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## CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2616)

**(1) ANNOUNCEMENT OF INTERIM RESULTS  
FOR THE SIX MONTHS ENDED JUNE 30, 2022;  
(2) CESSATION TO ACT AS THE CHIEF EXECUTIVE OFFICER,  
THE EXECUTIVE DIRECTOR, THE CHAIRMAN OF  
THE STRATEGY COMMITTEE  
AND AN AUTHORIZED REPRESENTATIVE OF THE COMPANY;  
AND  
(3) APPOINTMENT OF THE CHIEF EXECUTIVE OFFICER,  
THE EXECUTIVE DIRECTOR, THE  
CHAIRMAN OF THE STRATEGY COMMITTEE AND AN  
AUTHORIZED REPRESENTATIVE OF THE COMPANY**

The board (the “**Board**”) of directors (the “**Directors**”) of CStone Pharmaceuticals (the “**Company**” or “**CStone**”) is pleased to announce the unaudited condensed consolidated results of the Company and its subsidiaries (together, the “**Group**”, “**we**” or “**us**”) for the six months ended June 30, 2022 (the “**Reporting Period**”), together with comparative figures for the six months ended June 30, 2021. Unless otherwise defined herein, capitalized terms used in this announcement shall have the same meanings as those defined in the prospectus of our Company dated February 14, 2019 (the “**Prospectus**”) and our announcement of interim results for the six months ended June 30, 2021 dated August 26, 2021.

### FINANCIAL HIGHLIGHTS

#### International Financial Reporting Standards (“IFRS”) Measures:

- **Revenue** was RMB261.8 million for the six months ended June 30, 2022, composed of RMB161.4 million in sales of pharmaceutical products, representing sales of the Company’s pharmaceutical products (avapritinib, pralsetinib, newly launched ivosidenib), RMB87.3 million in license fee income, and RMB13.1 million in royalty income of sugemalimab, representing an increase of RMB182.4 million from RMB79.4 million for the six months ended June 30, 2021, primarily attributable to the increase in the total product sales of avapritinib and pralsetinib, and the revenue generated from newly launched ivosidenib and sugemalimab.
- **Research and development expenses** were RMB266.6 million for the six months ended June 30, 2022, representing a decrease of RMB246.2 million from RMB512.8 million for the six months ended June 30, 2021, primarily due to decrease in milestone fee and third party contracting cost and decrease in employee costs.
- **Administrative expenses** were RMB134.8 million for the six months ended June 30, 2022, representing a decrease of RMB19.3 million from RMB154.1 million for the six months ended June 30, 2021, primarily due to the decrease in employee costs.
- **Selling and marketing expenses** were RMB146.4 million for the six months ended June 30, 2022, representing an increase of RMB12.8 million from RMB133.6 million for the six months ended June 30, 2021, primarily attributable to sales force coverage expansion.

- **Loss for the period** was RMB361.6 million for the six months ended June 30, 2022, representing a decrease of RMB412.3 million from RMB773.9 million for the six months ended June 30, 2021, primarily attributable to the increase in revenue and 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 RMB218.9 million for the six months ended June 30, 2022, representing a decrease of RMB225.9 million from RMB444.8 million for the six months ended June 30, 2021, primarily due to decrease in milestone fee and third party contracting cost and decrease in employee costs.
- **Administrative and selling and marketing expenses** excluding the share-based payment expenses were RMB224.4 million for the six months ended June 30, 2022, representing an increase of RMB10.1 million from RMB214.3 million for the six months ended June 30, 2021, primarily attributable to sales force coverage expansion.
- **Loss for the period** excluding the share-based payment expenses was RMB257.1 million, representing a decrease of RMB375.4 million from RMB632.5 million for the six months ended June 30, 2021, primarily attributable to the increase in revenue and decrease in research and development expenses.

#### **BUSINESS HIGHLIGHTS**

The first half of 2022 has been fruitful for CStone with milestones across our maturing pipeline and business. Our commercial successes in the first half, 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 six months ended June 30, 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:

- RMB261.8 million in total revenue, including RMB174.5 million of commercial revenue which is composed of RMB161.4 million in sales of our precision medicines and RMB13.1 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, several of which have no competitors and therefore at highly advantageous market positions
- Four NDA approvals obtained for three products: sugemalimab for stage III NSCLC in mainland China, ivosidenib for isocitrate dehydrogenase 1 (“**IDH1**”)-mutant relapsed/refractory acute myeloid leukemia (“**R/R AML**”) in mainland China, pralsetinib for RET-mutant medullary thyroid cancer (“**MTC**”) & RET fusion-positive thyroid cancer (“**TC**”) in mainland China, and pralsetinib for RET fusion-positive non-small cell lung cancer (“**NSCLC**”) in Hong Kong, China
- Two NDAs filed: pralsetinib for RET fusion-positive NSCLC and TC, RET-mutant MTC in Taiwan, China and pralsetinib for RET fusion-positive NSCLC in Hong Kong, China

- Three positive topline data readouts for sugemalimab in various indications: relapsed or refractory extranodal natural killer/T-cell lymphoma (“**R/R ENKTL**”), first-line stage IV NSCLC and stage III NSCLC
- Seven data presentations/publications at/on global academic conferences/top-tier medical journals
- Two key clinical programs commenced: the first-in-human (“**FIH**”) global study of CS5001 (ROR1 ADC) and the pivotal study of lorlatinib for ROS1-positive advanced NSCLC in mainland China
- Over ten discovery projects in progress, including multi-specifics, antibody drug conjugates, and a proprietary platform for drugging intractable intracellular targets
- Further deepened our strategic partnerships with Pfizer, EQRx and Hengrui
- Successfully started pilot operations in our state-of-the-art manufacturing facility and achieved a technology transfer milestone for avapritinib

These achievements represent only a snapshot of what we have accomplished.

We have achieved healthy and steady growth in commercial capabilities, demonstrated again in our new product and indication launches, as well as increasing brand influence. We have remained focused on key innovative initiatives that will drive continuous growth: 1) enhancing clinical education and testing assistance to expand the pool of potential patients for our drugs; 2) further building-out scientific leadership by broadening the influence of guideline inclusions through academic activities; 3) optimizing our pricing strategy, improving hospital/direct-to-patient (“**DTP**”) pharmacy listing and entering into more insurance programs to expand accessibility and affordability; and 4) providing physician/patient education for better patient support and long-term medication. We have specifically focused our efforts on ensuring dedicated sales force coverage and enhancing sales productivity.

Our efforts to date have led to several successes. We have expanded our sales force coverage to approximately 700 hospitals as of the date of this announcement, up from 600 in 2021, accounting for approximately 70-80% of the relevant market for precision medicines. Currently, our in-market precision medicines have been included in 15 national guidelines, up from over ten at the time we released our 2021 annual results. In addition, they have been listed in 85 supplemental insurance plans, up from over 60 at the time we released our 2021 annual results.

Our clinical team has demonstrated the ability to translate our advantages in innovation, speed, and quality into tangible results for patients and our business. We successfully obtained four NDA approvals covering three products, including two FIC precision medicines as well as our flagship immuno-oncology backbone drug. During the Reporting Period, sugemalimab received approval from the National Medical Products Administration (“**NMPA**”) for patients with stage III NSCLC without disease progression after concurrent or sequential chemoradiotherapy, making it the world’s only anti-PD-1/PD-L1 monoclonal antibody approved in this patient population, significantly strengthened its market positioning and adoption momentum. Ivosidenib, a first-in-class drug, was approved in mainland China for adult patients with R/R AML who have an IDH1 mutation. In addition, pralsetinib received approval for RET-mutant MTC and RET fusion-positive TC in mainland China, and received approval for RET fusion-positive NSCLC in Hong Kong, China.

The broader spectrum of our clinical development success is reflected in the fact that CStone had four data presentations at the 2022 American Society of Clinical Oncology Annual Meeting (ASCO 2022) and the 2022 World Conference on Lung Cancer (WCLC 2022), and three publications on *The New England Journal of Medicine* and *The Lancet Oncology* as of the date of this announcement. These presentations and publications covered study results of sugemalimab in stage III NSCLC, stage IV NSCLC and R/R ENKTL, nofazinlimab combined with lenvatinib in hepatocellular carcinoma (“**HCC**”) and ivosidenib in first-line acute myeloid leukemia (“**AML**”). In addition to the late-stage clinical development programs, meaningful progresses have also been made in our two early-stage programs since the last report including the progression into proof-of-concept (“**PoC**”) expansion cohorts in the global phase I study of CS2006 (NM21-1480; PD-L1/4-1BB/HSA tri-specific) and robust enrolment of the FIH study of CS5001 (ROR1 ADC) in the U.S. and Australia.

Our research team has continued to make advances in our innovative early-stage programs, based on our “Gemstones on the Ring” research strategy. This strategy capitalizes on the modular “plug-and-play” nature of biologics. Following this research framework, we have in progress a total of over ten discovery projects and expect two potential FIC/BIC immune-oncology programs declaring pre-clinical candidates (“**PCCs**”) this year, including one tri-specific molecule against PD-L1, VEGF plus another immuno-oncology (“**IO**” or “**IO**”) target, and one antibody-cytokine fusion molecule. Additionally, we have made great strides in our proprietary cell-penetrating therapeutic platform for targeting intractable intracellular proteins by achieving PoC *in vitro* for one of the treatment modalities using this platform.

Lastly, we launched pilot operations of our manufacturing facility as expected. We are steadily advancing our readiness for full-scale operations to produce our products for clinical trials as well as commercial sales. 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 Center for Drug Evaluation of NMPA (“**CDE**”) for avapritinib in July 2022.

## **I. Multiple Product Launches and Continued Robust Commercial Efforts**

Since 2021, we have obtained a total of nine NDA approvals for four products, including four NDA approvals for three products as at the date of this announcement. Our commercial team continued its rapid execution of pre-launch and post-launch efforts to set the stage for market adoption of our products. TIBSOVO® (ivosidenib) received NDA approval in January 2022, achieved successful commercial launch in June 2022 (first prescriptions on June 8), and gained endorsement from all top KOLs in hematology.

Meanwhile, they have kept up robust efforts to engage the healthcare community, including healthcare providers, academic societies, patient groups, hospitals, pharmacies, payors, and other stakeholders, to provide education on our products and demonstrate our scientific leadership. In addition, they have expanded accessibility and affordability of our products through various patient identification programs and by working with payors to promote coverage of them in insurance programs.

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 RMB161.4 million in the first half of 2022 on the basis of a steady growth in the total product sales of GAVRETO® (pralsetinib) and AYWAKIT® (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 indication of advanced or metastatic RET-mutant MTC and RET fusion-positive TC was 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 700 hospitals as of the date of this announcement, up from 600 in 2021, accounting for approximately 70-80% of the relevant market for precision medicines where we believe we can maximize the return on our sales efforts.

- ***Launched anchor projects 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 alterations in NSCLC/TC and IDH1 mutation in hematologic cancers.
- We provided support programs for RET alterations testing in MTC patients, and expanded test assistance programs to IDH1 mutation patients.
- Besides pathologists, we strengthened clinicians' participation in test-related academic activities to further improve test awareness.

- ***Established broad industry and academic awareness of our brand and scientific leadership***
  - We included GAVRETO® (pralsetinib), AYVAKIT® (avapritinib) and TIBSOVO® (ivosidenib) in 15 of China’s national guidelines, i.e. Chinese Society of Clinical Oncology (“CSCO”) NSCLC/gastrointestinal stromal tumors (“GIST”) Guidelines, Chinese Medical Association Guidelines, and Guidelines on Clinical Practice of Molecular Tests in NSCLC, for treatment paradigms for multiple therapeutic areas (NSCLC, TC, GIST and AML).
  - We engaged in close collaboration with several industry associations – Chinese Society of Clinical Oncology, China Anti-Cancer Association, and Chinese Medical Doctor Association – on diagnostic and treatment standardization projects for GIST, NSCLC and hematological malignancies, further strengthening our industry connections and demonstrating our expertise.
  - We enhanced awareness of our products among physicians and key opinion leaders (“KOLs”) via proactive engagement and constant education. As of the date of this announcement, we have held over 80 academic meetings and events reaching over 80,000 leading KOLs and healthcare professionals (“HCPs”), resulting in an enhanced awareness within the healthcare community of our treatments.
  - We 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 research in collaboration with non-profit academic institutions. In particular, two real-world studies have reached milestones, including the finalization of the clinical study report of pralsetinib for the treatment of NSCLC in Bo’ao and the activation of two sites for avapritinib for the treatment of GIST.
- ***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 listing price of AYVAKIT® (avapritinib) was adjusted to increase affordability of the first treatment cycle. The patient assistance program (“PAP”) scheme of GAVRETO® (pralsetinib) was updated to support the long-term treatment of the patients.
  - We secured inclusion of AYVAKIT® (avapritinib) and GAVRETO® (pralsetinib) in 85 of the major commercial and government insurance programs, up from over 60 as disclosed in our 2021 annual results announcement.

- We continued strategic collaboration with Sinopharm Group Co., Ltd (“**Sinopharm**”) to broaden hospital and pharmacy distribution coverage for both GAVRETO<sup>®</sup> (pralsetinib) and AYVAKIT<sup>®</sup> (avapritinib). As of the date of this announcement, AYVAKIT<sup>®</sup> (avapritinib), GAVRETO<sup>®</sup> (pralsetinib) and TIBSOVO<sup>®</sup> (ivosidenib) have been listed in approximately 150 hospitals and 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<sup>®</sup> (pralsetinib), AYVAKIT<sup>®</sup> (avapritinib) and TIBSOVO<sup>®</sup> (ivosidenib) by facilitating enrolment in city insurance programs.
- ***Continued physician/patient education and support, for retention and long-term medication***

We kept operating disease management programs through online platforms, to provide education on long term treatment for HCPs, and to provide education sessions and follow-up service for patients, to support retention ratio.
  - ***Collaborating with global strategic partners to support global launches of IO backbone drugs***
    - We are closely collaborating with our partners Pfizer and EQRx on the development and commercialization of sugemalimab in mainland China and outside of Greater China, respectively.
    - With EQRx, we are working closely on global development and regulatory strategies for sugemalimab, including the U.S., the U.K. and the European Union (“EU”), as well as territories beyond these such as the Middle East, Turkey and Africa. 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 a Maturing 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 four NDA approvals and submitted two NDA filings as we rounded out our diverse and maturing 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 evidence by the facts that it took only six months for ivosidenib from NDA acceptance to NDA approval, and we had seven data presentations/publications at/on global academic conferences/top-tier medical journals.

Details are as follows:

- **Sugemalimab** (CS1001, PD-L1 antibody), became the only anti-PD-1/PD-L1 monoclonal antibody approved for both stage III and stage IV NSCLC.
  - 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 clinically 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 ex-China filing.
  - In January 2022, we announced that the registrational trial 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 ASCO 2022.
  - In January 2022, we completed enrolment for two key phase III registrational clinical trials, one for the first-line treatment of metastatic gastric adenocarcinoma/gastro-esophageal junction adenocarcinoma, and the other for the first-line treatment of metastatic esophageal squamous cell carcinoma.
  - For the markets outside of Greater China, we are working closely with EQRx on regulatory discussions for regulatory submissions for indications in stage III NSCLC, stage IV NSCLC, and R/R ENKTL in multiple countries and regions. For stage IV NSCLC, we expect the first filing outside of the U.S. in the next six months. Meanwhile, constructive conversations with the U.S. FDA are ongoing to gain greater clarity on the regulatory path. For R/R ENKTL, sugemalimab has received Breakthrough Therapy Designation (“**BT**D”) from the U.S. FDA and we expect the Biologics License Application (“**BL**A”) filing in 2023.

- **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 two 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 February 2022, we received the NDA acceptance from the Taiwan Food and Drug Administration (“**TFDA**”) for the treatment of patients with RET fusion-positive locally advanced or metastatic NSCLC, RET-mutant MTC and RET fusion-positive TC.
- **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.
- **Lorlatinib** (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. 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 ROR1 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 study has proceeded to PoC stage to further explore the safety and efficacy of CS2006 in selected tumor indications. Data from the dose escalation part is planned to be presented to the scientific community in the second half of 2022. We received the IND approval from the NMPA in September 2021. We presented the preclinical data at AACR 2022.

### III. Research Efforts Harness Biologics Modular Potential and Reinforce Core IO Franchise

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.

Our research team has continued to make momentous progress in advancing the early-stage innovative programs, predicated on our “Gemstones on the Ring” research strategy which capitalizes on the modular “plug-and-play” nature of biologics. Following this research framework, we have in progress a total of over ten discovery projects and expect two potentially FIC/BIC immune-oncology programs declaring PCCs this year. Additionally, we have made great strides in our proprietary cell-penetrating therapeutic platform for targeting intractable intracellular proteins by achieving PoC *in vitro* for one of the treatment modalities using this platform. We have established a sustainable innovative research engine that utilizes clinical insights and translational knowledge to drive discovery, and will continue to strengthen our model of innovation sourcing through organic research at our new global R&D Center in Suzhou, China, as well as collaboration with our business partners. These initiatives bolster our immuno-oncology and precision medicine franchises and enhance our capacity to meet our long-term target of filing one-two INDs per year.

We have made significant progress year-to-date with several initiatives:

- **Two FIC/BIC I/O programs** are on-track for pre-clinical candidate (“PCC”) declaration this year, including one tri-specific molecule against PD-L1, VEGF plus another I/O target, and one antibody-cytokine fusion molecule.
- **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 one of the treatment modalities and expect additional *in vitro/in vivo* PoCs with multiple treatment modalities by the end of this year.

#### 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 made significant progress on our relationship with Pfizer this year. In May 2022, we received the second indication approval of sugemalimab as a consolidation therapy to improve progression-free survival in patients with stage III NSCLC, after concurrent or sequential platinum-based chemoradiotherapy. Moreover, for the co-development program of lorlatinib for the treatment of ROS1-positive advanced NSCLC, the first patient was enrolled in the pivotal study in May 2022 under the joint efforts of CStone and Pfizer.

With EQRx, we are advancing regulatory submission in multiple countries and jurisdictions all around the world – the U.S., the U.K., and the EU – regarding the registration of sugemalimab for NSCLC and ENKTL indications. We are collaborating with EQRx to explore the feasibility of extending indications for this drug in the global market including gastric cancer and esophageal cancer. In addition, we are working with EQRx on a global phase III study of nofazinlimab in HCC in the U.S. and major EU markets.

In addition, we further strengthened the strategic partnership with Jiangsu Hengrui Pharmaceuticals Co., Ltd. (“**Hengrui**”). Last year, 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 the first half of 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.

#### V. Other Business Updates

**Manufacturing.** We have completed construction of our state-of-the-art manufacturing facility and began running pilot operations at the end of 2021 as projected. The manufacturing facility has a capacity of 26,000 liters for biologics and 1 billion tablets/capsules for small molecule drugs. 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.

## **FUTURE AND OUTLOOK**

### **The Next Twelve Months**

#### ***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 organically by maximizing deployment effectiveness and leveraging digital platform.
- Improving diagnosis rate and accuracy via collaboration with next generation sequencing companies and National Pathology Quality Control Center.
- Strengthening physician education with focus on differentiation in clinical and safety profile, and improve quality and influence on academic meetings.
- Strengthening accessibility with continued efforts in hospitals and DTPs listing.
- Improving affordability through pricing strategy optimization and commercial insurance/innovative payment plans.
- Enhancing patient management through digital platform.

#### ***Research & Development***

##### NDA approvals expected:

- Pralsetinib: NDA approval in Taiwan, China for the treatment of patients with RET fusion-positive locally advanced or metastatic NSCLC, RET-mutant MTC and RET fusion-positive TC in the fourth quarter of 2022 or the first quarter of 2023.
- Pralsetinib: NDA approval in mainland China for the first-line treatment of RET fusion-positive locally advanced or metastatic NSCLC in 2023.
- Sugemalimab: NDA approval for R/R ENKTL in mainland China in the first half of 2023.

##### NDA filings expected:

- Pralsetinib: NDA filing in mainland China for the first-line treatment of RET fusion-positive locally advanced or metastatic NSCLC in the second half of 2022.
- Sugemalimab: NDA filing for R/R ENKTL in mainland China in the second half of 2022.
- Sugemalimab: The first filing for stage IV NSCLC outside of the U.S. in the next six months.
- Sugemalimab: BLA filing for R/R ENKTL in the U.S. in 2023.

- Sugemalimab: NDA filing in mainland China for the first-line treatment of metastatic gastric adenocarcinoma/gastro-esophageal in the first half of 2023.
- Sugemalimab: NDA filing in mainland China for the first-line treatment of metastatic esophageal squamous cell carcinoma in the first half of 2023.

Topline readouts expected:

- Sugemalimab: topline readout of the phase III trial for the first-line treatment of metastatic gastric adenocarcinoma/gastro-esophageal junction adenocarcinoma in the fourth quarter of 2022 or the first quarter of 2023.
- Sugemalimab: topline readout of the phase III trial for the first-line treatment of metastatic esophageal squamous cell carcinoma in the fourth quarter of 2022 or the first quarter of 2023.
- Sugemalimab: topline readout of the phase III trial for stage III NSCLC OS interim analysis in the first half of 2023.
- Nofazinlimab: topline readout of the global phase III trial of nofazinlimab in combination with LENVIMA<sup>®</sup> (lenvatinib) in first-line treatment of patients with advanced HCC in the first half of 2023.

Early-clinical programs:

- CS2006: Initiation of PoC expansion cohorts of CS2006 monotherapy in selected solid tumor indications and data from the dose escalation part is planned to be presented to the scientific community.

Research programs:

- Advancing one-two FIC/BIC immune-oncology (I/O) programs in our discovery projects into preclinical development.
- Obtaining *in vitro/in vivo* PoC of the proprietary cell-penetrating therapeutic platform with one or more additional treatment modalities.

**Manufacturing**

Having launched pilot operations, in the current year we are progressing with the preparations for commercial-scale operations that will give us the ability to control the supply of our own products, whether for use in clinical trials or for commercial sales. The facility will have a production capacity of 26,000 litres for biologics and 1 billion tablets for small molecules. For the next 12 months, we will continue the technology transfer for multiple products which will reduce costs and improve long-term profitability of our products.

## Looking Beyond 2022

Our commercial, clinical, research and business development capabilities provide a solid basis for CStone to maximize shareholder value as we pursue ground-breaking science with a portfolio of in-market products, some of which secure approval and commercial distribution in global markets. To begin, we are further strengthening our commercial team and presence in the healthcare community that will facilitate the launch and uptake of our drugs in mainland China. We are continuing to expand and deepen our coverage of markets where prescriptions of precision medicines are concentrated.

Our clinical team is working efficiently to expand our portfolio of commercially available drugs and their total addressable market through a combination of indication expansions and geographic coverage. As a result, we are poised to establish a competitive presence in some of the most prevalent cancers.

At the research stage, we are carving out a competitive position in emerging modalities with potential FIC/BIC candidates that will reinforce our core IO and precision medicine franchise. Our improved pre-clinical innovation and development capabilities are on track to generate a greater and more sustainable volume of discovery programs and IND candidates that reach the post-PoC stage.

Our business development efforts will seek to unlock the full value of CStone's business through strategic partnership and deal making. With its leadership and search and evaluation team situated in the U.S., they have a clear line of sight into the most promising innovations in oncology as well as more direct access to assets and partners for strategic collaboration. Our strategy will remain centered on pipeline building transactions with a focus on FIC or BIC assets with global rights. Equally significant, they will prioritize multi-dimensional collaborations and portfolio deals over single asset in-licensing, while remaining flexible for assets of high clinical and commercial value. In addition, business development will also play a critical role and maximizing asset value through global development and commercial partnerships for CStone assets.

## MANAGEMENT DISCUSSION & ANALYSIS

### 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 nine 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.



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.
- 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 Chinese Guideline for Integrated Diagnosis and Treatment of Cancer (“CACA”) - NSCLC, CACA-TC and Chinese Expert Consensus on Nuclear Medicine Diagnosis and Treatment of Differentiated TC in Children and Adolescents.
- 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 online and the GAVRETO® (pralsetinib) annual launch celebration and RET Treatment Academic Week with approximately 20,000 HCPs joining online.
- Moreover, we expanded the scope of MTC testing, launched aid programs for testing, and continued collaborations with top gene sequencing test companies that further improved testing awareness and accessibility. During the Reporting Period, RET testing was recommended by additional national guidelines, such as the first Consensus on RET Gene Testing of Thyroid Cancer in China and Chinese Medical Association Guidelines for Clinical Diagnosis and Treatment of Lung Cancer 2022.

- ***AYVAKIT® (avapritinib)***

- AYVAKIT® (avapritinib), a FIC KIT/PDGFRα inhibitor, has been approved by the NMPA for the treatment of adults with unresectable or metastatic GIST harboring a PDGFRα exon 18 mutation, including PDGFRα D842V mutations. AYVAKIT® (avapritinib) has also been approved by the FDA and HK DoH for the treatment of patients with unresectable or metastatic PDGFRα D842V mutant GIST.
- We collaborated with the Chinese Medical Doctor Association, Chinese College of Surgeons and the CSCO Experts Committee on GIST to shape the paradigm of precision medicine and the ability to diagnose and treat GIST.
- On June 2, 2022, we held the second GIST Summit & AYVAKIT® (avapritinib) annual launch celebration, with approximately 10,000 physicians joining online.
- 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) launch meeting with 24 KOL and approximately 22,000 HCPs attending, including top KOLs.
  - Ivosidenib is recommended by four authoritative guidelines, including CSCO Hematological Malignancies Guideline (2022) and CACA–AML, etc. And it has become the first choice for treatment of AML with IDH1 mutation.
  
- ***Sugemalimab***
  - We continued to work closely with Pfizer to support the commercialization in mainland China, and with 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.
  - Currently, sugemalimab is available in approximately 30 hospitals and 200 DTP pharmacies.
  - 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.
  - On July 17, 2022, the national launch ceremony for this indication was held successfully reaching over 150 KOLs and 700 HCPs.

## **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 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 February 2022, we received the NDA acceptance from the TFDA for the treatment of patients with RET fusion-positive locally advanced or metastatic NSCLC, RET-mutant MTC and RET fusion-positive TC.

### **Trademarks**

Blueprint Medicines, AYVAKIT, GAVRETO and other 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.

### ***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 are conducting 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 only anti-PD-1/PD-L1 monoclonal antibody approved for both stage III and stage IV NSCLC.
- 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.
  - Data showed that sustained improvement in the median PFS by 10.5 months with sugemalimab over placebo among patients with unresectable stage III NSCLC who had not progressed following concurrent or sequential platinum-based chemoradiotherapy. The risk of disease progression or death was reduced by 35%, together with encouraging OS. The risk of death was lowered by 31%. Subgroup analyses demonstrated clinical benefits regardless of whether patients received concurrent or sequential chemoradiotherapy prior to sugemalimab.

- In January 2022, we announced that the pre-specified OS interim analysis showed sugemalimab in combination with chemotherapy significantly and clinically meaningfully improved the overall survival in stage IV NSCLC patients. We presented the detailed results at ASCO 2022. The positive OS data will be used for ex-China filing for sugemalimab.
  - Data showed that sugemalimab in combination with chemotherapy significantly prolonged the median OS by 8.5 months over placebo in combination with chemotherapy and lowered the risk of death by 35%. Survival benefits were observed across all subgroups regardless of tumor pathology types or PD-L1 expression levels.
- In January 2022, we announced that results of sugemalimab as 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 January 2022, the registrational trial of sugemalimab 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.
  - Data showed that sugemalimab significantly improved the objective response rate (ORR) compared to historical controls. In 78 evaluable patients, ORR assessed by Independent Radiology Review Committee (IRRC) was 46.2% with a complete response (CR) rate of 37.2%. The investigator-assessed ORR was highly consistent with IRRC's evaluation.
- We are working closely with EQRx to advance regulatory submission for the indications of stage III NSCLC, stage IV NSCLC, and R/R ENKTL in multiple territories, including the U.S., the U.K. and the EU. For stage IV NSCLC, we expect the first filing outside of the U.S. in the next six months. Meanwhile, constructive conversations with the U.S. FDA are ongoing to gain greater clarity on the regulatory path. For R/R ENKTL, sugemalimab has received the BTD from the U.S. FDA and we expect the BLA filing in 2023.
- In January 2022, we completed the enrolment for the phase III trial of sugemalimab in combination with standard-of-care chemotherapies for first-line treatment of patients with unresectable or metastatic gastric adenocarcinoma/gastro-esophageal junction adenocarcinoma.
- In January 2022, we completed the enrolment for the phase III trial of sugemalimab in combination with standard-of-care chemotherapies for first-line treatment of patients with unresectable or metastatic esophageal squamous cell carcinoma.

**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 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 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 as first-line treatment for unresectable HCC demonstrated an ORR of 45.0%, the median PFS was 10.4 months. Nofazinlimab was well tolerated with a manageable safety profile.

### ***Lorlatinib (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.

### ***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 potentially 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 study has proceeded to PoC stage to further explore the safety and efficacy of CS2006 in selected tumor indications. Data from the dose escalation part is planned to be presented to the scientific community in the second half of 2022. We received the IND approval from the NMPA in September 2021. We presented the preclinical data at AACR 2022.

## 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.

Our research team has continued to make momentous progress in advancing the early-stage innovative programs, predicated on our “Gemstones on the Ring” research strategy which capitalizes on the modular “plug-and-play” nature of biologics. Following this research framework, we have in progress a total of over ten discovery projects and expect two potentially first-in-class/best-in-class immune-oncology programs declaring PCCs this year. Additionally, we have made great strides in our proprietary cell-penetrating therapeutic platform for targeting intractable intracellular proteins by achieving PoC *in vitro* for one of the treatment modalities using this platform. We have established a sustainable innovative research engine that utilizes clinical insights and translational knowledge to drive discovery, and will continue to strengthen our model of innovation sourcing through organic research at our new global R&D Center in Suzhou, China, as well as collaboration with our business partners. These initiatives bolster our immuno-oncology and precision medicine franchises and enhance our capacity to meet our long-term target of filing one-two INDs per year.

**Two FIC/BIC I/O programs** are on-track for PCC declaration this year, including one tri-specific molecule against PD-L1, VEGF plus another I/O target, and one antibody-cytokine fusion molecule.

**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 one of the treatment modalities and expect additional *in vitro/in vivo* PoCs with multiple treatment modalities by the end of this year.

## 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 and EQRx.

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 been working closely to prepare for a successful launch and commercialization for 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 this indication 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 will conduct 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.

- ***EQRx***

- CStone is working closely with EQRx to advance regulatory submission in multiple countries and jurisdictions outside of Greater China, i.e. the U.S., the U.K. and the EU, etc. The regulatory pathways for sugemalimab in multiple indications are in discussion, including but not limited to stage IV NSCLC, stage III NSCLC and R/R ENKTL.
- 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 enrolment in March 2022 as planned, including patients enrolled in the U.S. and major EU markets with the joint efforts of CStone and EQRx.

- ***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 will be eligible for an upfront payment and potential milestone payments up to US\$200 million in addition to double-digit royalties. Hengrui will obtain the exclusive rights for research, development, registration, manufacturing, and commercialization of CS1002 in Greater China. CStone will retain 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 the first half of 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 continue to deepen relationships with DotBio, a biotech company specializing in next generation antibody therapies. Last year, we signed a global discovery collaboration to develop up to three pre-clinical FIC/BIC next-generation antibody therapies for which CStone would lead the design of the target combination based on the intended mechanism of action and DotBio will lead the design and engineering of the molecules. As part of this collaboration, CStone will take an equity position in DotBio. This partnership bolsters CStone’s Pipeline 2.0 strategy by adding a powerful new source of organic and transformative innovation to its R&D engine.

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”)**

During the Reporting Period, the impact of COVID-19 on our business operations was immaterial. 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. 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 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. With the aforementioned mitigation measures and the easing of COVID-19 restrictions, our business has been recovering since May 2022 and achieved healthy growth momentum thereafter.

## FINANCIAL INFORMATION

### CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE SIX MONTHS ENDED JUNE 30, 2022

	NOTES	For the six months ended June 30,	
		2022 RMB'000 (Unaudited)	2021 RMB'000 (Unaudited)
Revenue	3	261,765	79,449
Cost of revenue		<u>(92,723)</u>	<u>(31,215)</u>
Gross profit		169,042	48,234
Other income	5	5,808	12,315
Other gains and losses	5	14,314	(31,761)
Research and development expenses		(266,627)	(512,753)
Selling and marketing expenses		(146,352)	(133,584)
Administrative expenses		(134,818)	(154,105)
Finance costs		<u>(2,936)</u>	<u>(2,197)</u>
Loss for the period	6	(361,569)	(773,851)
<b>Other comprehensive income for the period:</b>			
<i>Item that may be reclassified subsequently to profit or loss:</i>			
Exchange differences arising on translation of foreign operations		<u>7</u>	<u>299</u>
Total comprehensive expense for the period		<u><u>(361,562)</u></u>	<u><u>(773,552)</u></u>
<b>Loss per share</b>	8		
– Basic (RMB)		<u><u>(0.31)</u></u>	<u><u>(0.67)</u></u>
– Diluted (RMB)		<u><u>(0.31)</u></u>	<u><u>(0.67)</u></u>

**CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION**  
**AT JUNE 30, 2022**

	<i>NOTES</i>	<b>June 30, 2022 RMB'000 (Unaudited)</b>	December 31, 2021 RMB'000 (Audited)
<b>Non-current assets</b>			
Property, plant and equipment		<b>162,056</b>	154,166
Right-of-use assets		<b>87,109</b>	28,631
Prepayments for acquisition of property, plant and equipment and intangible assets		<b>1,173</b>	5,126
Intangible assets		<b>173,881</b>	70,539
Financial assets measured at fair value through profit or loss (“FVTPL”)		<b>3,356</b>	3,188
Other receivables		<b>10,412</b>	52,158
		<u><b>437,987</b></u>	<u>313,808</u>
<b>Current assets</b>			
Trade receivables	<i>10</i>	<b>164,027</b>	117,598
Deposits, prepayments and other receivables		<b>162,806</b>	52,345
Financial assets measured at FVTPL		<b>95,417</b>	122,895
Inventories		<b>53,900</b>	61,363
Time deposits with original maturity over three months		<b>369,127</b>	860,720
Cash and cash equivalents		<b>731,458</b>	742,724
		<u><b>1,576,735</b></u>	<u>1,957,645</u>
<b>Current liabilities</b>			
Trade and other payables and accrued expenses	<i>11</i>	<b>818,855</b>	881,549
Bank borrowings		<b>29,557</b>	30,700
Deferred income		<b>7,451</b>	7,451
Lease liabilities		<b>44,764</b>	13,248
		<u><b>900,627</b></u>	<u>932,948</u>
<b>Net current assets</b>		<u><b>676,108</b></u>	<u>1,024,697</u>
<b>Total assets less current liabilities</b>		<u><b>1,114,095</b></u>	<u>1,338,505</u>

	<b>June 30, 2022 RMB'000 (Unaudited)</b>	December 31, 2021 RMB'000 (Audited)
<b>Non-current liabilities</b>		
Bank borrowings	123,270	115,811
Deferred income	1,022	1,247
Lease liabilities	39,201	14,439
	<u>163,493</u>	<u>131,497</u>
<b>Net assets</b>	<u><b>950,602</b></u>	<u><b>1,207,008</b></u>
<b>Capital and reserves</b>		
Share capital	797	796
Treasury shares held in the trusts	(6)	(11)
Reserves	949,811	1,206,223
<b>Total equity</b>	<u><b>950,602</b></u>	<u><b>1,207,008</b></u>

## NOTES

### 1. GENERAL

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

The condensed consolidated financial statements have been prepared in accordance with International Accounting Standard 34 “Interim Financial Reporting” issued by the International Accounting Standards Board (“IASB”) as well as the applicable disclosure requirements of Appendix 16 to the Rules Governing the Listing of Securities on the Stock Exchange.

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

### 2. APPLICATION OF AMENDMENTS TO INTERNATIONAL FINANCIAL REPORTING STANDARDS (“IFRSs”)

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

Other than additional accounting policies resulting from application of amendments to International Financial Reporting Standards (“IFRSs”), the accounting policies and methods of computation used in the condensed consolidated financial statements for the six months ended June 30, 2022 are the same as those presented in the Group’s annual financial statements for the year ended December 31, 2021.

#### **Application of amendments to IFRSs**

In the current interim period, the Group has applied the following amendments to IFRSs issued by the IASB, for the first time, which are mandatory effective for the Group’s annual period beginning on January 1, 2022 for the preparation of the Group’s condensed consolidated financial statements:

Amendments to IFRS 3	Reference to the Conceptual Framework
Amendment to IFRS 16	Covid-19-Related Rent Concessions beyond June 30, 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 the amendments to IFRSs in the current interim period has had no material impact on the Group’s financial positions and performance for the current and prior periods and/or on the disclosures set out in these condensed consolidated financial statements.

### 3. REVENUE

#### Disaggregation of revenue from contracts with customers

	For the six months ended June 30,	
	2022 RMB'000 (Unaudited)	2021 RMB'000 (Unaudited)
<b>Type of goods or services</b>		
Sales of pharmaceutical products	161,400	79,449
License fee income	87,268	–
Royalty income	13,097	–
	<u>261,765</u>	<u>79,449</u>
<b>Timing of revenue recognition</b>		
A point in time	<u>261,765</u>	<u>79,449</u>

### 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, provision of licensing of its intellectual property or commercialisation license to customers.

For the purpose of resource allocation and performance assessment, the Group's chief operating decision maker reviews the overall results and financial position of the Group prepared based on the same accounting policies as set out in Note 3 to the consolidated financial statements included in the Group's annual report for the year ended December 31, 2021 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 Group's revenue from external customers are all derived in the PRC based on the geographical location of the registered office of the immediate customers during the reporting periods.

### 5. OTHER INCOME AND OTHER GAINS AND LOSSES

#### Other income

	For the six months ended June 30,	
	2022 RMB'000 (Unaudited)	2021 RMB'000 (Unaudited)
Government grants income	4,058	5,316
Bank and other interest income	1,560	6,999
Others	190	–
	<u>5,808</u>	<u>12,315</u>

## Other gains and losses

	For the six months ended June 30,	
	2022 RMB'000 (Unaudited)	2021 RMB'000 (Unaudited)
Net (loss) gain on fair value changes of financial assets measured at FVTPL	(27,310)	163
Net gain on fair value of money market funds	570	6
Net foreign exchange gain (losses)	41,075	(31,936)
Others	(21)	6
	<u>14,314</u>	<u>(31,761)</u>

## 6. LOSS FOR THE PERIOD

	For the six months ended June 30,	
	2022 RMB'000 (Unaudited)	2021 RMB'000 (Unaudited)
Loss for the period has been arrived at after charging:		
Depreciation of:		
Property, plant and equipment	3,295	3,399
Right-of-use assets	16,832	5,322
Amortisation of intangible assets	6,123	2,354
Total depreciation and amortisation	26,250	11,075
Less: Capitalisation of depreciation of right-of-use assets in construction in progress	(10,459)	–
Total depreciation and amortisation charged to profit or loss	<u>15,791</u>	<u>11,075</u>
Directors' emoluments	40,851	80,680
Other staff costs:		
Salaries and other allowances	135,440	131,070
Performance related bonus	39,460	24,894
Retirement benefit scheme contributions	28,395	23,030
Share-based payment expenses	66,508	64,902
	<u>269,803</u>	<u>243,896</u>
	<u>310,654</u>	<u>324,576</u>
Cost of inventories recognised as cost of revenue	<u>62,396</u>	<u>19,383</u>
Write-down of inventories (included in cost of revenue)	<u>5,869</u>	<u>–</u>

## 7. INCOME TAX EXPENSE

No income tax expense for the six months ended June 30, 2021 and 2022 as the Group had no assessable profits derived from the operating entities of the Group.

## 8. LOSS PER SHARE

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

	<b>For the six months ended June 30,</b>	
	<b>2022</b>	2021
	<b>(Unaudited)</b>	(Unaudited)
<b>Loss (RMB' 000)</b>		
Loss for the period attributable to owners of the Company for the purpose of basic and diluted loss per share	<u><u>(361,569)</u></u>	<u><u>(773,851)</u></u>
<b>Number of shares (' 000)</b>		
Weighted average number of ordinary shares for the purpose of basic and diluted loss per share	<u><u>1,176,329</u></u>	<u><u>1,154,802</u></u>

The calculation of basic and diluted loss per share for both periods has considered the restricted share units that have been vested but not yet registered, but excluded the treasury shares held in trust which are accounted for as treasury share of the Company.

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

## 9. DIVIDENDS

No dividend was paid, declared, or proposed by the Company during the interim periods.

## 10. TRADE RECEIVABLES

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

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

	<b>June 30, 2022</b>	December 31, 2021
	<b>RMB' 000</b>	RMB' 000
	<b>(Unaudited)</b>	(Audited)
0 – 60 days	<u><u>164,027</u></u>	<u><u>117,598</u></u>

## 11. TRADE AND OTHER PAYABLES AND ACCRUED EXPENSES

	<b>June 30, 2022 RMB'000 (Unaudited)</b>	December 31, 2021 RMB'000 (Audited)
Trade payables	73,992	33,024
Other payables and accruals	<u>744,863</u>	<u>848,525</u>
	<b><u>818,855</u></b>	<b><u>881,549</u></b>

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

	<b>June 30, 2022 RMB'000 (Unaudited)</b>	December 31, 2021 RMB'000 (Audited)
Less than 60 days	53,093	32,514
61 – 90 days	514	510
Over 90 days	<u>20,385</u>	<u>–</u>
	<b><u>73,992</u></b>	<b><u>33,024</u></b>

## 12. EVENTS AFTER THE END OF THE REPORTING PERIOD

On August 25, 2022, the Company announced that Dr. Frank Ningjun Jiang had decided to retire from and will cease to serve as the Chief Executive Officer, the executive Director, the chairman of the Strategy Committee and an authorized representative of the Company for the purpose of Rule 3.05 of the Listing Rules, with effect from August 25, 2022. Subsequent to his retirement, Dr. Frank Ningjun Jiang will serve as the senior advisor of the Company until the end of this year. On the same date, the Company announced that Dr. Jianxin Yang, the senior vice president and chief medical officer of the Company, has been appointed as the Chief Executive Officer, the executive Director, the chairman of the Strategy Committee and an authorised representative of the Company for the purpose of Rule 3.05 of the Listing Rules, with effect from August 25, 2022.

## Financial Review

### *Six months ended June 30, 2022 Compared to Six months ended June 30, 2021*

	For the six months ended June 30,	
	2022 <i>RMB'000</i> (Unaudited)	2021 <i>RMB'000</i> (Unaudited)
Revenue	261,765	79,449
Cost of revenue	<u>(92,723)</u>	<u>(31,215)</u>
Gross profit	169,042	48,234
Other income	5,808	12,315
Other gains and losses	14,314	(31,761)
Research and development expenses	(266,627)	(512,753)
Selling and marketing expenses	(146,352)	(133,584)
Administrative expenses	(134,818)	(154,105)
Finance costs	<u>(2,936)</u>	<u>(2,197)</u>
Loss for the period	<u>(361,569)</u>	<u>(773,851)</u>
<b>Other comprehensive income for the period:</b>		
<i>Items that may be reclassified subsequently to profit or loss:</i>		
Exchange differences arising on translation of foreign operations	<u>7</u>	<u>299</u>
Total comprehensive expense for the period	<u><u>(361,562)</u></u>	<u><u>(773,552)</u></u>
<b>Non-IFRS measures:</b>		
Adjusted loss for the period	<u><u>(257,076)</u></u>	<u><u>(632,488)</u></u>

**Revenue.** Our revenue was RMB261.8 million for the six months ended June 30, 2022, composed of RMB161.4 million in sales of pharmaceutical products, representing sales of the Company's pharmaceutical products (avapritinib, pralsetinib, newly launched ivosidenib), RMB87.3 million in license fee income, and RMB13.1 million in royalty income of sugemalimab, representing an increase of RMB182.4 million from RMB79.4 million for the six months ended June 30, 2021, primarily attributable to the increase in the total product sales of avapritinib and pralsetinib, and the revenue generated from newly launched ivosidenib and sugemalimab.

**Other Income.** Our other income decreased by RMB6.5 million from RMB12.3 million for the six months ended June 30, 2021 to RMB5.8 million for the six months ended June 30, 2022. This was primarily due to lower interest income.

**Other Gains and Losses.** Our other gains and losses increased by RMB46.1 million from losses of RMB31.8 million for the six months ended June 30, 2021 to gains of RMB14.3 million for the six months ended June 30, 2022. This increase was primarily due to foreign exchange gain for the six months ended June 30, 2022, which was offset by losses on fair value of financial assets measured at FVTPL.

**Research and Development Expenses.** Our research and development expenses decreased by RMB246.2 million from RMB512.8 million for the six months ended June 30, 2021 to RMB266.6 million for the six months ended June 30, 2022. This decrease was primarily attributable to (i) a decrease of RMB238.6 million in milestone fee and third party contracting cost from RMB375.9 million for the six months ended June 30, 2021 to RMB137.3 million for the six months ended June 30, 2022 for different phases of our clinical trials; and (ii) share-based payment expenses decreased by RMB20.2 million while other employee cost increased by RMB12.9 million.

	<b>For the six months ended June 30,</b>	
	<b>2022</b>	<b>2021</b>
	<b>RMB'000</b>	<b>RMB'000</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
Employee cost	127,665	135,019
Milestone fee and third party contracting cost	137,272	375,853
Others	1,690	1,881
	<u>266,627</u>	<u>512,753</u>
<b>Total</b>	<b><u>266,627</u></b>	<b><u>512,753</u></b>

**Administrative Expenses.** Our administrative expenses decreased by RMB19.3 million from RMB154.1 million for the six months ended June 30, 2021 to RMB134.8 million for the six months ended June 30, 2022. This was primarily due to the decrease of RMB8.4 million in employee cost from RMB103.5 million for the six months ended June 30, 2021 to RMB95.1 million for the six months ended June 30, 2022.

	<b>For the six months ended June 30,</b>	
	<b>2022</b>	<b>2021</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
Employee cost	95,143	103,451
Professional fees	18,089	20,425
Rental expenses	576	1,688
Depreciation and amortization	10,573	9,767
Others	10,437	18,774
	<hr/>	<hr/>
<b>Total</b>	<b>134,818</b>	<b>154,105</b>
	<hr/> <hr/>	<hr/> <hr/>

***Selling and Marketing Expenses.*** Our selling and marketing expenses increased by RMB12.8 million from RMB133.6 million for the six months ended June 30, 2021 to RMB146.4 million for the six months ended June 30, 2022. The increase was primarily attributable to sales force coverage expansion.

	<b>For the six months ended June 30,</b>	
	<b>2022</b>	<b>2021</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
Employee cost	87,846	86,106
Professional fees	20,062	11,401
Others	38,444	36,077
	<hr/>	<hr/>
<b>Total</b>	<b>146,352</b>	<b>133,584</b>
	<hr/> <hr/>	<hr/> <hr/>

***Finance Costs.*** The finance costs increased by RMB0.7 million from RMB2.2 million for the six months ended June 30, 2021 to RMB2.9 million for the six months ended June 30, 2022, primarily due to the increase in bank borrowings.

### **Non-IFRS Measures**

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

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

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

	<b>For the six months ended June 30,</b>	
	<b>2022</b>	<b>2021</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
Loss for the period	<b>(361,562)</b>	(773,851)
Added:		
Share-based payment expenses	<u><b>104,486</b></u>	<u>141,363</u>
Adjusted loss for the period	<u><b>(257,076)</b></u>	<u>(632,488)</u>

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

	<b>For the six months ended June 30,</b>	
	<b>2022</b>	<b>2021</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
Research and development expenses for the period	<b>(266,627)</b>	(512,753)
Added:		
Share-based payment expenses	<u><b>47,753</b></u>	<u>67,984</u>
Adjusted research and development expenses for the period	<u><b>(218,874)</b></u>	<u>(444,769)</u>

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

	<b>For the six months ended June 30,</b>	
	<b>2022</b> <i>RMB'000</i> <b>(Unaudited)</b>	<b>2021</b> <i>RMB'000</i> <b>(Unaudited)</b>
Administrative and selling and marketing expenses for the period	<b>(281,170)</b>	(287,689)
Added:		
Share-based payment expenses	<u><b>56,733</b></u>	<u>73,379</u>
Adjusted administrative and selling and marketing expenses for the period	<u><b>(224,437)</b></u>	<u>(214,310)</u>

### **Employees and Remuneration Policies**

The following table sets forth a breakdown of our employees as at June 30, 2022 by function:

<b>Function</b>	<b>Number of employees</b>	<b>% of total number of employees</b>
Research and Development	184	32.34
Sales, General and Administrative	<u>385</u>	<u>67.66</u>
<b>Total</b>	<u><b>569</b></u>	<u><b>100.0</b></u>

As of June 30, 2022, we had 251 employees in Shanghai, 58 employees in Beijing, 82 employees in Suzhou and 178 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 HK\$2,236,605,705.24, (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).

As of June 30, 2022, our cash and cash equivalents and time deposits were RMB1,100.6 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%. As at June 30, 2022, our gearing ratio was 52.8% (as at December 31, 2021: 46.9%).

### **Charge on Assets**

As of June 30, 2022, the Group did not pledge any group assets (as of June 30, 2021: Nil).

## **OTHER FINANCIAL INFORMATION**

### **Significant Investments, Material Acquisitions and Disposals**

As at June 30, 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). Based on the Investment's underlying securities valuation, the fair value of the Investment as at June 30, 2022 was RMB95,417,000, representing approximately 4.7% of the total assets of the Group as at June 30, 2022. As such, the unrealized loss of the Investment for the six months ended June 30, 2022 amounted to RMB27,478,000.

## **Foreign Exchange Risk**

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

## **Bank Loans and Other Borrowings**

On January 7, 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. During the six months ended June 30, 2022, the Group has drawn down RMB13,042,000 and repaid RMB10,608,000 of principal and interest in accordance with the payment schedules.

## **Contingent Liabilities**

As of June 30, 2022, we did not have any material contingent liabilities (as of June 30, 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 of the Company (the “**Shares**”) were listed on the Stock Exchange on February 26, 2019.

### **Compliance with the Corporate Governance Code**

The Board is committed to achieving high corporate governance standards. During the Reporting Period, the Company has complied with all the code provisions as set out in the Corporate Governance Code (the “**CG Code**”) contained in Appendix 14 to the 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 on May 31, 2022. 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 Dr. Wei Li's taking up the role of the Chairman on May 31, 2022, 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 announcement of the Company dated May 31, 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 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**

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

## Use of Net Proceeds

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 as at December 31, 2021, the Company had utilised the entire net proceeds from the HK IPO. For details, please refer to the 2021 annual report of the Company.

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 June 30, 2022:

	<b>% of use of proceeds</b>	<b>Proceeds from the subscription (RMB million)</b>	<b>Actual usage up to June 30, 2022 (RMB million)</b>	<b>Unutilized net proceeds as of June 30, 2022 (RMB million)</b>
Fund the development activities under the collaboration agreement	<u>100.0%</u>	<u>1,355.9</u>	<u>627.6</u>	<u>728.3</u>

*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.

## Review of Interim Results

The independent auditors of the Company, namely Deloitte Touche Tohmatsu, have carried out a review of the interim financial information in accordance with the Hong Kong Standard on Review Engagement 2410 “Review of Interim Financial Information Performed by the Independent Auditor of the Entity” issued by the Hong Kong Institute of Certified Public Accountants. The Audit Committee has jointly reviewed with the management of the Company, the accounting principles and policies adopted by the Company and discussed internal control and financial reporting matters (including the review of the unaudited interim results for the six months ended June 30, 2022) of the Group. The Audit Committee considered that the interim results are in compliance with the applicable accounting standards, laws and regulations, and the Company has made appropriate disclosures thereof. The Audit Committee has also discussed matters with respect to the accounting policies and practices adopted by the Company and internal control with senior management of the Company.

## INTERIM DIVIDEND

The Board does not recommend the payment of an interim dividend for the six months ended June 30, 2022 (2021: Nil).

## PUBLICATION OF INTERIM RESULTS ANNOUNCEMENT AND INTERIM REPORT

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

The interim report for the six months ended June 30, 2022 containing all the information required by Appendix 16 to the Listing Rules will be despatched to shareholders and published on the websites of the Stock Exchange and the Company in due course.

## CESSATION TO ACT AS THE CHIEF EXECUTIVE OFFICER (“CEO”), THE EXECUTIVE DIRECTOR, THE CHAIRMAN OF THE STRATEGY COMMITTEE AND AN AUTHORIZED REPRESENTATIVE OF THE COMPANY

The Board announced that Dr. Frank Ningjun Jiang (“**Dr. Jiang**”), after leading CStone’s development for six years, had decided to retire from and will cease to serve as the CEO, the executive Director, the Chairman of the Strategy Committee and an authorized representative of the Company for the purpose of Rule 3.05 of the Listing Rules (“**Authorized Representative**”), with effect from August 25, 2022. In the following period of time, Dr. Jiang will serve as the Senior Advisor of the Company until the end of this year to ensure a smooth transition of the Company’s operations.

Dr. Wei Li, Chairman of the Board, said, “Dr. Jiang joined CStone as the founding CEO at the beginning of CStone’s establishment. With more than 20 years of experience in pharmaceutical innovation and multinational enterprise management, Dr. Jiang pioneered CStone’s path of pharmaceutical innovation in China. Under his leadership, CStone has attracted outstanding management teams worldwide and established an innovative strategy with a global vision. As a result, CStone was successfully listed on the Stock Exchange in merely three years, achieved the launch of four FIC/BIC innovative immune-oncology drugs with nine NDAs in six years, built a balanced oncology-focused pipeline of 15 innovative products, laying a solid foundation for its continuous climbing to new heights. We are very fortunate to have had such an outstanding leader as Dr. Jiang during a critical period in the establishment and development of the Company. The Board would like to take this opportunity to express its sincere gratitude to Dr. Jiang for his valuable contribution to the Company during his tenure of office.”

Dr. Jiang has confirmed that he had no disagreement with the Board and there were no matters relating to his cessation of tenure that should be brought to the attention of the shareholders of the Company or the Stock Exchange.

## **APPOINTMENT OF THE CEO, THE EXECUTIVE DIRECTOR, THE CHAIRMAN OF THE STRATEGY COMMITTEE AND AN AUTHORIZED REPRESENTATIVE OF THE COMPANY**

The Board announced that Dr. Jianxin Yang (“**Dr. Yang**”), the Senior Vice President and Chief Medical Officer of the Company, has been appointed as the CEO, the executive Director, the Chairman of the Strategy Committee and an Authorised Representative of the Company, with effect from August 25, 2022 (the “**Effective Date**”).

The biographical details of Dr. Yang is set out as follows:

Dr. Jianxin Yang (楊建新), M.D., Ph.D., aged 58, has been our Senior Vice President and Chief Medical Officer since December 2016. In this role, he is responsible for developing and implementing the overall clinical strategy.

Dr. Yang has over 25 years of experience in biomedical research and clinical development of oncology drugs in the U.S. and China. Prior to joining us, he served as the Senior Vice President and Head of Clinical Development at BeiGene, Ltd. (NASDAQ: BGNE, HKSE: 6160, the Star Market of SHSE: 688235) from July 2014 to December 2016. He led BeiGene, Ltd.’s clinical team in clinical development of its oncology pipeline, and led the development and management of over ten clinical trials worldwide, including the first anti-PD-1 mAb originated in China, BTK inhibitors and PARP inhibitors.

Prior to joining BeiGene, Ltd., Dr. Yang served as a Medical Director at Covance Inc. from September 2011 to July 2014. He served as Senior Chief Scientist for tumor biomarkers in Pfizer Inc., and served as a Research Scientist in the cancer genomics division at Tularik Inc. (acquired by Amgen Inc. in 2004).

Throughout his career, Dr. Yang has made significant contributions to the successful development of several anticancer drugs. He is also the author of over 50 publications and the inventor of nine patents.

Dr. Yang received a bachelor’s degree in medicine from Xianning Branch of Hubei Medical College (湖北醫學院咸寧分院), (currently known as Hubei Institute of Science and Technology (湖北科技學院)) in Hubei, China in July 1985 and a master’s degree in pathophysiology from Nanjing Medical College (南京醫學院), (currently known as Nanjing Medical University (南京醫科大學)) in Nanjing, China in July 1989. He then received his Ph.D. training in molecular biology with Nobel Laureates Drs. Michael S. Brown and Joseph L. Goldstein at the University of Texas Southwestern Medical Center at Dallas, U.S. in June 1995. He conducted his postdoctoral training in chemical biology with Dr. Stuart L. Schreiber at Harvard University in the United States from 1995 to 1998.

Save as disclosed above, Dr. Yang has not held directorship in any other listed public company in Hong Kong or overseas in the last three years.

The Company will enter into a letter of appointment with Dr. Yang in relation to his appointment as an executive Director, with effect from the Effective Date. Dr. Yang will hold office from the Effective Date until the next following general meeting of the Company, at which he will be eligible for re-election in accordance with and subject to the Memorandum and the Articles of Association of the Company (the “**Articles of Association**”). Upon being re-elected thereof, his appointment shall continue for a period of three years and until the conclusion of the annual general meeting of the Company after the re-election, or such earlier date pursuant to the Articles of Association.

The annual salary of Dr. Yang shall be US\$615,000. He is also entitled to receive discretionary bonuses and other benefits as may be determined by the Remuneration Committee of the Company having regard to the Company’s and his performance, subject to review by the Company from time to time pursuant to the Articles of Association. In addition, Dr. Yang is an eligible person under the share incentive schemes adopted by the Company. The above remuneration package for Dr. Yang was determined by the Board on the recommendation of the Remuneration Committee of the Company with reference to (1) Dr. Yang’s experience, knowledge and qualifications; (2) the remuneration paid by comparable companies; and (iii) the time commitment, duties and responsibilities of Dr. Yang as the CEO and the executive Director.

As at the date of the announcement, Dr. Yang was interested in 17,949,281 shares of the Company, including 6,672,423 shares beneficially owned by him and 11,276,858 shares underlying the options and restricted share units granted to him in accordance with the share incentive schemes adopted by the Company, which are required to be disclosed under Part XV of the Securities and Futures Ordinance (Cap 571 of the Laws of Hong Kong) (the “**SFO**”).

Save as disclosed above, and as far as the Board is aware, Dr. Yang (i) does not have any relationship with any Directors, senior management, substantial shareholders or controlling shareholder of the Company, nor does he hold any other positions with the Company or any of its subsidiaries; and (ii) is not interested or deemed to be interested in the shares, underlying shares or debentures of the Company or any of its associated corporations within the meaning of Part XV of the SFO.

Save as disclosed above, there is no other information in relation to the appointment of Dr. Yang that needs to be disclosed pursuant to any of the requirements set out in Rules 13.51(2)(h) to (v) of the Listing Rules and there is no other matters concerning Dr. Yang that should be brought to the attention of the shareholders of the Company.

The Board takes this opportunity to welcome Dr. Yang on his new appointments.

## **APPRECIATION**

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

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

Suzhou, the PRC, August 25, 2022

*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. Yanling Cao, 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.*