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, 2022

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, 2022 (the "**Reporting Period**"), together with comparative figures for the year ended December 31, 2021. Unless otherwise defined herein, capitalised 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, 2021 dated May 31, 2022.

FINANCIAL HIGHLIGHTS

International Financial Reporting Standards ("IFRS") Measures:

- **Revenue** was RMB481.4 million for the year ended December 31, 2022, composed of RMB364.3 million in sales of pharmaceutical products, representing sales of the Company's pharmaceutical products (avapritinib, pralsetinib and ivosidenib), RMB87.3 million in license fee income and RMB29.8 million in royalty income of sugemalimab, representing an increase of RMB237.7 million from RMB243.7 million for the year ended December 31, 2021, primarily attributable to the increase in the sales of the pharmaceutical products and royalty income of sugemalimab.

- **Research and development expenses** were RMB614.2 million for the year ended December 31, 2022, representing a decrease of RMB690.7 million from RMB1,304.9 million for the year ended December 31, 2021, primarily due to the decrease in milestone fee and third party contracting cost and the decrease in employee costs.

- **Administrative expenses** were RMB249.1 million for the year ended December 31, 2022, representing a decrease of RMB48.5 million from RMB297.6 million for the year ended December 31, 2021, primarily due to the decrease in professional fees and other fee.

- **Selling and marketing expenses** were RMB327.3 million for the year ended December 31, 2022, representing a decrease of RMB36.5 million from RMB363.8 million for the year ended December 31, 2021, primarily attributable to the decrease in marketing activities after the products launched in 2021.

- **Loss for the year** was RMB902.7 million for the year ended December 31, 2022, representing a decrease of RMB1,017.4 million from RMB1,920.1 million for the year ended December 31, 2021, primarily attributable to the increase in revenue and the decrease in research and development expenses.

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

- **Research and development expenses** excluding the share-based payment expenses were RMB559.1 million for the year ended December 31, 2022, representing a decrease of RMB623.0 million from RMB1,182.1 million for the year ended December 31, 2021, primarily due to the decrease in milestone fee and third party contracting cost and the decrease in employee costs.

- **Administrative and selling and marketing expenses** excluding the share-based payment expenses were RMB489.3 million for the year ended December 31, 2022, representing a decrease of RMB72.2 million from RMB561.5 million for the year ended December 31, 2021, primarily attributable to the decrease in marketing activities after the products launched in 2021.

- **Loss for the year** excluding the share-based payment expenses was RMB760.6 million, representing a decrease of RMB936.8 million from RMB1,697.4 million for the year ended December 31, 2021, primarily attributable to the increase in revenue and the decrease in research and development expenses.

BUSINESS HIGHLIGHTS

2022 has been a fruitful year for CStone with milestones across our evolving pipeline and business. Our commercial successes, including the launch of two First-in-Class ("**FIC**")/Best-in-Class ("**BIC**") therapies, put us in an elite tier of innovative biopharmaceutical companies from China as we now have four products in market and generating recurring revenue to provide financial strength and fund further growth initiatives. For the year ended December 31, 2022 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:

– RMB481.4 million in total revenue, including RMB394.1 million in commercial revenue which is composed of RMB364.3 million in sales of our precision medicines and RMB29.8 million in royalty income of sugemalimab

– Two new products launched: sugemalimab and ivosidenib, bringing us to a total of four products commercially launched and generating sales

– Five NDA approvals obtained for three products: sugemalimab for stage III non-small cell lung cancer ("**NSCLC**") in mainland China, ivosidenib for isocitrate dehydrogenase 1 ("**IDH1**")-mutant relapsed/refractory acute myeloid leukemia ("**R/R AML**") in mainland China, pralsetinib for rearranged during transfection ("**RET**")-mutant medullary thyroid cancer ("**MTC**") & RET fusion-positive thyroid cancer ("**TC**") in mainland China, pralsetinib for RET fusion-positive NSCLC in Hong Kong, China, and pralsetinib for RET fusion-positive NSCLC, RET-mutant MTC & RET fusion-positive TC in Taiwan, China

– Additional five NDAs currently under review: pralsetinib for first-line treatment of RET fusion-positive NSCLC in mainland China, sugemalimab for relapsed or refractory extranodal natural killer/T-cell lymphoma ("**R/R ENKTL**") in mainland China, sugemalimab for first-line stage IV NSCLC in the United Kingdom ("**U.K.**"), sugemalimab for first-line stage IV NSCLC in the European Union ("**E.U.**"), and sugemalimab for first-line gastric adenocarcinoma/gastroesophageal junction adenocarcinoma ("**GC/GEJ**") in mainland, China

– Five positive topline data readouts for sugemalimab in various indications: R/R ENKTL, first-line stage IV NSCLC, stage III NSCLC, first-line GC/GEJ and first-line esophageal squamous cell carcinoma ("**ESCC**")

– Eleven data presentations/publications at/on global academic conferences/top-tier medical journals

– Three key clinical programs commenced: the first-in-human ("**FIH**") global study of CS5001 (ROR1 ADC) in the United States of America ("**U.S.**") and Australia, first-patient-dosed in the pivotal study of lorlatinib for ROS1-positive advanced NSCLC in mainland China and enrolment completed for global phase III trial of nofazinlimab in combination with LENVIMA® (lenvatinib) in first-line advanced hepatocellular carcinoma ("**HCC**")

– Over ten discovery projects in progress, including multi-specifics, antibody drug conjugates, and a proprietary platform for drugging intractable intracellular targets; one pre-clinical candidate ("**PCC**") declared for a potential FIC/BIC immuno-oncology tri-specific antibody against PD-L1, VEGF plus another immuno-oncology ("**IO**") target

– Further advanced our strategic partnerships with Pfizer, Hengrui and EQRx through clinical development, regulatory registrations and commercial launches

– Achieved the technology transfer submission to Center for Drug Evaluation ("**CDE**") of National Medical Products Administration ("**NMPA**") for avapritinib and the technology transfer for pralsetinib is in progress smoothly

I. Multiple Product Launches and Continued Robust Commercial Efforts

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

- ***Steady and Continued Ramp Up in Product Sales***

  We generated overall net sales of RMB364.3 million in 2022 on the basis of a steady growth in the total product sales of GAVRETO® (pralsetinib) and AYVAKIT® (avapritinib), as well as a successful launch of TIBSOVO® (ivosidenib).

- ***Achieved Successful Launches of New Products and Indications***

  We expanded the number of in-market products and indications they cover with effective launches that position them to become meaningful future contributors to revenue.

  – TIBSOVO® (ivosidenib): Launched in mainland China, with 100% channel availability in major target hospitals and pharmacies.

  – GAVRETO® (pralsetinib): The indications of advanced or metastatic RET-mutant MTC and RET fusion-positive TC were launched in mainland China. Also, the indication of RET fusion-positive metastatic NSCLC was launched in Hong Kong, China.

  – CEJEMLY® (sugemalimab): A new indication was successfully launched in mainland China for the treatment of patients with unresectable stage III NSCLC whose disease has not progressed following concurrent or sequential platinum-based chemoradiotherapy.

- ***Expansion of sales force coverage in key markets for prescriptions of precision drugs***

  We have specifically focused our efforts on ensuring dedicated sales force coverage and successfully expanded our coverage to approximately 800 hospitals in over 180 cities as of the date of this announcement, up from 600 in 2021, accounting for approximately 75-80% of the relevant market for precision medicines where we believe we can maximize the return on our sales efforts.

- ***Formed a precision diagnostics ecosystem with key stakeholders to facilitate patient identification and support prescriptions***

  – We have signed collaboration agreements with top gene sequencing companies to further improve the testing rate for RET mutation in NSCLC/TC, platelet-derived growth factor receptor alpha ("**PDGFRA**") exon 18 mutation in gastrointestinal stromal tumor ("**GIST**") and IDH1 mutation in AML, with education sessions covering over 5,000 pathologists and clinicians.

  – We have strengthened partnership with National Pathology Quality Control Center ("**PQCC**") to standardize testing process and improve testing accuracy, with number of participating hospitals increasing by 60%.

  – We expanded financial support programs to RET mutation testing in MTC patients and IDH1 mutation testing in AML patients from only RET mutation in NSCLC patients before, covering approximately 1,000 patients.

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

  – GAVRETO® (pralsetinib), AYVAKIT® (avapritinib) and TIBSOVO® (ivosidenib) were included in 20 of China's national guidelines for testing and treatment in multiple therapeutic areas, such as NSCLC, TC, GIST and AML indication, etc. The newly included guidelines include 2022 CSCO Primary Lung Cancer Guideline, 2022 CSCO MTC Clinical Guideline, 2022 CSCO Hematologic Malignancy Guideline, 2022 China Anti Cancer Association ("**CACA**") Hematological Oncology Guideline, 2022 Chinese Guideline for Diagnosis and Treatment of Systemic Mastocytosis in adults, etc.

  – We engaged in close collaboration with several industry associations – CSCO, CACA, Chinese Medical Association, Chinese Medical Doctor Association etc., – on diagnosis and treatment standardization projects for GIST, NSCLC and hematological malignancies, further strengthening our industry connections and demonstrating our expertise.

  – We enhanced awareness and endorsement of our products among key opinion leaders ("**KOLs**") and healthcare professionals ("**HCPs**") via proactive engagement and constant education. As of the date of this announcement, we have held over 160 academic meetings and events reaching over 50,000 leading KOLs and HCPs, resulting in improved brand perception and product adoption within the healthcare community of our treatments.

– We initiated or sponsored leading KOLs in post-approval clinical projects such as investigator-initiated trials and real-world studies to generate additional data in multiple cancer indications which may support the adoption of our drugs. We funded nine studies in collaboration with non-profit academic institutions. In particular, two real-world studies and one investigator-initiated trial have reached milestones, including the finalization and publication in 2022 CSCO of the clinical study report of pralsetinib for the treatment of NSCLC in Bo'ao with all patients benefiting from treatment and duration of therapy ("**DOT**") is more than 12 months, and the activation of thirteen sites for avapritinib study for the treatment of GIST and three top hematology hospitals for the treatment of R/R AML with KIT D816V mutation. In addition, we also observed the data from pool analysis of avapritinib in GIST with exon 17/18 mutations have obvious benefits compared with standard treatment.

- ***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, the patient assistance program ("**PAP**") scheme of GAVRETO® (pralsetinib) was updated to support the long-term treatment of the patients. We adjusted the listing price of AYVAKIT® (avapritinib) and launched new PAP to improve affordability for GIST patients. We launched PAP for TIBSOVO® (ivosidenib) to increase affordability and DOT.

  – We secured inclusion of AYVAKIT® (avapritinib), GAVRETO® (pralsetinib) and TIBSOVO® (ivosidenib) in 130 of the major commercial and government insurance programs covering more than 90 million population, up from over 60 million population as disclosed in our 2021 annual results announcement.

  – We continued strategic collaboration with Sinopharm Group Co., Ltd ("**Sinopharm**") and formed new partnership with Shanghai Pharmaceuticals Holding Co., Ltd ("**SPH**") to broaden hospital and pharmacy distribution coverage for GAVRETO® (pralsetinib), AYVAKIT® (avapritinib) and TIBSOVO® (ivosidenib). As of the date of this announcement, AYVAKIT® (avapritinib), GAVRETO® (pralsetinib) and TIBSOVO® (ivosidenib) have been listed in approximately 220 hospitals and direct-to-patient pharmacies ("**DTPs**"), up from approximately 100 in 2021.

  – We continued strategic collaboration with three of the largest integrated innovative healthcare service platforms in mainland China – Shanghai Meditrust Health Co., Ltd., Beijing Yuanxin Technology Group Co., Ltd., and Medbanks Health Technology Co., Ltd. – to improve distribution and affordability of GAVRETO® (pralsetinib), AYVAKIT® (avapritinib) and TIBSOVO® (ivosidenib) by facilitating enrolment in city insurance programs.

- ***Continued patient education and support, for retention and long-term medication***

  We made continuous efforts in patient support via online patient communities and offline education sessions to improve patient retention and DOT. As of the date of this announcement, our online platform has over 5,000 subscribers and published over 200 patient stories and information. We held 130 patient education sessions, covering 15,000 potential patients.

- ***Collaborating with global strategic partners to support global launches of IO backbone drugs***

  – We are closely collaborating with our partners Pfizer on the commercialization of sugemalimab in mainland China.

  – For the launch readiness in China, we worked together with Pfizer to sign off all commercial agreements and set up ordering process and commercial/PAP goods supply. In addition, we have opened distributor accounts and supported bidding progress to ensure patient accessibility upon the NDA approval.

  – In 2022, sugemalimab has been recommended in the 2022 Chinese Society of Clinical Oncology ("**CSCO**") Non-Small Cell Lung Cancer guideline and 2022 CSCO Immunotherapy guideline for the treatment of stage III and stage IV NSCLC patients. In addition, sugemalimab has also been included in Ctong Stage III NSCLC Diagnosis and Therapy Expert Consensus and 2022 Chinese Medical Association guideline for clinical diagnosis and treatment of lung cancer.

  – With EQRx, we are working closely on development and regulatory strategies for sugemalimab outside of greater China, including the U.K. and the E.U., as well as additional regions. The global market size of PD-(L)1 for the treatment of NSCLC, gastric and esophageal cancers is forecasted to be approximately US$30 billion in 2026.

II. Innovation, High Quality and Rapid Execution Lead to Advances across an Evolving Pipeline

CStone followed through on an aggressive clinical agenda with further developments across its pipeline. As of the date of this announcement, we have secured five NDA approvals and submitted seven NDA filings as we rounded out our diverse and evolving pipeline of in-market and near-commercial ready drugs. In doing so, our clinical engine once again distinguished itself in terms of innovation, speed, and quality, as evidenced by the facts that it took only six months for ivosidenib from NDA acceptance to NDA approval, and we had eleven data presentations/publications at/on global academic conferences/top-tier medical journals.

Details are as follows:

- **Sugemalimab** (CS1001, PD-L1 antibody), became the first anti-PD-1/PD-L1 monoclonal antibody approved for both stage III and stage IV NSCLC in China.

  – In May 2022, we received the NDA approval from the NMPA for the treatment of patients with unresectable stage III NSCLC whose disease has not progressed following concurrent or sequential platinum-based chemoradiotherapy. Sugemalimab became the first anti-PD-1/PD-L1 monoclonal antibody approved in this patient population.

  – In May 2022, we announced that the final progression-free survival ("**PFS**") analysis of the registrational GEMSTONE-301 study further demonstrates sugemalimab's robust efficacy and significant clinical benefits shown in interim analysis in stage III NSCLC patients. In August 2022, we presented the detailed results at World Conference on Lung Cancer ("**WCLC**") 2022.

  – In September 2022, we received the NDA acceptance from the NMPA for the treatment of patients with R/R ENKTL with priority review granted.

  – In January 2022, we announced that the registrational GEMSTONE-201 study for R/R ENKTL met the primary endpoint and demonstrated a complete response ("**CR**") rate significantly exceeding that of the currently available targeted monotherapy for these patients. We presented the topline results in an oral abstract session at American Society of Clinical Oncology ("**ASCO**") 2022.

  – In February 2023, we received the NDA acceptance from the NMPA for the first-line treatment of patients with locally advanced or metastatic GC/GEJ.

  – In November 2022, we announced that the GEMSTONE-303 study for first-line treatment of patients with unresectable locally advanced or metastatic GC/GEJ has met its PFS primary endpoint. Sugemalimab in combination with chemotherapy demonstrated statistically significant and clinically meaningful improvement in PFS, compared with placebo plus chemotherapy.

  – In January 2022, we completed enrolment for two key phase III registrational clinical trials, one for the first-line treatment of unresectable locally advanced or metastatic GC/GEJ, and the other for the first-line treatment of unresectable locally advanced, recurrent, or metastatic ESCC.

– In January 2022, we announced that the pre-specified overall survival ("**OS**") interim analysis showed sugemalimab in combination with chemotherapy significantly and clinical meaningfully improved the overall survival in stage IV NSCLC patients, and the data has been presented at ASCO 2022. The positive OS data will be used for global fillings.

– In January 2023, we announced that the GEMSTONE-304 study for first-line treatment of unresectable locally advanced, recurrent, or metastatic ESCC, has 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.

– For the markets outside of Greater China, we are working closely with EQRx on discussions for regulatory submissions for indications in stage IV NSCLC and other indications in multiple countries and regions.

  • In December 2022, the marketing authorization application ("**MAA**") filing for sugemalimab in combination with chemotherapy as the first-line treatment of patients with metastatic NSCLC was accepted for review by the Medicines and Healthcare products Regulatory Agency ("**MHRA**") in the U.K.. This is the first MAA submission of sugemalimab outside of China.

  • In February 2023, the MAA filing for sugemalimab in combination with chemotherapy as first-line treatment of patients with metastatic NSCLC has been accepted for review by European Medicines Agency ("**EMA**").

• **Nofazinlimab** (CS1003, PD-1 antibody)

– In March 2022, we completed enrolment for the global phase III trial of nofazinlimab in combination with LENVIMA® (lenvatinib) in first-line treatment of patients with advanced HCC.

– In June 2022, we presented the results from the phase Ib study of nofazinlimab combined with lenvatinib as first-line treatment in Chinese HCC patients at ASCO 2022.

• **Pralsetinib** (CS3009, RET inhibitor) – We have secured three NDA approvals and have one NDA filing currently under review.

– In March 2022, we received the NDA approval from the NMPA for the treatment of patients with advanced or metastatic RET-mutant MTC and RET fusion-positive TC.

– In July 2022, we received the NDA approval from the Hong Kong Department of Health ("**HK DoH**") for the treatment of patients with RET fusion-positive locally advanced or metastatic NSCLC.

– 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 October 2022, we received the NDA acceptance 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.

• **Ivosidenib** (CS3010, IDH1 inhibitor) – We have secured our first NDA approval for this product.

– In January 2022, we received an NDA approval from the NMPA for the treatment of adults with R/R AML with an IDH1 mutation.

– In October 2022, we received Pediatric and Minority Serious Disease Designation from TFDA for IDH1-mutated R/R AML in adults.

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

– We are working with Pfizer to jointly develop lorlatinib for c-ros oncogene 1 ("**ROS1**")-positive advanced NSCLC in Greater China. In May 2022, we enrolled the first patient in the pivotal study of lorlatinib for the treatment of ROS1-positive advanced NSCLC. The enrolment continues at a steady pace.

• **CS5001** (LCB71, ROR1 ADC)

– After obtaining an approval of the IND application from the U.S. FDA and approval from the Australia Ethics Committee ("**EC**"), the FIH study of this potential best-in-class receptor tyrosine kinase-like orphan receptor 1 ("**ROR1**") antibody-drug conjugate ("**ADC**") has shown swift recruitment to the dose-escalation part in both countries. Additionally, we submitted an IND application to the NMPA in March 2022 and received the approval in May 2022. To enable biomarker-driven patient selection based on tumor ROR1 expression, we have identified candidate ROR1 antibody clones for immuno-histochemistry ("**IHC**") to support such precision medicine effort in the future.

- **CS2006** (NM21-1480, PD-L1/4-1BB/HSA tri-specific molecule)

  – The FIH study is ongoing and includes sites in the U.S. and Taiwan. The dose-escalation part of the study has been completed, and the maximum tolerated dose ("**MTD**") was not reached; preliminary data from the dose escalation part was presented at the Society of Immunotherapy Cancer ("**SITC**") 2022, which indicated a benign and differentiated safety profile with no notable liver toxicities; an unconfirmed Partial Response was observed in a colorectal cancer subject; meanwhile, full 4-1BB agonism was observed across a broad dose range providing complete inhibition of PD-L1, thus, clinically validating the concept of affinity-balancing built into the design of the molecule. The study has proceeded to proof-of-concept ("**PoC**") stage to further explore the safety and efficacy of CS2006 in selected tumor indications in U.S., E.U. and Taiwan. We received the IND approval from the NMPA in September 2021. We presented the preclinical data at American Association for Cancer Research ("**AACR**") 2022.

III. Building out Research Pipeline Leveraging Multiple Sources of Innovation

Precision medicines and immuno-oncology combinations remain our strategic focus. Antibody-drug conjugates which deliver cytotoxic agents to tumor with precision, and multi-specific biologics which can create new biology and are combinations of themselves represent two near-term modalities for early-development.

We have made significant progress in 2022 with several initiatives:

- **One FIC/BIC I/O program** declared PCC in 2022, which is a tri-specific molecule against PD-L1, VEGF plus another I/O target. Another FIC/BIC I/O program (antibody-cytokine fusion molecule) and up to two other I/O multi-specific programs are on track for PCC declaration in 2023.

- **Cell-penetrating therapeutic platform.** Many well-known oncology targets are intracellular proteins that are considered undruggable by current therapeutic approaches. We are developing a proprietary cell-penetrating therapeutic 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. We obtained *in vitro* PoC using this platform with several treatment modalities in 2022 and expect additional *in vitro/in vivo* PoCs with multiple additional treatment modalities in 2023.

IV. Strategic Relationships Advance Commercialization Activities and Pipeline Development

We continue to grow and deepen relationships with key global strategic partners 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.

To begin with, we continued to make significant and smooth progress on our relationship with Pfizer to explore China markets for sugemalimab. In addition, we are working with EQRx on exploring global markets for sugemalimab and a global phase III study of nofazinlimab in HCC.

In 2022, we entered into a new partnership with Roche Pharmaceuticals Co., Ltd ("**Roche**") who became the global marketing authorization holder ("**MAH**") for pralsetinib. As part of this agreement, we acquired full manufacturing right to pralsetinib. Locally manufactured supply is expected to provide significant cost saving and as a result improve CStone's overall profitability. In the meantime, Roche will be responsible for the manufacturing and supply of pralsetinib for China before our successful technology transfer. On February 22, 2023, Roche announced that Blueprint Medicines will regain global commercialization and development rights to pralsetinib in the future, excluding Greater China. Under the terms of the agreement, the termination will be effective within 12 months from the notification date of February 22, 2023. CStone is currently working together with Roche and Blueprint to take necessary step to maintain the marketing authorization for Pralsetinib and ensure continuity of supply of Pralsetinib for patients in China.

We further strengthened the strategic partnership with Jiangsu Hengrui Pharmaceuticals Co., Ltd. ("**Hengrui**"). In 2021, CStone and Hengrui established a strategic partnership by leveraging respective R&D and commercial expertise to accelerate the development and commercialization of our anti-CTLA-4 mAb (CS1002) to fully unleash its commercial value. 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.

V. Other Business Updates

Manufacturing. We are also in the process of technology transfer for multiple imported products which will reduce costs and improve long-term profitability of our products. Specifically, we have completed the technology transfer submission to CDE for avapritinib in July 2022 and bio-equivalence ("**BE**") has been demonstrated to support technology transfer. At the same time, the technology transfer for pralsetinib is in progress smoothly.

FUTURE AND OUTLOOK

We are working to bring a number of significant clinical and commercial developments to fruition that will be catalysts for our growth in the rest of 2023.

A detailed breakdown of expected developments for the remainder of 2023 is below.

Commercial Developments

Our commercial team is working rapidly to expand the addressable market for our products and maximize their commercial potential with a focus on the following:

- Improving market coverage by maximizing deployment effectiveness and leveraging digital platform.

- Improving diagnosis rate and accuracy via deep collaboration with diagnostic companies, industry associations (e.g. PQCC), patient platforms and big data companies.

- Strengthening branding and scientific leadership by leveraging the inclusion of guidelines, holding academic activities, and conducting post-approval clinical projects with focus on differentiation in clinical and safety profile.

- Strengthening accessibility with continued efforts in hospitals and DTPs listing.

- Improving affordability through pricing strategy optimization and commercial insurance/ innovative payment plans.

- Enhancing patient education and support through patient community engagement, education sessions and follow-ups leveraging digital platform.

Research & Development

NDA approvals expected:

- Pralsetinib: NDA approval in mainland China for the first-line treatment of RET fusion-positive locally advanced or metastatic NSCLC in the first half of 2023

- Avapritinib: Prescription Drug User Fee Act ("**PDUFA**") action date for the treatment of adults with indolent systemic mastocytosis in U.S. in May 2023

- Ivosidenib: MAA approval for the first-line treatment of AML and locally advanced or metastatic Cholangiocarcinoma with IDH1-mutated in E.U. in 2023

- Lorlatinib: enrollment completed of the registrational trial for ROS1-positive advanced NSCLC in 2023

- Sugemalimab: NDA approval for R/R ENKTL in mainland China in the second half of 2023

- Sugemalimab: MAA approval for the first-line treatment in stage IV NSCLC in U.K. in the second half of 2023 or the first half of 2024

- Sugemalimab: NDA approval for the first-line treatment in GC/GEJ in mainland China in the second half of 2023 or the first half of 2024

NDA filing expected:

- Sugemalimab: NDA filing in mainland China for the first-line treatment of metastatic ESCC in the first half of 2023

Topline readouts expected:

- Nofazinlimab: topline readout of the global phase III trial of nofazinlimab in combination with LENVIMA® (lenvatinib) in first-line treatment of patients with advanced HCC in Q4 2023 or Q1 2024

Early clinical programs:

- CS2006: continuation of PoC expansion of CS2006 monotherapy in selected solid tumor indications

- CS5001: plan to present CS5001 translational data at a major conference in 2023

- CS5001: first patient enrollment in mainland China in Q1 2023

- CS5001: data release from phase I trial for dose escalation in Q4 2023

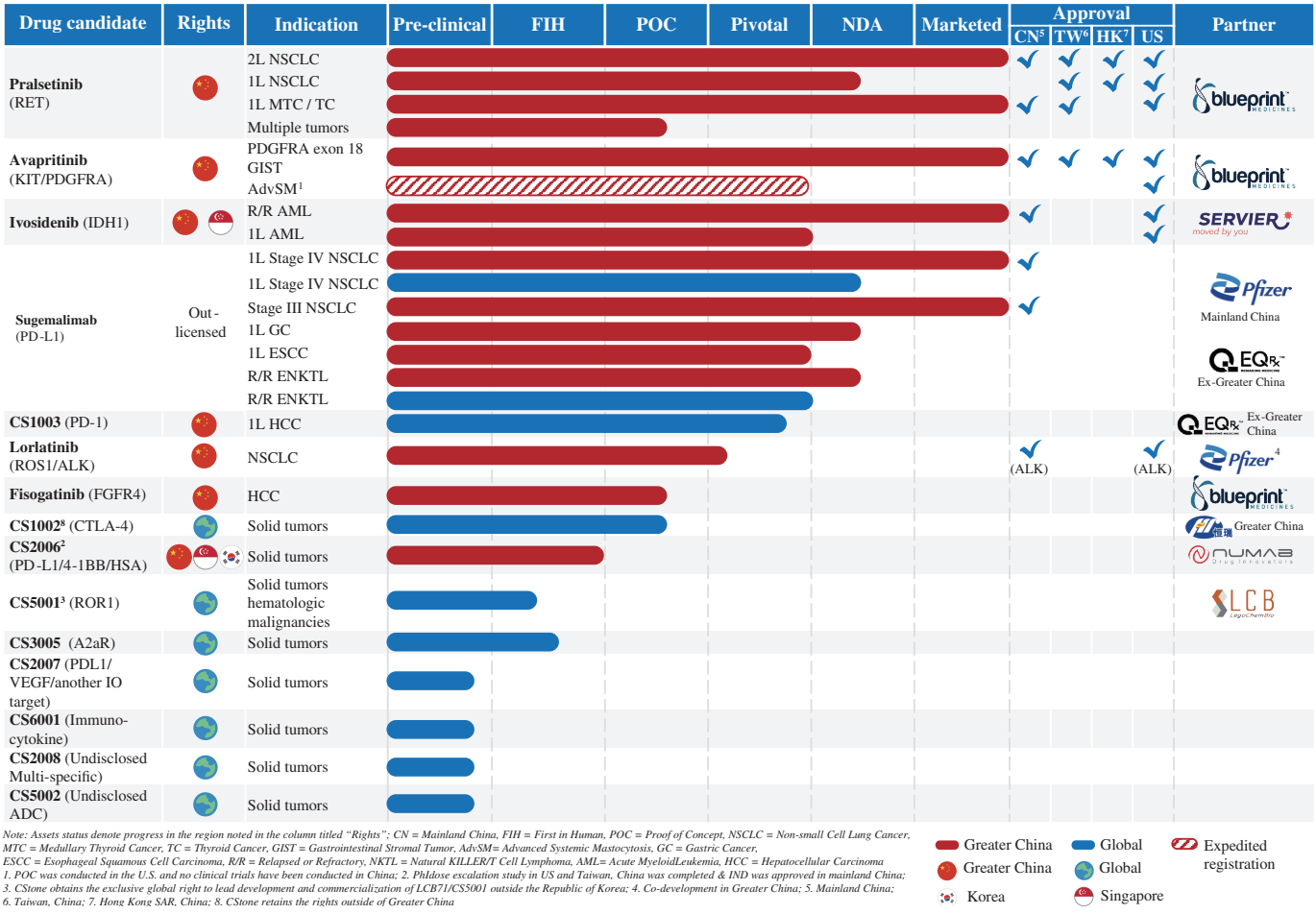
OUR VISION

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 world-class management team with extensive experience in innovative drug development, clinical research, and commercialization. The Company has built an oncology-focused pipeline of 15 drug candidates with a strategic emphasis on precision medicines and immuno-oncology combination therapies. Currently, CStone has received ten NDA approvals for four drugs. 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 denote progress in the region noted in the column titled "Rights"; CN = Mainland China, 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, AdvSM= Advanced Systemic Mastocytosis, GC = Gastric Cancer, ESCC = Esophageal Squamous Cell Carcinoma, R/R = Relapsed or Refractory, NKTL = Natural KILLER/T Cell Lymphoma, AML= Acute MyeloidLeukemia, HCC = Hepatocellular Carcinoma

1. POC was conducted in the U.S. and no clinical trials have been conducted in China; 2. PhIdose escalation study in US and Taiwan, China was completed & IND was approved in mainland China; 3. CStone obtains the exclusive global right to lead development and commercialization of LCB71/CS5001 outside the Republic of Korea; 4. Co-development in Greater China; 5. Mainland China; 6. Taiwan, China; 7. Hong Kong SAR, China; 8. CStone retains the rights outside of Greater China

BUSINESS REVIEW

Commercial Operations

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

Our commercial team's efforts have enhanced the accessibility and affordability of our products on the market to bolster sales. They have continued a proactive engagement program to broaden and deepen ties to the healthcare community and critical stakeholder groups as part of preparations for launching and commercialization of our drug candidates. Our commercial team has established coverage of over 800 hospitals across more than 180 cities, building coverage of hospitals that account for approximately 75-80% of the relevant market of precision medicines. They also successfully secured the inclusion of our drugs in major commercial and government-administered insurance plans as part of an effort to broaden patient access to our drugs by making them more affordable. As a result of these efforts, we achieved a steady growth of AYVAKIT® (avapritinib) and GAVRETO® (pralsetinib) and a healthy sales ramp up of TIBSOVO® (ivosidenib), generating a combined net sales of RMB364.3 million in 2022.

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. Our successful collaboration with EQRx will bring our drugs into the largest global healthcare markets, and ensure they are competitively positioned.

Details on our full commercial efforts are set out below:

- ***GAVRETO® (pralsetinib)***

  – GAVRETO® (pralsetinib), a FIC RET inhibitor in China, has been approved by the NMPA for the treatment of 1) adults with locally advanced or metastatic RET fusion-positive NSCLC previously treated with platinum-based chemotherapy; and 2) patients with advanced or metastatic RET-mutant MTC and RET fusion-positive TC. In addition, it has been approved by the HK DoH for the treatment of patients with RET fusion-positive locally advanced or metastatic NSCLC and has been approved by 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.

  – We ramped up our efforts to establish scientific and academic leadership for GAVRETO® (pralsetinib). During the Reporting Period, GAVRETO® (pralsetinib) was recommended by additional national guidelines, including 2022 CSCO Primary Lung Cancer Guideline, 2022 CSCO MTC Clinical Guideline, and 2022 Chinese Guideline for Integrated Diagnosis and Treatment of Cancer-MTC.

  – We leveraged the newly included national guidelines, such as the First Consensus on RET Gene Testing of TC in China to educate pathologists and clinicians on RET testing in NSCLC and TC to maximize the pool of patients identified. We also expanded the scope of financial aid programs to MTC testing to increase the testing rate. These efforts have led to an 80% RET testing rate in top 200 hospitals.

– In addition, we further strengthened the brand and share of voice for GAVRETO® (pralsetinib) by successfully holding a TC Precision Treatment Forum with approximately 16,000 HCPs joining, 17 events of RET Case Tour with participants around 400,000 person-time, the GAVRETO® (pralsetinib) annual launch celebration and RET Treatment Academic Week with approximately 30,000 HCPs joining.

– We continued to improve the accessibility and affordability of GAVRETO® (pralsetinib). As of the date of this announcement, GAVRETO® (pralsetinib) has been included in 130 commercial and government insurance programs and listed in approximately 200 hospitals and DTPs. PAP scheme of GAVRETO® (pralsetinib) was updated in June 2022 to support the long-term treatment of the 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 HK DoH for the treatment of patients with unresectable or metastatic PDGFRA D842V mutant GIST.

– AYVAKIT® (avapritinib) is recommended by several authoritative guidelines. During the Reporting Period, AYVAKIT® (avapritinib) was recommended by additional national guidelines, including 2022 Chinese Guideline for Diagnosis and Treatment of Systemic Mastocytosis in adults.

– We collaborated with the Chinese Medical Doctor Association, Chinese College of Surgeons and the CSCO Experts Committee on GIST to help shape the paradigm of precision medicine and the ability to diagnose and treat GIST.

– We further improved testing awareness and accessibility of PDGFRA exon 18 mutation in GIST through continuous collaborations with top diagnostics companies, PQCC and peers. The testing rate of PDGFRA exon 18 in GIST has been improved to 70% in top 200 hospitals.

– Moreover, we continued to proactively engage with top KOLs and HCPs to improve the product perception and adoption of AYVAKIT® (avapritinib). In May 2022, we held the second GIST Summit & AYVAKIT® (avapritinib) annual launch celebration, with approximately 12,000 physicians joining. Our collaboration with CSCO on GIST Precision Treatment Case Competition and Gastrointesinal Oncology Satellite Meeting engaged over 40,000 HCPs and strengthened AYVAKIT® (avapritinib)'s leading position in GIST.

– We continued to improve the accessibility and affordability of AYVAKIT® (avapritinib). As of the date of this announcement, AYVAKIT® (avapritinib) has been included in 90 commercial and government insurance programs and listed in approximately 80 hospitals and DTPs. We adjusted the listing price of AYVAKIT® (avapritinib) and launched new PAP to improve affordability for GIST patients. In addition, AYVAKIT® (avapritinib) received approval for National Health Insurance application in Taiwan, China, which has been effective since June 1, 2022.

- ***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.

  – Our commercial team made tremendous efforts in the product's launch readiness, laying a solid foundation for a healthy sales ramp up. Specifically, we achieved 18 prescriptions in 15 hospitals in 13 cities on the first day of launch. And the drug is available in all the major target hospitals and pharmacies in over 25 cities and more than 20 provinces.

  – On July 16, 2022, we successfully held TIBSOVO® (ivosidenib) National Launch Meeting with 24 national top KOLs and approximately 22,000 HCPs attending. We also held 5 regional launch meetings, 2023 AML Precision Treatment Forums, and AML Case Tours, etc., with over 30,000 HCPs attending in total.

  – Ivosidenib is recommended by six authoritative guidelines, including 2022 CSCO Hematologic Malignancy Guideline, 2022 CACA Hematological Oncology Guideline, and China Adult AML Clinical Guideline, 2022 Expert Consensus on Pathological Diagnosis of Intrahepatic Cholangiocarcinoma, etc. And it has become the first choice for treatment of AML with IDH1 mutation.

  – We formed collaboration with top diagnostics company in hematology, such as Kinstar Global, to co-educate pathologists and clinicians on testing awareness and quality of IDH1 mutation in AML. We also launched testing aid programs for IDH1 mutation patients. IDH1 testing has become a standard process in hematology department in our covered hospitals and testing rate has reached 75% in Top 200 hospitals in less than one year.

  – We have made significant progress in improving accessibility and affordability of TIBSOVO® (ivosidenib) in 7 months post launch. As of the date of this announcement, TIBSOVO® (ivosidenib) has been included in 80 commercial and government insurance programs and listed in approximately 70 hospitals and DTPs. We launched PAP for TIBSOVO® (ivosidenib) to increase affordability and extend DOT in November 2022.

- ***Sugemalimab***

  – We continued to work closely with Pfizer to support the commercialization in mainland China. At the same time, we are also closely collaborating with our partners EQRx to support the global launch (outside Greater China).

  – For the launch readiness in China, we worked together with Pfizer to sign off all commercial agreements and set up ordering process and commercial/PAP goods supply. In addition, we have opened distributor accounts and supported bidding progress to ensure patient accessibility upon the NDA approval.

  – In May 2022, we received the NDA approval from the NMPA for the treatment of patients with unresectable stage III NSCLC following concurrent or sequential chemoradiotherapy.

– In 2022, sugemalimab has been recommended in the 2022 CSCO NSCLC guideline and 2022 CSCO Immunotherapy guideline for the treatment of stage III and stage IV NSCLC patients. In addition, sugemalimab has also been included in Ctong Stage III NSCLC Diagnosis and Therapy Expert Consensus and 2022 Chinese Medical Association guideline for clinical diagnosis and treatment of lung cancer.

– In September 2022, we successfully completed sugemalimab MAH transfer to Pfizer in mainland China.

– With EQRx, we are working closely on development and regulatory strategies for sugemalimab outside of greater China, including the U.K. and the E.U., as well as additional regions. The global market size of PD-(L)1 for the treatment of NSCLC, gastric and esophageal cancers is forecasted to be approximately US$30 billion in 2026.

Clinical Development

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

Pralsetinib (CS3009, RET inhibitor)

- In March 2022, we received the NDA approval from the NMPA for the treatment of patients with advanced or metastatic RET-mutant MTC and RET fusion-positive TC.

- In July 2022, we received the NDA approval from the HK DoH for the treatment of patients with RET fusion-positive locally advanced or metastatic NSCLC.

- 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 October 2022, we received the NDA acceptance 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 December 2022, we presented updated results from the phase I/II ARROW trial in Chinese patients with RET fusion-positive NSCLC at ESMO Asia Congress 2022. 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 pralsetinib had a generally well-tolerated safety profile.

Avapritinib (CS3007, KIT/PDGFRA inhibitor)

- In December 2022, we published the results from the NAVIGATOR China bridging study of avapritinib in The Oncologist.

Trademarks

Blueprint Medicines, AYVAKIT, GAVRETO and associated logos are trademarks of Blueprint Medicines Corporation.

Ivosidenib (CS3010, IDH1 inhibitor)

- In January 2022, we received an NDA approval from the NMPA for the treatment of adults with R/R AML with an IDH1 mutation. Ivosidenib was the first IDH1 inhibitor approved in China for the treatment of patients with R/R AML.

- In October 2022, we received Pediatric and Minority Serious Disease Designation from TFDA for IDH1-mutated R/R AML in adults.

Sugemalimab (CS1001, PD-L1 antibody)

- Sugemalimab is an investigational monoclonal antibody directed against PD-L1 that has been approved by the NMPA in China for both stage III and stage IV NSCLC patients. 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. As of the date of this announcement, we succeeded in five registrational trials for sugemalimab, including one phase II registrational study for lymphoma and four phase III registrational studies in stage IV NSCLC, stage III NSCLC, gastric cancer, and esophageal cancer, respectively.

- In May 2022, we received the NDA approval from the NMPA for the treatment of patients with unresectable stage III NSCLC whose disease has not progressed following concurrent or sequential platinum-based chemoradiotherapy. Sugemalimab became the first anti-PD-1/PD-L1 monoclonal antibody approved in this patient population.

- In May 2022, we announced that the final PFS analysis of the registrational GEMSTONE-301 study further demonstrates sugemalimab's robust efficacy and significant clinical benefits shown in interim analysis in stage III NSCLC patients. In August 2022, we presented the detailed results at WCLC 2022.

- In January 2022, we announced that the pre-specified OS interim analysis showed sugemalimab in combination with chemotherapy significantly and clinical meaningfully improved the overall survival in stage IV NSCLC patients. We presented the detailed results at ASCO 2022.

- In January 2022, we announced the results for the first-line treatment of stage IV NSCLC and consolidation therapy of stage III NSCLC were published in the world-leading oncology journal *The Lancet Oncology*, respectively.

- In September 2022, we received the NDA acceptance from the NMPA in patients with R/R ENKTL with priority review granted.

- In January 2022, the registrational trial GEMSTONE-201 in patients with R/R ENKTL met the primary endpoint. We presented the detailed results in an oral abstract session at 2022 ASCO Annual Meeting.

- In February 2023, we received the NDA acceptance from the NMPA in the first-line treatment of patients with locally advanced or metastatic GC/GEJ.

- In November 2022, we announced that the GEMSTONE-303 study for the first-line treatment of of patients with unresectable locally advanced or metastatic GC/GEJ has met its PFS primary endpoint. Sugemalimab in combination with chemotherapy demonstrated statistically significant and clinically meaningful improvement in investigator assessed PFS, compared with placebo plus chemotherapy.

- In January 2023, we announced that the GEMSTONE-304 study for the first-line treatment of unresectable locally advanced, recurrent, or metastatic ESCC, has met its primary endpoints. Sugemalimab in combination with chemotherapy demonstrated a statistically significant and clinically meaningful improvement in Blinded Independent Central Review (BICR)-assessed PFS and OS compared with placebo in combination with chemotherapy.

- In January 2022, we completed enrolment for two key phase III registrational clinical trials, one for the first-line treatment of unresectable locally advanced or metastatic GC/GEJ, and the other for the first-line treatment of unresectable locally advanced, recurrent, or metastatic ESCC.

- For the markets outside of Greater China, we are working closely with EQRx on discussions for regulatory submissions for indications in stage IV NSCLC and other indications in multiple countries and regions.

  – In December 2022, the MAA filing for sugemalimab in combination with chemotherapy as first-line treatment of patients with metastatic NSCLC was accepted for review by the MHRA in the U.K.. This is the first MAA submission of sugemalimab outside of China.

  – In February 2023, the MAA filing for sugemalimab in combination with chemotherapy as first-line treatment of patients with metastatic NSCLC was accepted for review by EMA.

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 2022, we completed the prespecified enrolment for the global phase III trial of nofazinlimab in combination with LENVIMA® (lenvatinib) as first-line treatment in patients with advanced HCC.

- In June 2022, we presented the updated results from the phase Ib study of nofazinlimab combined with lenvatinib as first-line treatment in Chinese HCC patients at ASCO 2022. Results showed that nofazinlimab in combination with lenvatinib demonstrated promising and durable efficacy in Chinese patients with advanced HCC.

Lorlatinib (ALK/ROS-1 inhibitor)

- We are working with Pfizer to jointly develop lorlatinib for ROS1-positive advanced NSCLC in Greater China. In December 2021, we received the IND approval from NMPA. In May 2022, we enrolled the first patient in this pivotal study. This is the first pivotal trial of lorlatinib for the treatment of ROS1-positive NSCLC in the world. The enrolment continues at a steady pace.

CS5001 (LCB71, ROR1 ADC)

- After obtaining an approval of the IND application from the U.S. FDA and approval from the Australia EC, the FIH study of this potential best-in-class ROR1 ADC has commenced with swift recruitment to the dose-escalation part ongoing in both countries. Additionally, we submitted an IND application to the NMPA in March 2022 and received the approval in May 2022. To enable biomarker-driven patient selection based on tumor ROR1 expression, we have identified candidate ROR1 antibody clones for IHC with good sensitivity and selectivity to support such precision medicine effort in the future.

CS2006 (NM21-1480, PD-L1/4-1BB/HSA tri-specific molecule)

- The FIH study is ongoing and includes sites in the U.S. and Taiwan, China. The dose-escalation part of the study has been completed, and the MTD was not reached; preliminary data from the dose escalation part was presented at SITC 2022, which indicated a benign and differentiated safety profile with no notable liver toxicities; a partial response was observed in a patient with MSS-CRC; meanwhile, full 4-1BB agonism was observed across a broad dose range providing complete inhibition of PD-L1, thus, clinically validating the concept of affinity-balancing built into the design of the molecule (preclinical data presented at AACR 2022). The study has proceeded to PoC stage to further explore the safety and efficacy of CS2006 in selected tumor indications in U.S., E.U. and Taiwan. We received the IND approval from the NMPA in September 2021.

Research

Precision medicines and immuno-oncology combinations remain our strategic focus. Antibody-drug conjugates which deliver cytotoxic agents to tumor with precision, and multi-specific biologics which can create new biology and are combinations of themselves represent two near-term modalities for early-development.

One FIC/BIC I/O program declared **PCC** in 2022, which is a tri-specific molecule against PD-L1, VEGF plus another I/O target. Another FIC/BIC I/O program (antibody-cytokine fusion molecule) and up to two other I/O multi-specific programs are on track for PCC declaration in 2023.

Cell-penetrating therapeutic platform. Many well-known oncology targets are intracellular proteins that are considered undruggable by current therapeutic approaches. We are developing a proprietary cell-penetrating therapeutic 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. We obtained *in vitro* PoC using this platform with several treatment modalities in 2022 and expect additional *in vitro/in vivo* PoCs with multiple additional treatment modalities by the end of 2023.

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, EQRx and DotBio.

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

- ***Pfizer***

  – In December 2021, we received the first approval of sugemalimab for stage IV NSCLC including both squamous and non-squamous patients. CStone and Pfizer have worked closely together to successfully launch and commercialize sugemalimab by educating the healthcare community about its BIC clinical results and 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. It is the world's first anti-PD-1/PD-L1 monoclonal antibody successfully approved as a consolidation therapy to improve progression-free survival in patients with stage III NSCLC, after concurrent or sequential platinum-based chemoradiotherapy. The national launch ceremony for unresectable stage III NSCLC was held successfully on July 17, 2022.

  – In June 2021, CStone and Pfizer jointly announced that they have 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 for the treatment of ROS1-positive advanced NSCLC under the joint efforts of CStone and Pfizer. The clinical supply was imported, and the site start-up activities were conducted as planned despite the challenges presented by the COVID-19 lockdown in 2022.

- ***EQRx***

  – CStone is working closely with EQRx to advance regulatory submission in multiple countries and jurisdictions outside of Greater China. The regulatory pathways for sugemalimab in multiple indications are in discussion, including stage IV NSCLC and other indications. In December 2022, the U.K.'s MHRA accepted for review the MAA for sugemalimab in combination with chemotherapy as first-line treatment of patients with metastatic NSCLC, thus marking an important milestone in CStone's globalization efforts. In February 2023, the MAA filing for sugemalimab in combination with chemotherapy as first-line treatment of patients with metastatic NSCLC was accepted for review by EMA.

  – For the global phase III registrational trial of nofazinlimab in combination with lenvatinib as the first-line treatment for patients with advanced HCC, we completed the prespecified patient enrolment in March 2022 as planned.

- ***Hengrui***

  – In November 2021, we established a strategic partnership with Hengrui by signing an exclusive licensing agreement on the Greater China right of 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. This strategic partnership could help us to fully unlock the commercial potential of this asset. 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.

- ***DotBio***

  – In 2022, we had a productive collaboration with DotBio, a biotech company specializing in next generation antibody therapies. CStone led the design of a FIC/BIC multispecific target combination based on the intended mechanism of action and DotBio led the design and engineering of the molecules. Several bi and tri-specific prototype molecules are under testing with sequence handover expected in 2023.

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")

The Company followed government mandates and took various mitigation measures to ensure employees' safety and minimize disruptions to business operations.

Critical aspects of our business remain functional. Up to the date of this announcement, the pandemic has not hindered recruitment for our registrational trials, and we have been able to ensure continuous treatment and monitoring to mitigate the risk of patient dropout. We have been expanding hospital and physician coverage in areas adjacent to the regions impacted by COVID-19 where patients may seek treatment in 2022. We have been using digital platforms where possible, such as for virtual KOL engagement, managing long-term treatment of patients, and resolving logistics and supply issues.

However, lockdowns in some parts of Eastern and Northern China in April/May 2022 and travel restrictions due to pandemic throughout the year led to disruptions to physician-patient interactions and posed challenges to supply chain management. These partially impacted our business in some Tier 1 cities in China for the Reporting Period, as travel of patient from surrounding areas and inpatient services was restricted. Our business has been recovering since January 2023.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE YEAR ENDED DECEMBER 31, 2022

	NOTES	For the year ended December 31, 2022 RMB'000 (Audited)	2021 RMB'000 (Audited)
Revenue	3	**481,363**	243,718
Cost of revenue		**(202,985)**	(106,832)
Gross profit		**278,378**	136,886
Other income	5	**18,722**	45,773
Other gains and losses	5	**(776)**	(134,188)
Research and development expenses		**(614,162)**	(1,304,945)
Selling and marketing expenses		**(327,301)**	(363,788)
Administrative expenses		**(249,062)**	(297,596)
Finance costs	6	**(8,477)**	(2,242)
Loss for the year	7	**(902,678)**	(1,920,100)
Other comprehensive income for the year:			
Item that may be reclassified subsequently to profit or loss:			
Exchange differences arising on translation of foreign operations		**405**	399
Total comprehensive expense for the year		**(902,273)**	(1,919,701)
Loss per share	9		
– Basic (RMB)		**(0.77)**	(1.65)
– Diluted (RMB)		**(0.77)**	(1.65)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

AT DECEMBER 31, 2022

	NOTES	**December 31, 2022** ***RMB'000*** **(Audited)**	December 31, 2021 *RMB'000* (Audited)
Non-current assets			
Property, plant and equipment		**138,379**	154,166
Right-of-use assets		**68,187**	28,631
Prepayments for acquisition of property, plant and equipment and intangible assets		**–**	5,126
Intangible assets		**159,699**	70,539
Financial assets measured at fair value through profit or loss ("**FVTPL**")		**3,482**	3,188
Other receivables		**21,763**	52,158
		391,510	313,808
Current assets			
Account receivables	*11*	**77,133**	117,598
Deposits, prepayments and other receivables		**105,505**	52,345
Financial assets measured at FVTPL		**–**	122,895
Inventories		**22,188**	61,363
Time deposits with original maturity over three months		**483,407**	860,720
Cash and cash equivalents		**558,684**	742,724
		1,246,917	1,957,645
Current liabilities			
Account and other payables and accrued expenses	*12*	**869,366**	872,871
Refund liabilities		**25,198**	8,678
Bank borrowings	*13*	**8,567**	30,700
Deferred income		**7,000**	7,451
Lease liabilities		**36,351**	13,248
		946,482	932,948
Net current assets		**300,435**	1,024,697
Total assets less current liabilities		**691,945**	1,338,505

	NOTES	**December 31, 2022** ***RMB'000*** **(Audited)**	December 31, 2021 *RMB'000* (Audited)
Non-current liabilities			
Bank borrowings	*13*	**218,986**	115,811
Deferred income		**1,247**	1,247
Lease liabilities		**22,386**	14,439
		242,619	131,497
Net assets		**449,326**	1,207,008
Capital and reserves			
Share capital		**802**	796
Treasury shares held in the trusts		**(2)**	(11)
Reserves		**448,526**	1,206,223
Total equity		**449,326**	1,207,008

NOTES

1. GENERAL

CStone Pharmaceuticals (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 of Hong Kong Limited (the "**Stock Exchange**") since February 26, 2019. The addresses of the registered office and principal place of business of the Company are disclosed in the corporate information section to the annual report.

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 AMENDMENTS TO INTERNATIONAL FINANCIAL REPORTING STANDARDS ("IFRSs")

Amendments to IFRSs that are mandatorily effective for the current year

In the current year, the Company and its subsidiaries (the "**Group**") has applied the following amendments to IFRSs issued by the International Accounting Standards Board (the "**IASB**") for the first time, which are mandatorily effective for the Group's annual periods beginning on January 1, 2022 for the preparation of the consolidated financial statements:

Amendments to IFRS 3	Reference to the Conceptual Framework
Amendment to IFRS 16	Covid-19-Related Rent Concessions beyond 30 June 2021
Amendments to IAS 16	Property, Plant and Equipment – Proceeds before Intended Use
Amendments to IAS 37	Onerous Contracts – Cost of Fulfilling a Contract
Amendments to IFRSs	Annual Improvements to IFRSs 2018-2020

The application of these 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 these consolidated financial statements.

New and amendments to IFRSs in issue but not yet effective

The Group has not early applied the following new and amendments to IFRSs that have been issued but are not yet effective:

IFRS 17 (including the June 2020 and and December 2021 Amendments to IFRS 17)	Insurance Contracts[1]
Amendments to IFRS 10 and IAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture[2]
Amendments to IAS 16	Lease Liability in a Sale and Leaseback[3]
Amendments to IAS 1	Classification of Liabilities as Current or Non-current[3]
Amendments to IAS 1	Non-current Liabilities with Covenants[3]
Amendments to IAS 1 and IFRS Practice Statement 2	Disclosure of Accounting Policies[1]
Amendments to IAS 8	Definition of Accounting Estimate[1]
Amendments to IAS 12	Deferred Tax related to Assets and Liabilities arising from a Single Transaction[1]

[1] Effective for annual periods beginning on or after January 1, 2023

[2] Effective for annual periods beginning on or after a date to be determined

[3] Effective for annual periods beginning on or after January 1, 2024

Except for the amendments to IFRSs mentioned below, the directors of the Company anticipate that the application of all these new and amendments to IFRSs will have no material impact on the consolidated financial statements in the foreseeable future.

Amendments to IAS 12 Deferred Tax related to Assets and Liabilities arising from a Single Transaction

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.

For leasing transactions in which the tax deductions are attributable to the lease liabilities, the Group applies IAS 12 requirements to the relevant assets and liabilities separately. Temporary differences on initial recognition of the relevant assets and liabilities are not recognised due to application of the initial recognition exemption.

Upon the application of the amendments, the Group will recognise 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 differences associated with the right-of-use assets and the lease liabilities.

The amendments are effective for the Group's annual reporting period beginning on January 1, 2023. At December 31, 2022, the carrying amounts of right-of-use assets and lease liabilities which are subject to the amendments amounted to RMB68,187,000 and RMB58,737,000, respectively, in which the Group will recognise the related deferred tax assets and deferred tax liabilities of RMB11,086,000 and RMB9,557,000, respectively. The cumulative effect of initially applying the amendments will be recognised as an adjustment to the opening balance of retained earnings (or other component of equity, as appropriate) at the beginning of the earliest comparative period presented.

3. REVENUE

Disaggregation of revenue from contracts with customers

	For the year ended December 31,	
	2022	2021
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Type of goods or services		
Sales of pharmaceutical products	**364,299**	162,764
License fee income	**87,268**	80,954
Royalty income	**29,796**	–
	481,363	243,718
Timing of revenue recognition		
A point in time	**481,363**	243,718

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:

Geographical markets

	For the year ended December 31,	
	2022	2021
	RMB'000	*RMB'000*
	(Audited)	(Audited)
The PRC (excluding Hong Kong and Taiwan)	**476,527**	243,718
Others	**4,836**	–
	481,363	243,718

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,	
	2022	2021
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Customer A	**287,780**	158,941
Customer B	**–**	49,057
Customer C	**97,064**	31,897
Customer D	**73,296**	–

5. OTHER INCOME/OTHER GAINS AND LOSSES

Other income

	For the year ended December 31,	
	2022	2021
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Bank and other interest income	**9,672**	9,803
Government grants income	**8,639**	35,970
Others	**411**	–
	18,722	45,773

Other gains and losses

	For the year ended December 31,	
	2022	2021
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Net loss on fair value changes of financial assets measured at FVTPL	**(62,028)**	(64,214)
Net gain on fair value of money market funds	**99**	10
Net foreign exchange gain (losses)	**61,492**	(69,130)
Loss on disposal of property, plant and equipment	**–**	(901)
Others	**(339)**	47
	(776)	(134,188)

6, FINANCE COSTS

	For the year ended December 31,	
	2022	2021
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Interest on lease liabilities	**4,265**	1,254
Interest on bank borrowings	**7,543**	3,871
	11,808	5,125
Less: amounts capitalised in the cost of qualifying assets	**(3,331)**	(2,883)
	8,477	2,242

7. LOSS FOR THE YEAR

	For the year ended December 31,	
	2022	2021
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Loss for the year has been arrived at after charging:		
Depreciation of:		
Property, plant and equipment	**6,586**	5,611
Right-of-use assets	**35,752**	11,300
Amortisation of intangible assets	**12,661**	5,750
Total depreciation and amortisation	**54,999**	22,661
Less: amounts capitalised in the cost of qualifying assets	**(10,459)**	–
Total depreciation and amortisation charged to profit or loss	**44,540**	22,661
Directors' emoluments	**83,640**	120,698
Other staff costs:		
Salaries and other allowances	**275,206**	262,551
Performance related bonus	**86,381**	75,904
Retirement benefit scheme contributions	**55,896**	49,745
Share-based payment expenses	**67,690**	109,393
	485,173	497,339
	568,813	618,291
Auditor's remuneration	**2,100**	1,620
Impairment losses recognised on construction in progress (included in research and development expenses)	**23,412**	–
Write-down of inventories (included in cost of revenue)	**8,757**	24,816
Cost of inventories recognised as cost of revenue	**91,754**	47,797

8. INCOME TAX EXPENSE

No income tax has been incurred by the Group for the years ended December 31, 2021 and 2022.

9. 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,	
	2022	2021
	(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	**(902,678)**	(1,920,100)
Number of shares ('000)		
Weighted average number of ordinary shares for the purpose of basic and diluted loss per share	**1,172,839**	1,165,209

The calculation of basic and diluted loss per share for both years has considered the restricted share units ("**RSU**") that have been vested but not yet registered, but 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.

10. DIVIDENDS

No dividend was paid or declared by the Company during the years ended December 31, 2021 and 2022, nor has any dividend been proposed since the end of the reporting period.

11. 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.

	At December 31,	
	2022	2021
	RMB'000	*RMB'000*
	(Audited)	(Audited)
0 – 60 days	**46,563**	117,598
61 – 90 days	**258**	–
> 90 days	**30,312**	–
	77,133	117,598

12. ACCOUNT AND OTHER PAYABLES AND ACCRUED EXPENSES

	At December 31,	
	2022	2021
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Account payables	**290,414**	414,293
Other payable and accruals	**578,952**	458,578
	869,366	872,871

The credit period on account payables is ranged from 0 to 90 days. Ageing analysis of the Group's account payables presented based on invoice dates at the end of the reporting period is as follow:

	At December 31,	
	2022	2021
	RMB'000	*RMB'000*
	(Audited)	(Audited)
0 – 30 days	**96,629**	359,092
31 – 60 days	**22,736**	18,096
61 – 90 days	**55,073**	4,948
> 90 days	**115,976**	32,157
	290,414	414,293

13. BANK BORROWINGS

	At December 31,	
	2022	2021
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Unsecured and unguaranteed	**100,000**	22,933
Secured and unguaranteed	**127,553**	123,578
	227,553	146,511

	At December 31,	
	2022	2021
	RMB'000	*RMB'000*
	(Audited)	(Audited)
The carrying amounts of the above bank borrowing are repayable*:		
Within 1 year	**8,567**	30,700
Within a period of more than 1 year but not exceeding 2 years	**218,986**	7,767
Within a period of more than 2 years but not exceeding 5 years	**–**	108,044
	227,553	146,511
Less: Amounts due within 12 months shown under current liabilities	**(8,567)**	(30,700)
Amounts show under non-current liabilities	**218,986**	115,811

* The amounts due are based on scheduled repayment dates set out in the loan agreements.

14. EVENTS AFTER THE REPORTING PERIOD

(i) Completion of the placing

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$4.63 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 RMB347.56 million).

(ii) Proposed cancellation and re-grants of share options under the Post-IPO ESOP

On January 6, 2023, the Group has proposed to cancel 6,200,000 and 15,062,427 outstanding share options of Dr. Yang and employees, respectively, pursuant to the terms of the Post-IPO ESOP and to re-grant of 4,340,000 and 10,543,700 new share options, subject to acceptance, to Dr. Yang and employees ("Existing Grantees"), respectively, representing approximately 70% of the cancelled share options held by such Existing Grantees, and representing approximately 1.24% of the total shares of the Company in issue at December 31, 2022. On March 7, 2023, the shareholders of the Company approved the proposed cancellation and re-grant of options under the Post-IPO ESOP in the Company's extraordinary general meeting. Up to the date of issue of this announcement, the management of the Company is still in the process of assessing the financial impact of the proposed cancellation and re-grant of share options under the Post-IPO ESOP.

Financial Review

Year ended December 31, 2022 Compared to Year ended December 31, 2021

	For the year ended December 31,	
	2022	2021
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Revenue	**481,363**	243,718
Cost of revenue	**(202,985)**	(106,832)
Gross profit	**278,378**	136,886
Other income	**18,722**	45,773
Other gains and losses	**(776)**	(134,188)
Research and development expenses	**(614,162)**	(1,304,945)
Selling and marketing expenses	**(327,301)**	(363,788)
Administrative expenses	**(249,062)**	(297,596)
Finance costs	**(8,477)**	(2,242)
Loss for the year	**(902,678)**	(1,920,100)
Other comprehensive income for the year:		
Item that may be reclassified subsequently to profit or loss:		
Exchange differences arising on translation of foreign operations	**405**	399
Total comprehensive expense for the year	**(902,273)**	(1,919,701)
Non-IFRS measures:		
Adjusted loss for the year	**(760,616)**	(1,697,429)

Revenue. Our revenue was RMB481.4 million for the year ended December 31, 2022, composed of RMB364.3 million in sales of pharmaceutical products, representing sales of the Company's pharmaceutical products (avapritinib, pralsetinib and ivosidenib), RMB87.3 million in license fee income and RMB29.8 million in royalty income of sugemalimab, representing an increase of RMB237.7 million from RMB243.7 million for the year ended December 31, 2021, primarily attributable to the increase in the sales of the pharmaceutical products and royalty income of sugemalimab.

Other Income. Our other income decreased by RMB27.1 million from RMB45.8 million for the year ended December 31, 2021 to RMB18.7 million for the year ended December 31, 2022. This was primarily due to less government grants.

Other Gains and Losses. Our other gains and losses decreased by RMB133.4 million from losses of RMB134.2 million for the year ended December 31, 2021 to loss of RMB0.8 million for the year ended December 31, 2022. This decrease was primarily due to foreign exchange gain for the year ended December 31, 2022 vs foreign exchange loss for the year ended December 31, 2021.

Research and Development Expenses. Our research and development expenses decreased by RMB690.7 million from RMB1,304.9 million for the year ended December 31, 2021 to RMB614.2 million for the year ended December 31, 2022. This decrease was primarily attributable to (i) a decrease of RMB655.6 million in milestone fee and third party contracting cost from RMB1,032.1 million for the year ended December 31, 2021 to RMB376.5 million for the year ended December 31, 2022 for different phases of our clinical trials; and (ii) employee cost decreased by RMB55.4 million.

	For the year ended December 31,	
	2022	2021
	RMB'000	*RMB'000*
Employee cost	**212,108**	267,470
Milestone fee and third party contracting cost	**376,524**	1,032,138
Others	**25,530**	5,337
Total	**614,162**	1,304,945

Administrative Expenses. Our administrative expenses decreased by RMB48.5 million from RMB297.6 million for the year ended December 31, 2021 to RMB249.1 million for the year ended December 31, 2022. This decrease was primarily attributable to (i) a decrease of RMB22.9 million in professional fees from RMB65.3 million for the year ended December 31, 2021 to RMB42.4 million for the year ended December 31, 2022. (ii) a decrease of RMB23.2 million in other fees.

	For the year ended December 31,	
	2022	2021
	RMB'000	*RMB'000*
Employee cost	**161,451**	168,570
Professional fees	**42,394**	65,256
Rental expenses	**3,069**	2,475
Depreciation and amortization	**21,367**	17,347
Others	**20,781**	43,948
Total	**249,062**	297,596

Selling and Marketing Expenses. Our selling and marketing expenses decreased by RMB36.5 million from RMB363.8 million for the year ended December 31, 2021 to RMB327.3 million for the year ended December 31, 2022. The decrease was primarily attributable to less marketing activities after the products launched in 2021.

	For the year ended December 31,	
	2022	2021
	RMB'000	*RMB'000*
Employee cost	**195,255**	182,251
Professional fees	**48,584**	62,775
Others	**83,462**	118,762
Total	**327,301**	363,788

***Finance Costs*.** The finance costs increased by RMB6.3 million from RMB2.2 million for the year ended December 31, 2021 to RMB8.5 million for the year ended December 31, 2022, primarily due to the increase in interests on bank borrowings and on lease liabilities for office premises renting.

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 period to period 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,	
	2022	2021
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Loss for the year	**(902,678)**	(1,920,100)
Added:		
Share-based payment expenses	**142,062**	222,671
Adjusted loss for the year	**(760,616)**	(1,697,429)

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,	
	2022	2021
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Research and development expenses for the year	**(614,162)**	(1,304,945)
Added:		
Share-based payment expenses	**55,015**	122,835
Adjusted research and development expenses for the year	**(559,147)**	(1,182,110)

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,	
	2022	2021
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Administrative and selling and marketing expenses for the year	**(576,363)**	(661,384)
Added:		
Share-based payment expenses	**87,047**	99,836
Adjusted administrative and selling and marketing expenses for the year	**(489,316)**	(561,548)

Employees and Remuneration Policies

The following table sets forth a breakdown of our employees at December 31, 2022 by function:

Function	**Number of employees**	**% of total number of employees**
Research and Development	166	34.87
Sales, General and Administrative	310	65.13
Total	476	100.0

At December 31, 2022, we had 232 employees in Shanghai, 54 employees in Beijing, 34 employees in Suzhou and 156 employees in other regions of the PRC and overseas. Our employees' remuneration comprises salaries, bonuses, employee provident fund and 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).

At December 31, 2022, our cash and cash equivalents and time deposits were RMB1,042.1 million, as compared to RMB1,603.4 million as of December 31, 2021. The decrease was mainly due to the payment of research and development expenses and development milestone to the partners.

Gearing Ratio

Gearing ratio is calculated using total liabilities divided by total assets and multiplied by 100%. At December 31, 2022, our gearing ratio was 72.6% (December 31, 2021: 46.9%).

Charge on Assets

At December 31, 2022, the Group did not pledge any group assets (December 31, 2021: Nil).

OTHER FINANCIAL INFORMATION

Significant Investments, Material Acquisitions and Disposals

At December 31, 2022, 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.

Other Investments

From July to November 2021, the Company placed orders with CMB International Securities Limited ("**CMBIS**") to subscribe in notes linked to a segregated portfolio held under a company registered in Cayman Islands (the "**Investment**"). The majority of the segregated portfolio was used to invest in the shares and options of companies listed on the PRC, Hong Kong and the US exchange, with the remainder invested in a private equity and held in cash.

The aggregate amount committed to the Investment was approximately HK$227.7 million (equivalent to approximately RMB189.2 million). During the year ended December 31, 2022, the Company redeemed such Investment at an amount of HK$76,925,000 (equivalent to RMB70,217,000) in cash and the Company had taken over the 1,000,000 class X units of a private equity which the management of the Company assessed its fair value is nil after considering the expected return of the underlying investments. As such, the realized loss of the Investment for the year ended December 31, 2022 amounted to RMB62,028,000.

Foreign Exchange Risk

Our financial statements are expressed in RMB, but certain of our cash and cash equivalents, time deposits, other receivables, financial assets measured at FVTPL and account 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

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. During the year ended December 31, 2022, the Group has drawn down RMB113,042,000 and repaid RMB32,000,000 of principal and interest in accordance with the payment schedules.

Contingent Liabilities

At December 31, 2022, we did not have any material contingent liabilities (December 31, 2021: Nil).

CORPORATE GOVERNANCE AND OTHER INFORMATION

The Company was incorporated in the Cayman Islands with limited liability on December 2, 2015, and 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 14 to the Rules Governing the Listing of Securities on the Stock Exchange ("**Listing Rules**"), except for the deviation explained below.

In accordance with Code Provision C.2.1 of Part 2 of the CG Code, the roles of the chairman and chief executive should be separate and should not be performed by the same individual. The roles of Chairman and Chief Executive Officer of the Company had been performed by Dr. Frank Ningjun Jiang until he ceased to act as the Chairman and Chief Executive Officer on May 31, 2022 and August 25, 2022, respectively. While this constituted a deviation from Code Provision C.2.1 of Part 2 of the CG Code, our Board believed that this structure did not impair the balance of power and authority between our Board and the management of our Company, given that the balance of power and authority was ensured by the operations of our Board which comprises experienced and high caliber individuals who meet regularly to discuss issues affecting the operations of our Company. Moreover, the overall strategic and other key business, financial and operational policies of our Group are made collectively after thorough discussion at both our Board and senior management levels.

Subsequent to and as from the cessation of Dr. Frank Ningjun Jiang's acting as the Chairman and Chief Executive Officer, and Dr. Wei Li's taking up the role of the Chairman and Dr. Jianxin Yang's taking up the role of Chief Executive Officer, on May 31, 2022 and August 25, 2022, respectively, the Company has fully complied with the requirements under Code Provision C.2.1 of Part 2 of the CG Code. For further details, please refer to the announcements of the Company dated May 31, 2022 and August 25, 2022.

The Company 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 10 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

In February 2023, the Company successfully raised net proceeds (after deducting the placing commission and other related expenses and professional fees) of approximately HK$389.07 million through a placing of 84,800,000 new shares under general mandate granted to the Board by a resolution of the Shareholders at the annual general meeting of the Company held on June 30, 2022. The proceeds are planned to be used for commercialization and indication expansion of marketed products, development of pipeline products, business development activities and other general corporate purposes. For details, please refer to the announcements of the Company dated February 8, 2023 and February 15, 2023.

An extraordinary general meeting of the Company was held on Tuesday, March 7, 2023 for the purpose of considering and approving (i) the proposed re-grants of Options under the Post-IPO ESOP; (ii) the proposed grant of Options to Dr. Yang under the Post-IPO ESOP; (iii) the proposed amendments to the Post-IPO ESOP; (iv) the proposed amendments to the Post-IPO RSU scheme; (v) the proposed adoption of the Scheme Mandate Limit; and (vi) the proposed adoption of the Service Provider Sublimit. Capitalized terms used in this paragraph shall have the same meaning as defined in the circular of the Company dated February 15, 2023. For details, please refer to the circular of the Company dated February 15, 2023 and the poll results announcement of the Company dated March 7, 2023.

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

Use of Net Proceeds

Our Shares were listed on the Main Board of the Stock Exchange on February 26, 2019 (the "**Listing**"). The Group received net proceeds (after deduction of underwriting commissions and related costs and expenses) from the initial public offering in Hong Kong (the "**HK IPO**", initial public offering, "**IPO**") and the exercise of over-allotment option of approximately RMB2,090.16 million. There was no change in the intended use of net proceeds as previously disclosed in the Prospectus and at December 31, 2021, the Company had utilised the entire net proceeds from the HK IPO. For details, please refer to the annual report of the Company for the year ended December 31, 2021.

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. 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 or delay.

The table below sets out the planned applications of the proceeds and actual usage up to December 31, 2022:

	% of use of proceeds	Proceeds from the subscription *(RMB million)*	Unutilized net proceeds at December 31, 2021 *(RMB million)*	Actual usage during the Reporting Period *(RMB million)*	Unutilized net proceeds at December 31, 2022 *(RMB million)*
Fund the development activities under the collaboration agreement	100.0%	1,355.9	950.2	415.3	534.9

Note: The unutilised net proceeds are planned to be put into use by December 31, 2023.

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, 2022 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, 2022 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 15, 2023. 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 dividend for the year ended December 31, 2022 (2021: 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 will be 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, 2022 containing all the information required by Appendix 16 to the Listing Rules will be despatched to shareholders of the Company and published on the respective 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

Suzhou, PRC, March 15, 2023

As at the date of this announcement, the Board 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.