA. The termination of this License Agreement will not affect the upfront and milestone payments previously received from EQRx. We are currently exploring potential partnership opportunities for both sugemalimab and nofazinlimab outside of Greater China.

- ***DotBio***

  – In 2023, 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.

The Impact of the Novel Coronavirus ("COVID-19")

For the year ended December 31, 2023 and as of the date of this announcement, the impact of COVID-19 on our commercial operations is minimal, except that the breakout of COVID in early 2023 has led to decline of outpatient and inpatient for oncology treatment in major hospitals nationwide. Our business has been recovering since January 2023.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE YEAR ENDED DECEMBER 31, 2023

	NOTES	For the year ended December 31, 2023 RMB'000 (Audited)	2022 RMB'000 (Audited)
Revenue	3	**463,842**	481,363
Cost of revenue		**(159,547)**	(202,985)
Gross profit		**304,295**	278,378
Other income	5	**50,608**	18,722
Other gains and losses	5	**199,544**	(776)
Research and development expenses		**(527,799)**	(614,162)
Selling and marketing expenses		**(199,349)**	(327,301)
Administrative expenses		**(182,714)**	(249,062)
Finance costs		**(11,819)**	(8,477)
Loss for the year	6	**(367,234)**	(902,678)
Other comprehensive (expense) income:			
Item that may be reclassified subsequently to profit or loss:			
Exchange differences arising on translation of foreign operations		**(770)**	405
Total comprehensive expense for the year		**(368,004)**	(902,273)
Loss per share			
– Basic (RMB)	8	**(0.29)**	(0.77)
– Diluted (RMB)		**(0.29)**	(0.77)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

AT DECEMBER 31, 2023

	NOTES	**December 31, 2023** ***RMB'000*** **(Audited)**	December 31, 2022 *RMB'000* (Audited)
Non-current assets			
Property, plant and equipment		**105,664**	138,379
Right-of-use assets		**47,704**	68,187
Intangible assets		**173,045**	159,699
Financial assets measured at fair value through profit or loss ("**FVTPL**")		**3,541**	3,482
Other receivables		**2,258**	21,763
		332,212	391,510
Current assets			
Account receivables	*10*	**172,438**	77,133
Deposits, prepayments and other receivables		**21,850**	105,505
Inventories		**108,828**	22,188
Time deposits with original maturity over three months		**30,000**	483,407
Cash and cash equivalents		**996,671**	558,684
		1,329,787	1,246,917
Current liabilities			
Account and other payables and accrued expenses	*11*	**681,442**	869,366
Refund liabilities		**22,698**	25,198
Bank borrowings		**105,986**	8,567
Contract liabilities		**6,885**	–
Lease liabilities		**33,327**	36,351
Deferred income		**–**	7,000
		850,338	946,482
Net current assets		**479,449**	300,435
Total assets less current liabilities		**811,661**	691,945

	NOTES	**December 31, 2023** ***RMB'000*** **(Audited)**	December 31, 2022 *RMB'000* (Audited)
Non-current liabilities			
Account payables	*11*	**68,729**	–
Bank borrowings		**213,000**	218,986
Contract liabilities		**61,967**	–
Lease liabilities		**11,135**	22,386
Deferred income		**–**	1,247
		354,831	242,619
Net assets		**456,830**	449,326
Capital and reserves			
Share capital		**860**	802
Treasury shares held in the trusts		**(8)**	(2)
Reserves		**455,978**	448,526
Total equity		**456,830**	449,326

NOTES

1. GENERAL

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 consolidated financial statements are presented in Renminbi ("**RMB**"), which is also the same as the functional currency of the Company.

2. APPLICATION OF NEW AND AMENDMENTS TO IFRSs

New and amendments to IFRSs that are mandatorily effective for the current year

In the current year, the Group has applied the following new and amendments to IFRSs issued by the the International Accounting Standards Board, for the first time, which are mandatory effective for the Group's annual period beginning on January 1, 2023 for the preparation of the Group's consolidated financial statements:

IFRS 17 (including the June 2020 and December 2021 Amendments to IFRS 17)	Insurance Contracts
Amendments to IAS 1 and IFRS Practice statement 2	Disclosure of Accounting Polices
Amendments to IAS 8	Definition of Accounting Estimates
Amendments to IAS 12	Deferred Tax related to Assets and Liabilities arising from a Single Transaction
Amendments to IAS 12	International Tax Reform – Pillar Two model Rules

Except as described below, the application of the other new and amendments to IFRSs in the current year has had no material impact on the Group's financial positions and performance for the current and prior years and/or on the disclosures set out in the consolidated financial statements.

2.1 Impacts on application of Amendments to IAS 12 Deferred Tax related to Assets and Liabilities arising from a Single Transaction

The Group has applied the amendments for the first time in the current year. The amendments narrow the scope of the recognition exemption of deferred tax liabilities and deferred tax assets in paragraphs 15 and 24 of IAS 12 *Income Taxes* so that it no longer applies to transactions that, on initial recognition, give rise to equal taxable and deductible temporary differences.

In accordance with the transition provision:

(i) the Group has applied the new accounting policy retrospectively to leasing transactions that occurred on or after January 1, 2022; and

(ii) the Group also, as at January 1, 2022, recognised a deferred tax asset (to the extent that it is probable that taxable profit will be available against which the deductible temporary difference can be utilised) and a deferred tax liability for all deductible and taxable temporary difference associated with right-of-use-assets and lease liabilities.

The application of the amendments has had no material impact on the Group's financial position and performance, except that the Group disclose the related deferred tax assets and deferred tax liabilities of RMB9,557,000 and RMB11,086,000 respectively on a gross basis as at December 31, 2022, but it has no impact on the retained earnings at the earliest period presented.

2.2 Impacts on application of Amendments to IAS 1 and IFRS Practice Statement 2 Disclosure of Accounting Policies

The Group has applied the amendments for the first time in the current year. IAS 1 *Presentation of Financial Statements* is amended to replace all instances of the term "significant accounting policies" with "material accounting policy information". Accounting policy information is material if, when considered together with other information included in an entity's financial statements, it can reasonably be expected to influence decisions that the primary users of general purpose financial statements make on the basis of those financial statements.

The amendments also clarify that accounting policy information may be material because of the nature of the related transactions, other events or conditions, even if the amounts are immaterial. However, not all accounting policy information relating to material transactions, other events or conditions is itself material. If an entity chooses to disclose immaterial accounting policy information, such information must not obscure material accounting policy information.

IFRS Practice Statement 2 *Making Materiality Judgements* (the "**Practice Statement**") is also amended to illustrate how an entity applies the "four-step materiality process" to accounting policy disclosures and to judge whether information about an accounting policy is material to its financial statements.

The application of the amendments has had no material impact on the Group's financial positions and performance but has affected the disclosure of the Group's accounting policies for the year ended December 31, 2023.

3. REVENUE

Disaggregation of revenue from contracts with customers

	For the year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Type of goods or services		
Sales of pharmaceutical products	**336,712**	364,299
License fee income	**95,704**	87,268
Royalty income	**31,426**	29,796
	463,842	481,363
Timing of revenue recognition		
A point in time	**463,842**	481,363

4. 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 all 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 geographical location of the registered office of the customers, during the year is as follows:

	For the year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
	(Audited)	(Audited)
The PRC (excluding Hong Kong and Taiwan)	**370,234**	476,527
France	**82,717**	–
Others	**10,891**	4,836
	463,842	481,363

Information about major customers

Revenue from the customers of the corresponding years contributing over 10% of the total sales of the Group are as follow:

	For the year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Customer A	**242,314**	287,780
Customer B	**67,130**	97,064
Customer C	**(note)**	73,296
Customer D	**82,717**	N/A
Customer E	**60,000**	N/A

Note: The Group carried out transactions with this customer for the year ended December 31, 2023 but the amount of the transaction was less than 10% of the total revenue of the Group.

5. OTHER INCOME/OTHER GAINS AND LOSSES

Other income

	For the year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Bank and other interest income	**24,886**	9,672
Government grants income	**17,752**	8,639
Income from sales of scrap materials	**6,705**	411
Amortisation of payments received for exclusive promotion rights granted	**1,148**	–
Others	**117**	–
	50,608	18,722

Other gains and losses

	For the year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Gain on disposal of an intangible asset	**179,467**	–
Net foreign exchange gains	**20,360**	61,492
Net gain on fair value of money market funds	**242**	99
Net loss on fair value changes of financial assets measured at FVTPL	**59**	(62,028)
Net loss on disposal of property, plant and equipment	**(576)**	–
Others	**(8)**	(339)
	199,544	(776)

6. LOSS FOR THE YEAR

	For the year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Loss for the year has been arrived at after charging (crediting):		
Depreciation of:		
Property, plant and equipment	**5,636**	6,586
Right-of-use assets	**37,999**	35,752
Amortisation of intangible assets	**14,555**	12,661
Total depreciation and amortisation	**58,190**	54,999
Less: amounts capitalised in the cost of qualifying assets	**–**	(10,459)
Total depreciation and amortisation charged to profit or loss	**58,190**	44,540
Directors' emoluments	**59,498**	83,640
Other staff costs:		
Salaries and other allowances; including redundancy cost amounting of RMB30,937,000 (2022:RMB535,000)	**235,870**	275,206
Performance related bonus	**9,828**	86,381
Retirement benefit scheme contributions	**46,498**	55,896
Share-based payment expenses	**(14,109)**	67,690
	278,087	485,173
	337,585	568,813
Auditor's remuneration	**2,214**	2,100
Impairment losses recognised on construction in progress (included in research and development expenses)	**26,404**	23,412
Write-down of inventories (included in cost of revenue)	**8,822**	8,757
Cost of inventories recognised as cost of revenue	**60,599**	91,754

7. INCOME TAX EXPENSE

No income tax expense for the years ended December 31, 2022 and 2023 as the Group had no assessable profits derived from the operating entities of the Group.

8. LOSS PER SHARE

The calculation of the basic and diluted loss per share for the year is as follows:

	For the year ended December 31,	
	2023	2022
	(Audited)	(Audited)
Loss (RMB'000)		
Loss for the year attributable to owners of the Company for the purpose of basic and diluted loss per share	**(367,234)**	(902,678)
Number of shares ('000)		
Weighted average number of ordinary shares for the purpose of basic and diluted loss per share	**1,263,073**	1,172,839

The calculation of basic and diluted loss per share for both years has excluded the treasury shares held in trusts of the Company.

Diluted loss per share for both years did not assume the exercise of share options awarded under the employee stock option and the vesting of unvested RSU as their inclusion would be anti-dilutive.

9. DIVIDENDS

No dividend was paid or declared by the Company during the years ended December 31, 2022 and 2023, nor has any dividend been proposed since the end of the reporting year.

10. 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.

	December 31, 2023	December 31, 2022
	RMB'000	*RMB'000*
	(Audited)	(Audited)
0 – 60 days	**28,447**	46,563
61 – 90 days	**20**	258
Over 90 days	**143,971**	30,312
	172,438	77,133

11. ACCOUNT AND OTHER PAYABLES AND ACCRUED EXPENSES

	December 31, 2023	December 31, 2022
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Account payables	**315,106**	290,414
Other payables and accruals	**435,065**	578,952
	750,171	869,366
Analysed as:		
– Non-current	**68,729**	–
– Current	**681,442**	869,366
	750,171	869,366

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.

	December 31, 2023	December 31, 2022
	RMB'000	*RMB'000*
	(Audited)	(Audited)
0 – 30 days	**171,216**	96,629
31 – 60 days	**24,520**	22,736
61 – 90 days	**39,850**	55,073
Over 90 days	**79,520**	115,976
	315,106	290,414

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

Year ended December 31, 2023 Compared to Year ended December 31, 2022

	For the year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Revenue	**463,842**	481,363
Cost of revenue	**(159,547)**	(202,985)
Gross profit	**304,295**	278,378
Other income	**50,608**	18,722
Other gains and losses	**199,544**	(776)
Research and development expenses	**(527,799)**	(614,162)
Selling and marketing expenses	**(199,349)**	(327,301)
Administrative expenses	**(182,714)**	(249,062)
Finance costs	**(11,819)**	(8,477)
Loss for the year	**(367,234)**	(902,678)
Other comprehensive (expense) income:		
Item that may be reclassified subsequently to profit or loss:		
Exchange differences arising on translation of foreign operations	**(770)**	405
Total comprehensive expense for the year	**(368,004)**	(902,273)
Non-IFRS measures:		
Adjusted loss for the year	**(330,241)**	(760,616)

Revenue. Our revenue was RMB463.8 million for the year ended December 31, 2023, composed of RMB336.7 million in sales of pharmaceutical products (avapritinib, pralsetinib and ivosidenib), RMB95.7 million in license fee income and RMB31.4 million in royalty income of sugemalimab, representing a year-on-year increase of RMB10.1 million, or 8.6%, in license fee and royalty income which largely offset a decrease in revenue from sales of pharmaceutical products, such that total revenue decreased by RMB17.5 million, or 3.6%, year on year.

Other Income. Our other income increased by RMB31.9 million from RMB18.7 million for the year ended December 31, 2022 to RMB50.6 million for the year ended December 31, 2023. This was primarily due to more bank and other interest income.

Other Gains and Losses. Our other gains and losses increased by RMB200.3 million from losses of RMB0.8 million for the year ended December 31, 2022 to gains of RMB199.5 million for the year ended December 31, 2023. This increase was primarily due to net gain of RMB179.5 million related to the transfer of license for the ivosidenib business in the year ended December 31, 2023.

Research and Development Expenses. Our research and development expenses decreased by RMB86.4 million from RMB614.2 million for the year ended December 31, 2022 to RMB527.8 million for the year ended December 31, 2023. This decrease was primarily attributable to (i) a decrease of RMB109.0 million in employee cost from RMB212.1 million for the year ended December 31, 2022 to RMB103.1 million for the year ended December 31, 2023; and (ii) a decrease of RMB14.8 million in milestone fee and third party contracting cost for different phases of our clinical trials from RMB376.5 million for the year ended December 31, 2022 to RMB361.7 million for the year ended December 31, 2023, which was partially offset by an increase of RMB37.6 million in depreciation and others.

	For the year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Milestone fee and third party contracting cost	**361,691**	376,524
Employee cost	**103,051**	212,108
Depreciation and others	**63,057**	25,530
Total	**527,799**	614,162

Administrative Expenses. Our administrative expenses decreased by RMB66.4 million from RMB249.1 million for the year ended December 31, 2022 to RMB182.7 million for the year ended December 31, 2023. This decrease was primarily attributable to a decrease of RMB50.1 million in employee cost from RMB161.5 million for the year ended December 31, 2022 to RMB111.4 million for the year ended December 31, 2023.

	For the year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Employee cost	**111,436**	161,451
Professional fees	**31,955**	42,394
Depreciation and amortization	**19,049**	21,367
Rental expenses	**3,513**	3,069
Others	**16,761**	20,781
Total	**182,714**	249,062

Selling and Marketing Expenses. Our selling and marketing expenses decreased by RMB128.0 million from RMB327.3 million for the for the year ended December 31, 2022 to RMB199.3 million for the year ended December 31, 2023. The decrease was primarily attributable to decrease in employee cost by RMB72.2 million and professional fees by RMB32.2 million.

	For the year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Employee cost	**123,098**	195,255
Professional fees	**16,353**	48,584
Others	**59,898**	83,462
Total	**199,349**	327,301

Finance Costs. The finance costs increased by RMB3.3 million from RMB8.5 million for the year ended December 31, 2022 to RMB11.8 million for the year ended December 31, 2023, primarily due to an increase in interest on bank borrowings.

Non-IFRS Measures

To supplement the Group's consolidated financial statements, which are presented in accordance with the IFRS, the Company also uses adjusted loss for the year 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 for the year represents the loss for the year excluding the effect of certain non-cash items and onetime events, namely the share-based payment expenses. The term adjusted loss for the year 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 year to year and company to company to the extent applicable.

The table below sets forth a reconciliation of the loss to adjusted loss during the years indicated:

	For the year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Loss for the year	**(367,234)**	(902,678)
Added:		
Share-based payment expenses	**36,993**	142,062
Adjusted loss for the year	**(330,241)**	(760,616)

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

	For the year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Research and development expenses for the year	**(527,799)**	(614,162)
Added:		
Share-based payment expenses	**(6,911)**	55,015
Adjusted research and development expenses for the year	**(534,710)**	(559,147)

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 years indicated:

	For the year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Administrative and selling and marketing expenses for the year	**(382,063)**	(576,363)
Added:		
Share-based payment expenses	**43,904**	87,047
Adjusted administrative and selling and marketing expenses for the year	**(338,159)**	(489,316)

Employees and Remuneration Policies

The following table sets forth a breakdown of our employees as of December 31, 2023 by function:

Function	Number of employees	% of total number of employees
Research and Development	122	53.04
Sales, General and Administrative	108	46.96
Total	230	100.0

As of December 31, 2023, we had 142 employees in Shanghai, 31 employees in Beijing, 20 employees in Suzhou and 37 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 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 December 31, 2023, our cash and cash equivalents and time deposits were RMB1,026.7 million, as compared to RMB1,042.1 million as of December 31, 2022. The decrease was mainly due to the payment of 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 December 31, 2023, our gearing ratio was 72.5% (December 31, 2022: 72.6%).

Charge on Assets

At December 31, 2023, the amount of assets pledged by the Group to certain banks to secure bank loan facilities granted to the Group was RMB101,936,000 (December 31, 2022: Nil).

OTHER FINANCIAL INFORMATION

Significant Investments, Material Acquisitions and Disposals

As at December 31, 2023, 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 December 31 2023, the Group's bank borrowings were all denominated in RMB. In 2020, the Group obtained two new bank loan facilities amounting to RMB175 million and RMB25 million, respectively, for the purpose of the construction of the facilities and working capital. In 2022, the Group obtained one new bank loan facility amounting to RMB100 million for the purpose of working capital. In 2023, the Group obtained three new bank loan facilities amounting to RMB100 million, RMB80 million and RMB50 million for the purpose of working capital. During the year ended December 31, 2023, the Group has drawn down RMB350,000,000 and repaid RMB268,749,000 of principal and interest in accordance with the payment schedules.

Contingent Liabilities

As of December 31, 2023, we did not have any material contingent liabilities (as of December 31, 2022: 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 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 during the Reporting Period.

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

The Company is no longer an eligible stock on the Hang Seng Composite Index on February 16, 2024 and with effect from March 4, 2024, the Company is no longer included on the Hong Kong Stock Connect.

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 December 31, 2023:

	% of use of proceeds	**Proceeds from the subscription** *(RMB million)*	**Unutilized net proceeds as of December 31, 2022** *(RMB million)*	**Actual usage during the Reporting Period** *(RMB million)*	**Unutilized net proceeds as of December 31, 2023** *(RMB million)*
Fund the development activities under the collaboration agreement	100%	1,355.9	534.9	125.6	409.3

Note: The unutilized net proceeds are planned to be put into use by December 31, 2025.

As of the date of this announcement, the Board is aware that there has been a delay in the expected timeline for the use of proceeds when compared to the implementation plan as disclosed in the interim report for the six months ended June 30, 2023. To the best knowledge of the Directors, the delay in use of proceeds was mainly attributable to changes in the joint development plan for assets that the Company is developing with Pfizer, taking into account the current status of Pfizer's pipeline.

The Company expects to utilize the unutilized proceeds based on clinical development plan as stipulated in the Collaboration Agreement. As the collaboration evolves, the Company will continue to evaluate and adopt a prudent and flexible approach for utilising the net proceeds effectively and efficiently for the long-term benefit and development of the Group. The expected timeline of full utilisation is based on the Directors' best estimation barring unforeseen circumstances, and would be subject to change based on the future development of market conditions.

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 placees 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 December 31, 2023:

	% of use of proceeds	**Proceeds from the placing** *(RMB million)*	**Actual usage during the Reporting Period** *(RMB million)*	**Unutilized net proceeds as of December 31, 2023** *(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	67.62	–
Development of pipeline products including but not limited to CS5001 (a potentially best-in-class ROR1 ADC)	50%	169.06	115.59	53.47
Business development activities to enrich the Company's pipeline and fully utilize the Company's proven clinical capabilities	20%	67.62	15.31	52.31
General corporate purposes	10%	33.82	14.71	19.11
Total	100%	338.12	213.23	124.89

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 annual financial results for the year ended December 31, 2023 are in compliance with the relevant accounting standards, rules and regulations and appropriate disclosures have been duly made.

Scope of Work of Messrs. Deloitte Touche Tohmatsu

The figures in respect of the Group's consolidated statement of financial position, consolidated statement of profit or loss and other comprehensive income and the related notes thereto for the year ended December 31, 2023 as set out in this preliminary announcement have been agreed by the Group's auditor, Messrs. Deloitte Touche Tohmatsu, to the amounts set out in the audited consolidated financial statements of the Group for the year as approved by the Board of Directors on March 27, 2024. The work performed by Messrs. Deloitte Touche Tohmatsu in this respect did not constitute an assurance engagement and consequently no opinion or assurance conclusion has been expressed by Messrs. Deloitte Touche Tohmatsu on this announcement.

FINAL DIVIDEND

The Board does not recommend the payment of a final dividend for the year ended December 31, 2023 (2022: Nil).

ANNUAL GENERAL MEETING

The date of the annual general meeting of the Company (the "**AGM**") will be announced in due course. Shareholders of the Company should refer to details regarding the AGM in the circular of the Company, the notice of AGM and form of proxy accompanying thereto to be dispatched by the Company.

PUBLICATION OF ANNUAL RESULTS ANNOUNCEMENT AND ANNUAL REPORT

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

The annual report for the year ended December 31, 2023 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, March 27, 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.