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**CStone Pharmaceuticals**  
**基石藥業**

*(Incorporated in the Cayman Islands with limited liability)*  
**(Stock Code: 2616)**

**ANNOUNCEMENT OF ANNUAL RESULTS  
FOR THE YEAR ENDED DECEMBER 31, 2019**

The board of directors (the “**Board**”) of CStone Pharmaceuticals (the “**Company**”) is pleased to announce the audited consolidated results of the Company and its subsidiaries (together, the “**Group**”, “**we**” or “**us**”) for the year ended December 31, 2019, together with comparative figures for the year ended December 31, 2018. Unless otherwise defined herein, capitalized terms used in this announcement shall have the same meanings as those defined in the prospectus of the Company dated February 14, 2019 (the “**Prospectus**”).

**FINANCIAL HIGHLIGHTS**

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

The research and development expenses excluding the share-based payment expenses increased by RMB461.8 million from RMB726.9 million for the year ended December 31, 2018 to RMB1,188.7 million for the year ended December 31, 2019, primarily attributable to additional trials which increased clinical development costs.

The administrative expenses excluding the share-based payment expenses increased by RMB58.3 million from RMB79.3 million for the year ended December 31, 2018 to RMB137.6 million for the year ended December 31, 2019, primarily attributable to increase in employee costs.

The loss excluding the effect of the fair value changes of the conversion feature of preferred shares and share-based payment expenses increased by RMB468.7 million from RMB672.6 million for the year ended December 31, 2018 to RMB1,141.3 million for the year ended December 31, 2019, primarily due to increase in research and development expenses and administrative expenses, while partially offset by increase in interest income.

## **International Financial Reporting Standards (“IFRS”) Numbers:**

- Other income increased by RMB63.5 million from RMB20.5 million for the year ended December 31, 2018 to RMB84.0 million for the year ended December 31, 2019, primarily attributable to increase in interest income from bank deposits and time deposits.
- Other gains and losses decreased by RMB104.6 million from losses of RMB742.0 million for the year ended December 31, 2018 to losses of RMB637.4 million for the year ended December 31, 2019, primarily attributable to a narrowed loss on fair value changes of derivative financial liabilities, which was a non-cash, one-time adjustment upon the Listing as required under the IFRS.
- Research and development expenses increased by RMB545.4 million from RMB850.2 million for the year ended December 31, 2018 to RMB1,395.6 million for the year ended December 31, 2019, primarily attributable to additional trials which increased clinical development costs.
- Administrative expenses increased by RMB150.5 million from RMB191.0 million for the year ended December 31, 2018 to RMB341.5 million for the year ended December 31, 2019, primarily attributable to increase in employee costs.
- As a result of the above factors, the loss for the year increased by RMB515.3 million from RMB1,793.1 million for the year ended December 31, 2018 to RMB2,308.4 million for the year ended December 31, 2019, primarily due to increase in research and development expenses and administrative expenses, while partially offset by increase in interest income.

## **BUSINESS HIGHLIGHTS**

On February 26, 2019 (the “**Listing Date**”), the Company was successfully listed on The Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”). Over the past year, significant advancement has been made with respect to our product pipeline and business operations:

### **Late-stage assets:**

- CS1001 (PD-L1 antibody) - In 2019, we have made notable progress to advance our lead immuno-oncology (“**IO**”) asset CS1001 in the clinic, qualifying it as a promising anti-PD-L1 with unique advantage and significant differentiation. Data presented at 3 major congresses (Chinese Society of Clinical Oncology (“**CSCO**”), European Society for Medical Oncology (“**ESMO**”), and The American Society of Hematology (“**ASH**”)) have demonstrated that CS1001 is safe and efficacious in multiple solid tumors and lymphomas, including esophageal, gastric, cholangiocarcinoma/gall bladder, and microsatellite instability-high (“**MSI-H**”)/mismatch repair deficient (“**dMMR**”) cancer, as well as natural killer T-cell lymphoma (“**NKTL**”). Its outstanding activity in esophageal cancer and NKTL in particular reveals the potential of CS1001 as a best-in-class drug candidate. Based on these proof-of-concept data, we have initiated two additional registrational trials of CS1001 in China for patients with advanced gastric cancer and esophageal cancer, and dosed the first patient in April 2019 and December 2019, respectively. Together with the 4 initiated in 2018 (Stage III non-small cell lung cancer (“**NSCLC**”), stage IV NSCLC, NKTL and classical Hodgkin lymphoma (“**cHL**”)), we are currently conducting 6 registrational trials for CS1001. We expect top-line results of the Phase III trial of CS1001 in combination with standard-of-care chemotherapies in patients with first-line Stage IV squamous or non-squamous NSCLC to be available in the second half of 2020. Furthermore, we plan to consult with Center for Drug Evaluation (“**CDE**”) on our cHL and NKTL regulatory strategy and expect to submit an NDA in China for cHL and potentially also NKTL in the second half of 2020.

- CS1003 (PD-1 antibody) - Preliminary data of the Phase Ia study of CS1003 monotherapy were presented at the CSCO 2019 annual meeting, which showed that CS1003 was safe and tolerable. Anti-tumor activity of CS1003 was observed in multiple tumor types. We have initiated a global Phase III trial of CS1003 in combination with LENVIMA® (lenvatinib), a standard-of-care tyrosine kinase inhibitor (“TKI”) in patients with advanced hepatocellular carcinoma (“HCC”) and dosed the first patient in December 2019.
- Ivosidenib (CS3010) - In May 2019, an NDA for the isocitrate dehydrogenase-1 inhibitor TIBSOVO® (ivosidenib) has been submitted to the Taiwan Food and Drug Administration (“TFDA”) for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (“R/R AML”) containing an isocitrate dehydrogenase-1 mutation (“IDH1m”); marketing approval is expected in 2020. Two registrational trials in IDH1m AML are ongoing in China: one in IDH1m R/R AML, anticipating trial completion in 2020 and NDA submission in China by the first half of 2021; and another in newly diagnosed IDH1m AML patients who are not eligible for intensive therapy.
- Avapritinib (CS3007) – On January 9, 2020, the KIT/PDGFR4 inhibitor AYVAKIT™ (avapritinib) received U.S. Food and Drug Administration (“U.S. FDA”) approval for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (“GIST”) harboring a PDGFR4 exon 18 mutation, including PDGFR4 D842V mutations. As a result, we plan to submit an NDA in Taiwan in the first half of 2020 for this indication. Two registration trials for the avapritinib were initiated in China in patients with unresectable or metastatic GIST. One trial is a China pharmacokinetics bridging study for the indication of advanced GIST with a PDGFR4 exon 18 mutation. We expect the top-line results from the trial to become available and to submit an NDA in China in the first half of 2020. Another trial is conducted in third-line GIST as part of a global Phase III trial comparing avapritinib with regorafenib. Enrollment has been completed for this study and top-line results from the global trial are expected to be available in the second quarter of 2020 with NDA submission in China in the second half of 2020.
- Pralsetinib (CS3009) - As part of a global pivotal Phase I/II trial of pralsetinib, an investigational RET inhibitor, for the treatment of RET-altered NSCLC, medullary thyroid cancer (“MTC”), and other advanced solid tumors, we have completed enrollment in China for the cohort study for the indication of RET fusion-positive NSCLC as a second-line treatment and expect an NDA submission for this indication in China in the second half of 2020. Furthermore, we have initiated an additional registrational cohort for first-line RET fusion-positive NSCLC and expect to dose the first patient in the first half of 2020.

#### **Early-stage assets:**

- Novel combinations—With combination therapy as a core strategy and the unique advantage of leveraging our 3 IO backbone agents (anti-PD-L1, anti-PD-1, and anti-CTLA4), a total of six combinations with assets from our internal pipeline and external partners are in development: i) CS1002 (CTLA-4 antibody) plus CS1003 (PD-1 antibody), with the first patient dosed in January 2020; ii) CS1001 with fisogatinib (CS3008; FGFR4 inhibitor) in HCC; iii) CS1001 with regorafenib; iv) CS1003 with regorafenib; all with first-patient-dosed achieved in December 2019; and two other combination studies planned, including v) CS1001 with a PARP inhibitor (IMP4297); and vi) CS1001 with a multi-kinase inhibitor (donafenib).

- Other early-stage assets—We have also made significant headway on other early clinical-stage programs including CS3005 (A2aR antagonist), CS3002 (CDK4/6 inhibitor), CS3003 (HDAC6 inhibitor) and CS3006 (MEK inhibitor). In January 2020, we dosed the first patient for CS3002 and CS3005 in the respective phase I studies.

**Business development and other key activities:**

- We have continued to enhance our value through external collaborations with global leading biotechs and biopharmaceutical companies.
  - In May 2019, we entered into a global clinical collaboration with Bayer HealthCare LLC (“**Bayer**”) to evaluate CS1001 in combination with Bayer’s oral multi-kinase inhibitor Stivarga® (regorafenib) (targeting VEGFR, KIT, RET, BRAF, FGFR and CSF1R, etc.), as a treatment for multiple types of cancer including gastric cancer. In December 2019, the first patient was dosed in a Phase Ib trial of CS1001 in combination with regorafenib.
  - In April 2019, we entered into an exclusive regional licensing agreement with Numab Therapeutics AG (“**Numab**”) for the development and commercialization of NM21-1480 (ND021), a potential best-in-class monovalent, tri-specific antibody-based molecule targeting PD-L1, 4-1BB, and human serum albumin. The agreement provides us exclusive rights to develop and commercialize NM21-1480 in Greater China, South Korea and Singapore and can potentially provide us with access to Numab’s novel multi-specific technology platform.
- Moving forward, we will focus on pursuing strategic partnership that will accelerate CStone value creation.
- In March 2019, we appointed four internationally-renowned oncologists: Paul A. Bunn, Jr., MD, Elizabeth M. Jaffee, MD, Weiping Zou, MD, Ph.D. and Richard S. Finn, MD, as members of our Scientific Advisory Board. The addition of these four experts will considerably augment our public profile in the oncology field and provide valuable insights into our R&D strategies and processes.
- In August 2019, we entered into an agreement (with a state-owned enterprise under the Suzhou Industrial Park) to build an approximately 100,000 square meters R&D center and manufacturing facility in the Suzhou Industrial Park for large and small molecule drug development and commercial production. We expect the construction of the facility to commence in the first half of 2020.
- In October 2019, we entered into an agreement with Jiangsu Industrial Technology Research Institute (江蘇省產業技術研究院)(JITRI) and formed JITRI-CStone Innovation Center to further promote a two-way collaboration with industry partners and innovation centers in China and around the world.
- In December 2019, Ms. Shirley Zhao, MD, MBA, joined us as the General Manager for Greater China and Head of Commercial to lead and scale up a full-fledged commercial organization. Ms. Zhao will be responsible for continuing to scale up the commercial team and infrastructure in preparation for multiple product launches in mainland China, Hong Kong and Taiwan over the next two years. Upon regulatory approval, we expect to launch ivosidenib by the end of 2020 and avapritinib in 2021 in Taiwan, and to launch avapritinib, pralsetinib and CS1001 (PD-L1 antibody) in 2021 in mainland China with well-established local operation.

## MANAGEMENT DISCUSSION AND ANALYSIS

### OUR VISION

Our vision is to become globally recognized as a leading Chinese biopharmaceutical company by bringing innovative and differentiated oncology therapies to cancer patients worldwide.

### OVERVIEW

Founded in 2015, we are a clinical-stage biopharmaceutical company focused on developing and commercializing innovative immuno-oncology and molecularly targeted drugs to address significant unmet medical needs in cancer treatment. The Company has built an oncology-focused pipeline of 15 drug candidates with a strategic emphasis on IO combination therapies, including our three IO backbone drug candidates (PD-L1, PD-1, and CTLA-4 antibodies) at clinical stage. Currently, five late-stage candidates are in pivotal trials. We believe that our pipeline has both the scale and mix to enable a winning combination therapy strategy and allows us to develop one of the largest oncology combination therapy portfolios among all China-based biopharmaceutical companies. For details of any of the foregoing, please refer to the rest of this announcement and, where applicable, the Prospectus and prior announcements published on the websites of the Stock Exchange and the Company.

Our core product candidate, CS1001, is a fully human, full-length anti-PD-L1 monoclonal antibody. CS1001 mirrors natural G-type immune globulin 4 (IgG4) human antibody, which can reduce the risk of immunogenicity and potential toxicities in patients, potentially representing a unique advantage over similar drugs. To complement our IO backbone drug candidates, we obtained exclusive licenses from Agios Pharmaceuticals, Inc. (NASDAQ: AGIO) (“**Agios**”) for ivosidenib (CS3010) and Blueprint Medicines Corporation (NASDAQ: BPMC) (“**Blueprint Medicines**”) for avapritinib (CS3007), pralsetinib (CS3009), and fisogatinib (CS3008) to develop and commercialize the four molecularly targeted compounds in Greater China. All four compounds have achieved proof-of-concept for their lead indications based on clinical data from the respective global trials. The U.S. FDA approved TIBSOVO® (ivosidenib) in July 2018 as the first treatment of IDH1m R/R AML in its class globally. Avapritinib is also the first drug candidate in its class globally for the treatment targeting PDGFRA D842V mutations and the U.S. FDA approved AYWAKIT™ (avapritinib) for the treatment of adults with unresectable or metastatic GIST harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutations in January 2020. Pralsetinib (CS3009) and fisogatinib (CS3008) each has the potential to be a first-in-class precision therapy option globally.



## **Business Review**

We have made significant progress with respect to our product pipeline and presented key data for our PD-L1 (CS1001) monoclonal antibody in esophageal cancer, gastric cancer, cholangiocarcinoma, microsatellite instable high and NKTL and Phase I clinical data for PD-1 (CS1003) and CTLA-4 (CS1002) monoclonal antibodies at CSCO, ESMO and ASH in the second half of 2019.

## **Late-stage Product Candidate**

### ***CS1001 (PD-L1 antibody)***

- Our core product candidate, CS1001, is an investigational monoclonal antibody directed against programmed cell death ligand 1 (PD-L1) that is currently being investigated in pivotal clinical trials in China. As a fully-human, full-length anti-PD-L1 monoclonal antibody, CS1001 mirrors 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 December 31, 2019, we have dosed more than 1,100 patients in CS1001's clinical trials.
- Several pivotal studies are underway for CS1001, focusing primarily on specific tumor types that are prevalent in China:
  - Two Phase II registrational clinical trials of CS1001 as monotherapy for the treatment of cHL and NKTL respectively. We expect to submit an NDA for cHL in the second half of 2020 if the data meet the National Medical Products Administration (“NMPA”) requirements. We presented promising clinical data for NKTL at the annual meeting of ASH in December 2019. We are consulting with the NMPA regarding NDA criteria for the indication of NKTL and expect to submit an NDA in 2020 if the data meet the NMPA requirements;
  - A Phase III trial of CS1001 in patients with Stage III NSCLC as monotherapy in the maintenance setting following chemoradiation;

- A Phase III trial of CS1001 in combination with standard-of-care chemotherapies in patients with first-line Stage IV squamous or non-squamous NSCLC. We expect enrollment completion in the first half and top-line results to be available in the second half of 2020;
  - A Phase III trial of CS1001 in combination with standard-of-care chemotherapies for first-line treatment in patients with unresectable or metastatic gastric cancer; and
  - A Phase III trial of CS1001 in combination with standard-of-care chemotherapies for first-line treatment in patients with unresectable or metastatic esophageal cancer.
- To capitalize on the significant market opportunity in China, we are strategically developing combination therapies of CS1001 with candidates from our internal pipeline and external partners: (i) in December 2019, the first patient was dosed in a Phase Ib trial of CS1001 in combination with regorafenib in Australia; (ii) in December 2019, the first patient was dosed in a Phase I trial of CS1001 in combination with fisogatinib (CS3008) for the treatment of patients with HCC in China; (iii) in December 2019, a Phase Ib trial of CS1001 in combination with IMP4297 was initiated in Australia in collaboration with IMPACT; and (iv) in 2020, a Phase I/II trial of CS1001 in combination with donafenib is planned to be initiated in China in collaboration with Suzhou Zelgen Biopharmaceuticals Co., Ltd..

**Cautionary Statement required by Rule 18A.05 of the Listing Rules:** WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CS1001 SUCCESSFULLY.

### ***CS1003 (PD-1 antibody)***

We completed the dose escalation part of a Phase I trial of CS1003 (PD-1 antibody) as monotherapy in patients with advanced solid tumors in Australia and we received IND clearance from the U.S. FDA in October 2018 to expand this trial to the United States. We also completed a bridging Phase I trial of CS1003 in patients with advanced tumors in China. We presented preliminary Phase Ia data of CS1003 monotherapy at the 2019 CSCO meeting and showed that CS1003 was safe and tolerable. Preliminary anti-tumor activity of CS1003 was observed in multiple tumor types. We have initiated a global Phase III registrational trial of CS1003 in combination with LENVIMA<sup>®</sup> (lenvatinib), a standard-of-care TKI therapy in patients with advanced HCC in the second half of 2019. In addition, we dosed the first patient in a Phase Ib trial of CS1003 in combination with regorafenib in Australia in December 2019.



### ***Ivosidenib (CS3010; IDH1 inhibitor)***

We obtained an exclusive license from Agios for further clinical development and commercialization of ivosidenib in mainland China, Hong Kong, Macau, and Taiwan in June 2018. In May 2019, an NDA for ivosidenib was submitted to the TFDA for the treatment of adult patients with R/R AML containing an IDH1m; marketing approval is expected in 2020. Two registrational trials in IDH1m AML are ongoing in China: one in IDH1m R/R AML, anticipating trial completion in 2020 and NDA submission in China by the first half of 2021; and another in newly diagnosed IDH1m AML patients who are not eligible for intensive therapy.

### ***Avapritinib (CS3007; KIT/PDGFR $\alpha$ inhibitor)***

We obtained an exclusive license from Blueprint Medicines for the development and commercialization of avapritinib in mainland China, Hong Kong, Macau, and Taiwan in June 2018. On January 9, 2020, our partner, Blueprint Medicines, announced that the U.S. FDA approved avapritinib for the treatment of adults with unresectable or metastatic GIST harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutations. As a result, we plan to file an NDA in Taiwan in the first half of 2020 for this indication. In April 2019, we received the approval from the NMPA to start a China pharmacokinetics bridging study of avapritinib for the indication of unresectable or metastatic GIST with a PDGFRA exon 18 mutation, dosed the first patient in August 2019, and completed enrollment in October 2019. We expect the top-line results from the trial to become available and to submit an NDA in China in the first half of 2020. As part of a global Phase III trial for the indication of third-line GIST comparing avapritinib with regorafenib, we dosed the first patient in China in July 2019 and the completion of global trial enrollment was announced in November 2019. We expect the global top-line results to be available in the second quarter of 2020 and to submit an NDA in China for the treatment of third line GIST in the second half of 2020. We also plan to communicate with the NMPA on a potential trial waiver of avapritinib for the treatment of advanced SM using foreign data from the PATHFINDER study.

### ***Pralsetinib (CS3009; RET inhibitor)***

We obtained an exclusive license from Blueprint Medicines for the development and commercialization of pralsetinib in mainland China, Hong Kong, Macau, and Taiwan in June 2018. We received clinical trial application (“CTA”) approval from the NMPA in March 2019 to join a global Phase I/II clinical trial of pralsetinib in patients with RET-altered NSCLC, MTC and other advanced solid tumors, and dosed the first patient in August 2019 to generate pharmacokinetics, safety and efficacy data for NDA submission in China. We dosed the last patient for the cohort study for the indication of RET fusion-positive NSCLC as a second-line treatment in October 2019. We expect to submit an NDA in China for this indication in the second half of 2020. Furthermore, in August 2019, the NMPA approved our supplemental CTA for the first-line treatment of RET fusion-positive NSCLC in the same study. We expect to dose the first patient for this registrational study in the first half of 2020.

## Other Clinical or IND-stage Candidates

- Fisogatinib (CS3008; FGFR4 inhibitor) - We obtained an exclusive license from Blueprint Medicines for the development and commercialization of fisogatinib in mainland China, Hong Kong, Macau, and Taiwan in June 2018. Fisogatinib is currently being evaluated by Blueprint Medicines in an ongoing Phase I trial in patients with advanced HCC. Preliminary data have indicated that fisogatinib may offer an effective treatment option for certain HCC patients. In January 2019, we received IND approval for fisogatinib from the NMPA to join the dose-expansion portion of the global Phase I trial. We dosed the first patient in May 2019 and completed enrollment in December 2019. In addition, we received CTA approval from the NMPA in May 2019 to start a Phase I trial of fisogatinib in combination with CS1001 (PD-L1 antibody) in patients with HCC, and dosed the first patient in December 2019.
- CS1002 (CTLA-4 antibody) - We have completed the dose escalation part of a Phase I trial of CS1002 as a single agent in patients with advanced solid tumors in Australia. We presented preliminary Phase I data of CS1002 at the 2019 CSCO meeting and showed that CS1002 treatment was well-tolerated and demonstrated pharmacodynamic changes consistent with CTLA-4 inhibition. The first patient was dosed for the dose escalation part of the Phase I clinical trial of CS1002 in combination with CS1003 (PD-1 antibody) for the treatment of patients with solid tumors in Australia in January 2020. In addition, we have received IND approval for CS1002 from the NMPA in August 2018 and the first patient was dosed in a Phase I trial of CS1002 in China in December 2019.
- CS3006 (MEK inhibitor) - We are conducting Phase I clinical trials of CS3006 (MEK inhibitor) as a single agent in Australia and China.
- CS3003 (HDAC6 inhibitor) - We received IND/CTA approvals for CS3003 (HDAC6 inhibitor) in China and Australia in March 2019 and April 2019 respectively.
- CS3002 (CDK4/6 inhibitor) - The first patient was dosed in January 2020 in a Phase I trial of CS3002 as a single agent for the treatment of patients with solid tumors in Australia and China. Subsequently, we plan to initiate a combination study with an immune checkpoint inhibitor in 2021.
- CS3005 (A2aR antagonist) - The first patient was dosed in January 2020 in a Phase I trial of CS3005 as a single agent for the treatment of patients with solid tumors in Australia and China. Subsequently, we plan to initiate a combination study with an immune checkpoint inhibitor in 2021.

## Selected Pre-clinical Candidate

- CS1009 (another immune checkpoint inhibitor) - We are conducting preclinical studies to support IND/CTA applications of CS1009 and plan to submit the applications in China in 2020.
- NM21-1480 (PD-L1 × 4-1BB × HSA tri-specific antibody) - We plan to submit IND application of NM21-1480, a PD-L1 × 4-1BB × HSA tri-specific antibody we licensed from Numab, in Taiwan in the first half of 2020 and conduct a Phase I trial of NM21-1480 for the treatment of patients with solid tumors as a monotherapy in the second half of 2020.

## RESEARCH AND DEVELOPMENT

We focus on the research and development of innovative immuno-oncology and molecularly targeted drugs for the treatment of cancer. Our drug discovery and pre-clinical research team conducts drug discovery, formulation development, process development, and pre-clinical research of new drug candidates. As of December 31, 2019, we had submitted 26 IND/CTA applications for ten drug candidates and obtained 16 IND/CTA approvals for ten drug candidates, including eight from NMPA (China) for CS1001 combo (PD-L1 antibody), CS3003 (HDAC6 inhibitor), CS3007 (avapritinib), CS3008 (FGFR4 inhibitor), CS3009 (pralsetinib) and CS3010 (ivosidenib), and six from TGA (Australia) for CS1001 combo (PD-L1 antibody), CS1002 combo (CTLA-4 antibody), CS3002 (CDK4/6 inhibitor), CS3003 (HDAC6 inhibitor) and CS3005 (A2aR antagonist), and one from TFDA (Taiwan) for CS1001 combo (PD-L1 antibody), and one from MedSafe (New Zealand) for CS1003 (PD-1 antibody). We also submitted one NDA application for ivosidenib to TFDA, and was granted Priority Review designation and Bridging Study Evaluation trial waiver. Our research team will continue to advance the pre-clinical drug candidates in our pipeline towards IND. We plan to submit IND/CTA for CS1002/CS1003 combo, CS1009 (IO target) and NM21-1480 (PD-L1/4-1BB/HSA antibody), and NDA for avapritinib (CS3007), pralsetinib (CS3009) and CS1001 (PD-L1 antibody) in 2020.

Our current clinical development activities mainly relate to the clinical advancement of our 11 clinical and IND stage drug candidates. As at December 31, 2019, we have initiated 28 clinical trials, including six registrational trials for our core product candidate, CS1001 (PD-L1 antibody), one registrational trial for CS1003 (PD-1) and six registrational/registration enabling trials for three licensed-in products (ivosidenib, avapritinib and pralsetinib). By the end of 2020, we expect to have more than 30 ongoing and/or completed trials in China and globally.

We have announced our strategy of Pipeline 2.0 in October 2019 on our Suzhou R&D day. We will focus on developing first-in-class molecules to target novel biology, tumor microenvironment, multi-specific biologics, and cancer vaccines.

Our research and development expenses on non-IFRS basis were approximately RMB727 million and RMB1,189 million for the year ended December 31, 2018 and December 31, 2019 respectively. As of December 31, 2019, we had filed 13 patent applications in China under the Patent Cooperation Treaty, or PCT, for material intellectual properties.

## **BUSINESS DEVELOPMENT**

In May 2019, we entered into a global clinical collaboration with Bayer to evaluate the safety, tolerability, pharmacokinetics and antitumor activity of our PD-L1 monoclonal antibody drug CS1001 in combination with Bayer's oral multi-kinase inhibitor Stivarga® (regorafenib) (targeting VEGFR, KIT, RET, BRAF, FGFR and CSF1R, etc.), as a treatment for multiple types of cancer including gastric cancer. This is the first global proof of concept study carried out as a collaboration between the two companies. CStone will be the study sponsor and Bayer will provide regorafenib throughout the clinical trial program. In December 2019, the first patient was dosed in a Phase Ib trial of CS1001 in combination with regorafenib.

In April 2019, we entered into an exclusive regional licensing agreement with Numab that potentially provides us with access to Numab's novel multi-specific technology platform. Specifically, the agreement is for the development and commercialization of NM21-1480, a potential best-in-class monovalent, tri-specific antibody-based molecule targeting PD-L1, 4-1BB, and human serum albumin. The Company will fund the research and development of NM21-1480 up to completion of an initial Phase Ib clinical trial pursuant to the terms of the licensing agreement dated April 26, 2019. In exchange, we obtained exclusive rights to develop and commercialize NM21-1480 in Greater China (including mainland China, Hong Kong, Macau and Taiwan), South Korea and Singapore without further financial obligations.

## **EVENTS AFTER THE REPORTING PERIOD**

Since the outbreak of the novel coronavirus (“**COVID-19**”), the Company has adopted immediate measures to maintain effective and high-quality level of operation. We are proactively managing the progress of ongoing trials to ensure that study protocols are followed and no significant disruptions will affect delivery of the results.

In an upcoming general meeting, the Shareholders would be presented a resolution to approve the granting of share options to Dr. Frank Ningjun Jiang details of which was disclosed in the announcement of the Company on August 15, 2019, pursuant to Rule 17.03(4) of the Listing Rules.

## **FUTURE AND OUTLOOK**

Our business model is designed to accelerate the development of innovative drugs. We focus on clinical development, which has long been a bottleneck in the innovative drug development value chain in China, through both adaptive clinical trial design and clinical trial operational excellence.

Leveraging our strong internal research capabilities, we continue to identify and develop new drug candidates to advance to clinical stage. We will continue to advance our five pre-clinical assets towards the IND stage and develop new internal assets through our in-house research capability and collaboration with top academic institutions and world-leading CROs.

Looking into 2020, we expect to receive NDA approval for TIBSOVO® in R/R AML in Taiwan and submit 5 NDAs for PD-L1, avapritinib and pralsetinib in mainland China and/or Taiwan. We expect up to 7 key data readouts, including PD-L1 in stage III and stage IV NSCLC registrational trial, stage IV NSCLC squamous and non-squamous Ph Ib trial, avapritinib in third-line GIST and PDFGRA exon 18 GIST, and pralsetinib in second-line NSCLC and first-line MTC.

With the expected NDA approvals above, and strong commercial capability buildup by acquiring top talents in Greater China market, we are confident in maximizing the commercial potential of our 5 late-stage clinical drug candidates with worldwide or Greater China rights. We expect to launch ivosidenib in Taiwan in the second half of 2020 and several other drugs in China in 2021. We will focus on internal salesforce buildup while exploring potential value-creative strategic partnerships both in China and globally. With clear and aspirational commercial strategy established, we will build a strong full-fledged commercial team of approximately 200 by year-end 2020 and be commercially ready with robust launch plans developed for mainland China and Taiwan. With our deep understanding of local market business environment, we will develop robust market access strategy to address the unmet medical needs in China. We will enhance public relations and digital marketing activities to build up corporate and product branding. We further enhance engagement of key opinion leaders and cancer society. These will be supported by operation and commercial excellence, as well as talent acquisition and people development activities.

## FINANCIAL INFORMATION

The Board announces the consolidated audited results of the Group for the year ended December 31, 2019, with comparative figures for the corresponding period in the previous year as follows:

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

	NOTES	For the year ended December 31,	
		2019 RMB'000	2018 RMB'000 (restated)
Other income	4	83,962	20,497
Other gains and losses	4	(637,365)	(741,979)
Research and development expenses		(1,395,624)	(850,197)
Administrative expenses		(341,476)	(190,991)
Listing expenses		(17,638)	(30,459)
Finance costs		(303)	–
Loss for the year	5	<u>(2,308,444)</u>	<u>(1,793,129)</u>
<b>Other comprehensive (expense) income:</b>			
<i>Items that may be reclassified subsequently to profit or loss:</i>			
Exchange differences arising on translation of foreign operations		(1,802)	–
Fair value gain on investments in debt instruments measured at fair value through other comprehensive income (“FVTOCI”)		408	3,125
Reclassified to profit or loss upon disposal of debt instruments at FVTOCI		(758)	(1,298)
Other comprehensive (expense) income for the year		<u>(2,152)</u>	<u>1,827</u>
Total comprehensive expense for the year		<u><u>(2,310,596)</u></u>	<u><u>(1,791,302)</u></u>

		<b>For the year ended</b>	
		<b>December 31,</b>	
	<i>NOTES</i>	<b>2019</b>	2018
		<b>RMB'000</b>	<b>RMB'000</b>
			(restated)
Loss for the year attributable to:			
Owners of the Company			
– ordinary shareholders		(2,068,740)	(469,830)
– preferred shareholders		(239,704)	(1,275,447)
		<u>(2,308,444)</u>	<u>(1,745,277)</u>
Non-controlling interests		–	(47,852)
		<u>(2,308,444)</u>	<u>(1,793,129)</u>
Total comprehensive expense for the year attributable to:			
Owners of the Company			
– ordinary shareholders		(2,070,824)	(469,338)
– preferred shareholders		(239,772)	(1,274,112)
		<u>(2,310,596)</u>	<u>(1,743,450)</u>
Non-controlling interests		–	(47,852)
		<u>(2,310,596)</u>	<u>(1,791,302)</u>
<b>Loss per share</b>			
Basic ( <i>RMB Yuan</i> )	7	<u>(2.39)</u>	<u>(2.79)</u>
Diluted ( <i>RMB Yuan</i> )		<u>(2.39)</u>	<u>(2.79)</u>

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	<i>NOTES</i>	<b>As at December 31,</b>	
		<b>2019</b>	<b>2018</b>
		<b>RMB'000</b>	<b>RMB'000</b>
<b>Non-current assets</b>			
Property, plant and equipment		14,185	14,473
Right-of-use assets		4,469	–
Deposits for acquisition of property, plant and equipment and intangible assets		3,572	58
Other intangible assets		1,305	897
Other receivables	9	40,271	11,742
		<u>63,802</u>	<u>27,170</u>
<b>Current assets</b>			
Deposits, prepayments and other receivables	9	143,599	46,984
Other investments classified as financial assets measured at fair value through profit or loss (“FVTPL”)		11,946	16,792
Debt instruments at FVTOCI		4,811	78,620
Restricted bank deposit		620	–
Time deposits		1,599,431	761,216
Cash and cash equivalents		1,126,436	701,336
		<u>2,886,843</u>	<u>1,604,948</u>
<b>Current liabilities</b>			
Trade and other payables and accrued expenses	10	449,440	93,574
Deferred income		4,180	–
Lease liabilities		4,344	–
Derivative financial liabilities	11	–	1,015,648
		<u>457,964</u>	<u>1,109,222</u>
<b>Net current assets</b>		<u>2,428,879</u>	<u>495,726</u>
<b>Total assets less current liabilities</b>		<u>2,492,681</u>	<u>522,896</u>
<b>Non-current liabilities</b>			
Deferred income		11,099	7,565
<b>Net assets</b>		<u>2,481,582</u>	<u>515,331</u>
<b>Capital and reserves</b>			
Ordinary share capital		687	29
Preferred share capital	11	–	94
Treasury shares held in the trusts		(30)	–
Reserves		2,480,925	515,208
<b>Total equity</b>		<u>2,481,582</u>	<u>515,331</u>



## NOTES

### 1. BASIS OF PREPARATION

The consolidated financial statements have been prepared in accordance with the accounting policies which conform to International Financial Reporting Standards (“IFRSs”) issued by International Accounting Standards Board (the “IASB”). In addition, the consolidated financial statements include applicable disclosures required by the Listing Rules and by the Hong Kong Companies Ordinance.

Other than changes in accounting policies resulting from application of new and amendments to IFRSs, the accounting policies and methods of computation used in the consolidated financial statements for the year ended December 31, 2019 are the same as those presented in the Group’s annual financial statements for the year ended December 31, 2018.

### 2. PRINCIPAL ACCOUNTING POLICIES

In the current year, the Group has applied, for the first time, the following new and amendments to IFRSs which are mandatory effective for the annual period beginning on or after January 1, 2019 for the preparation of the Group’s consolidated financial statements:

IFRS 16	<i>Leases</i>
IFRIC 23	<i>Uncertainty over Income Tax Treatments</i>
Amendments to IAS 19	<i>Plan Amendment, Curtailment or Settlement</i>
Amendments to IAS 28	<i>Long-term Interests in Associates and Joint Ventures</i>
Amendments to IFRSs	<i>Annual Improvements to IFRSs 2015–2017 Cycle</i>

On transition, the Group has made the following adjustments upon application of IFRS 16:

As at January 1, 2019, the Group recognized additional lease liabilities and right-of-use assets at amounts equal to the related lease liabilities adjusted by any prepaid rent by applying IFRS 16.C8(b)(ii) transition. Any difference at the date of initial application is recognized in the opening accumulated losses and comparative information has not been restated.

The Group recognized lease liabilities of RMB5,942,000 and right-of-use assets of RMB6,229,000 on January 1, 2019.

When recognizing the lease liabilities for leases previously classified as operating leases, the Group has applied incremental borrowing rates of the relevant group entities at the date of initial application. The weighted average incremental borrowing rate applied by the relevant group entities range from 4.89% to 5.34%.

	<b>As at January 1, 2019</b> <i>RMB’000</i>
Operating lease commitments disclosed as at December 31, 2018	9,048
Lease liabilities discounted at relevant incremental borrowing rates	7,828
Less: Practical expedient—leases with lease term ending within 12 months from the date of initial application	(1,671)
Recognition exemption—low value assets (excluding short-term leases of low value leases)	(215)
Lease liabilities relating to operating leases recognized upon application of IFRS 16 as at January 1, 2019	<u>5,942</u>
Analyzed as	
Current	3,351
Non-current	<u>2,591</u>
	<u>5,942</u>

The carrying amount of right-of-use assets as at January 1, 2019 comprises the following:

	<i>Notes</i>	<b>Right-of-use assets</b> <i>RMB'000</i>
Right-of-use assets relating to operating leases recognized upon application of IFRS 16		5,942
Reclassified from prepaid rent	<i>(a)</i>	223
Adjustments on rental deposits as at January 1, 2019	<i>(b)</i>	64
		<u>6,229</u>
By class:		
Lease properties		6,016
Motor vehicles		213
		<u>6,229</u>

The following adjustments were made to the amounts recognized in the consolidated statement of financial position as at January 1, 2019. Line items that were not affected by the changes have not been included.

	<i>Notes</i>	<b>Carrying amounts previously reported at December 31, 2018</b> <i>RMB'000</i>	<b>Adjustments</b> <i>RMB'000</i>	<b>Carrying amounts under IFRS 16 as at January 1, 2019</b> <i>RMB'000</i>
<b>Non-current Assets</b>				
Right-of-use assets		–	6,229	6,229
Other receivables				
– Rental deposits paid	<i>(b)</i>	1,798	(64)	1,734
<b>Current Assets</b>				
Deposits, prepayments and other receivables				
– Prepaid rent	<i>(a)</i>	223	(223)	–
<b>Current Liabilities</b>				
Lease liabilities		–	3,351	3,351
<b>Non-current Liabilities</b>				
Lease liabilities		–	2,591	2,591
		<u>–</u>	<u>2,591</u>	<u>2,591</u>

- (a) Prepaid rent for office premises was classified as prepayment as at December 31, 2018. Upon application of IFRS 16, the prepaid rent was reclassified as right-of-use assets.
- (b) Before the application of IFRS 16, the Group considered refundable rental deposits paid as rights and obligations under leases to which IAS 17 applied. Based on the definition of lease payments under IFRS 16, such deposits are not payments relating to the right to use the underlying assets and were adjusted to reflect the discounting effect at transition. Accordingly, RMB64,000 was adjusted from refundable rental deposits paid to right-of-use assets.

### 3. SEGMENT INFORMATION

The Group has been operating in one reportable segment, being the research and development of highly complex biopharmaceutical products. The Group's chief operating decision maker ("CODM") has been identified as the chief executive of the Group.

For the purpose of resource allocation and performance assessment, the CODM reviews the overall results and financial position of the Group as a whole prepared based on the same accounting policies.

#### Geographical information

Substantially, all of the Group's non-current assets and capital expenditure are located or utilized in the People's Republic of China (the "PRC").

### 4. OTHER INCOME AND OTHER GAINS AND LOSSES

#### Other income

	2019 <i>RMB'000</i>	2018 <i>RMB'000</i> (restated)
Bank and other interest income	67,287	7,947
Government grants income ( <i>note</i> )	16,675	12,550
	<u>83,962</u>	<u>20,497</u>

*Note:* Government grants include subsidies from the PRC government which are specifically for (i) the capital expenditure incurred for plant and machinery and is recognized over the useful life of the related assets; and (ii) the incentive and other subsidies for IPO, research and development activities which are recognized upon compliance with the attached conditions; and (iii) other government grants related to income that are receivable as compensation for expenses or losses already incurred or for the purpose of giving immediate financial support to the Group with no future related costs are recognized in profit or loss in the period in which they become receivable.

#### Other gains and losses

	2019 <i>RMB'000</i>	2018 <i>RMB'000</i> (restated)
Gain on fair value changes of other investments classified as financial assets measured at FVTPL	457	1,145
Changes in fair value of money market funds	7,265	11,605
Gain on disposal of debt instruments at FVTOCI	758	1,298
Loss on disposal of property, plant and equipment	(104)	–
Loss on fair value changes of derivative financial liabilities ( <i>note 11</i> )	(756,464)	(885,569)
Net foreign exchange gains	110,723	129,542
	<u>(637,365)</u>	<u>(741,979)</u>

*Note:* Comparative figures of changes in fair value of money market funds have been reclassified from other income to other gains and losses to conform to the current year's presentation as the directors of the Company consider that the new presentation is more relevant and appropriate to the consolidated financial statements.

## 5. LOSS FOR THE YEAR

	2019 <i>RMB'000</i>	2018 <i>RMB'000</i>
Loss for the year has been arrived at after charging:		
Depreciation of property, plant and equipment	6,397	5,105
Depreciation of right-of-use assets	4,890	–
Amortization of other intangible assets	293	161
	<hr/>	<hr/>
Total depreciation and amortization	11,580	5,266
Directors' emoluments	167,245	141,294
Other staff costs:		
Salaries and other allowances	129,198	52,576
Performance related bonus	31,749	7,158
Retirement benefit scheme contributions	18,643	7,667
Share-based payment expenses	250,659	100,577
	<hr/>	<hr/>
Total staff costs	597,494	309,272
Auditors' remuneration	1,900	563
Minimum lease payments under operating leases in respect of office premises	–	3,752
	<hr/> <hr/>	<hr/> <hr/>

## 6. INCOME TAX EXPENSE

The Company is tax exempt under the laws of the Cayman Islands.

On 21 March 2018, the Hong Kong Legislative Council passed The Inland Revenue (Amendment) (No.7) Bill 2017 (the “**Bill**”), which introduces the two-tiered profits tax rates regime. The Bill was signed into law on 28 March 2018 and was gazetted on the following day. Under the two-tiered profits tax rates regime, the first HK\$2 million of profits of the qualifying group entity will be taxed at 8.25%, and profits above HK\$2 million will be taxed at 16.5%. No Hong Kong profit tax was provided for as there was no estimated assessable profit of CStone Pharm (HK) Holding Limited (“**CStone HK**”, formerly known as CStone Pharmaceuticals Limited) that was subject to Hong Kong profit tax during the reporting period.

Under the law of the PRC on Enterprise Income Tax (the “**EIT Law**”) and implementation regulations of the EIT Law, the tax rate of the Company's PRC subsidiaries is 25% for both years.

Under the Treasury Law Amendment (Enterprise Tax Plan Base Rate Entities) Bill 2017 of Australia, corporate entities who qualify a small business entity are eligible for the lower corporate tax rate at 27.5%. CStone Pharmaceuticals Australia Pty, Ltd. is qualified as small business entity and is subject to a corporate tax rate of 27.5% for both years.

As at December 31, 2019, the Group has unused tax losses of approximately RMB2,577 million (2018: RMB1,139 million) available for offset against future profits. No deferred tax asset has been recognized in respect of the tax losses due to the unpredictability of future profit streams.

As at December 31, 2019, the Group has deductible temporary differences related to government grants income of RMB15.3 million (2018: RMB7.6 million). No deferred tax asset has been recognized in relation to such deductible temporary differences as it is not probable that taxable profit will be available against which the deductible temporary differences can be utilized.

## 7. LOSS PER SHARE

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

	2019 <i>RMB'000</i>	2018 <i>RMB'000</i>
<b>Loss</b>		
Loss for the year attributable to owners of the Company	(2,308,444)	(1,745,277)
Add: Loss attributable to preferred shareholders	<u>239,704</u>	<u>1,275,447</u>
Loss for the purpose of basic and diluted loss per share	<u><u>(2,068,740)</u></u>	<u><u>(469,830)</u></u>
<b>Number of shares</b>		
Weighted average number of ordinary shares for the purpose of basic and diluted loss per share	<u><u>866,728,184</u></u>	<u><u>168,583,668</u></u>

The weighted average number of ordinary shares for the purpose of calculating basic loss per share for the year has been determined on the assumption that the capitalization issue had been effective since January 1, 2018.

During the year ended December 31, 2019, the calculation of basic and diluted loss per share has considered the restricted share units that have been vested but not yet registered but excluded the treasury shares held in trust of the Company.

The calculation of diluted loss per share has not considered share options awarded under the employee stock option, the unvested restricted share units, the conversion of Preferred Shares and over-allotment options as their inclusion would be anti-dilutive.

## 8. DIVIDENDS

No dividend was paid nor declared by the Company during the years ended December 31, 2019 and 2018, nor has any dividend been proposed since the end of the reporting period.

## 9. DEPOSITS, PREPAYMENTS AND OTHER RECEIVABLES

	2019 <i>RMB'000</i>	2018 <i>RMB'000</i>
Rental deposits ( <i>note a</i> )	2,840	1,798
Prepayments	41,835	34,091
Other receivables	496	1,284
Receivables from a director and key management personnels of the Company ( <i>note b</i> )	96,977	1,391
Value-added tax recoverable	41,722	11,850
Deferred issue costs	<u>–</u>	<u>8,312</u>
	<u><u>183,870</u></u>	<u><u>58,726</u></u>
Analyzed as:		
Non-current	40,271	11,742
Current	<u>143,599</u>	<u>46,984</u>
	<u><u>183,870</u></u>	<u><u>58,726</u></u>

Notes:

- (a) Rental deposits were adjusted upon the initial application of IFRS 16. Details of the adjustment are set out in note 2.
- (b) As at December 31, 2019, the balances mainly represents the amounts due from Dr. Jiang and several key managements in respect of withholding tax for employee individual income tax associated with vested restricted share units. Subsequent to the year end, RMB59,162,000 was collected from Dr. Jiang and the remaining balances was accounted for as deduction from equity for shares withheld upon the modification of Pre-IPO Incentivization Plan in January 2020 which permit the Company to withhold the number of equity instruments equal to the monetary value of the employee's tax obligation from the total number of equity instruments that otherwise would have been issued to the employee upon vesting of the share awards. As at December 31, 2018, the balance represents receivables form Dr. Jiang and it is unsecured, interest-free and repayable on demand. The maximum outstanding balance of amount due from Dr. Jiang during the year ended December 31, 2019 is RMB59,162,000 (2018: RMB1,391,000).

## 10. TRADE AND OTHER PAYABLES AND ACCRUED EXPENSES

	2019 <i>RMB'000</i>	2018 <i>RMB'000</i>
Trade payables	37,304	4,559
Accrued expenses		
– Research and development ( <i>note a</i> )	270,099	43,012
– Legal and professional fees	3,723	1,742
– Issue costs and listing expenses	–	27,270
– Others	8,121	2,131
	<u>281,943</u>	<u>74,155</u>
Other payables	2,131	1,801
Other tax payable ( <i>note b</i> )	97,589	1,570
Payables in respect of acquisition of property, plant and equipment	–	340
Staff payroll payable	30,473	11,149
	<u>449,440</u>	<u>93,574</u>

Notes:

- (a) Amounts included service fees paid to outsourced service providers including CRO and outsourced service providers.
- (b) Amounts included withholding tax payable for employee's individual income tax associated with vested restricted share units of approximately RMB 96,845,000. The amounts was sub-sequently settled to the tax bureau in January 2020.

The credit period on trade purchase is 0 to 90 days. Aging analysis of the Group's trade payables based on the invoice dates at the end of the reporting period is as follows:

	2019 <i>RMB'000</i>	2018 <i>RMB'000</i>
Less than 30 days	26,471	4,331
31 – 60 days	10,833	–
61 – 90 days	–	84
Over 90 days	–	144
	<u>37,304</u>	<u>4,559</u>

## 11. PREFERRED SHARES

During the year ended December 31, 2016, the Company entered into share purchase agreements with several independent third party investors and issued Series A Preferred Share to the investors. Furthermore, during the year ended December 31, 2018, the Company issued Series B Preferred Shares to several independent third party investors and employees.

The par value per preferred share is US\$0.0001 and the difference between the par value and the subscription price less the fair value of conversion features at issuance of Preferred Shares is accounted for under the share premium.

All Series A and Series B Preferred Shares were automatically converted into 143,703,471 ordinary shares upon the successful IPO of the Company on February 26, 2019.

### Conversion features

The Preferred Shares are considered as equity instruments and are determined by deducting the fair value of the conversion features from the gross proceeds.

The Group has recognized the conversion features attached to the Preferred Shares as financial liabilities measured at FVTPL.

The change in fair value of the conversion features attached to the Preferred Shares is charged to profit or loss and is included in the loss on fair value changes of derivative financial liabilities under the “other gains and losses” line item. Management considered that there is no credit risk of the financial liabilities that drives the change of its fair value. As at February 26, 2019, the conversion features were valued by the directors of the Company with reference to valuation report carried out by an independent qualified professional valuer.

The Company used the back-solve method to determine the underlying share value of the Company and performed an equity allocation based on Binomial Option Pricing model (the “OPM model”) to arrive at the fair value of the conversion features.

The directors of the Company estimated the risk-free interest rate based on the yield of the United States Treasury Bonds with a maturity life close to the period from the respective valuation dates to the expected liquidation dates. Volatility was estimated on each valuation date based on average of historical volatilities of the comparable companies in the same industry for a period from the respective valuation dates to expected liquidation dates.

	At January 1, 2018 <i>RMB'000</i>	(Cancellation)/ Issuance <i>RMB'000</i>	Fair value changes <i>RMB'000</i>	At December 31, 2018 <i>RMB'000</i>	Fair value changes <i>RMB'000</i>	Automatic conversion of Preferred Shares upon IPO <i>RMB'000</i>	At December 31, 2019 <i>RMB'000</i>
Series A							
– Tranche 1	48,531	(55,724)	328,407	321,214	258,641	(579,855)	–
– Tranche 2	37,964	(100,087)	311,551	249,428	194,411	(443,839)	–
– Tranche 3	–	10,269	20,425	30,694	16,264	(46,958)	–
– Tranche 4	–	145,250	90,434	235,684	192,502	(428,186)	–
Series B	–	43,876	134,752	178,628	94,646	(273,274)	–
	<u>86,495</u>	<u>43,584</u>	<u>885,569</u>	<u>1,015,648</u>	<u>756,464</u>	<u>(1,772,112)</u>	<u>–</u>

## FINANCIAL REVIEW

	Year ended December 31,	
	2019	2018
	<i>RMB'000</i>	<i>RMB'000</i> (Restated)
Other income	83,962	20,497
Other gains and losses	(637,365)	(741,979)
Research and development expenses	(1,395,624)	(850,197)
Administrative expenses	(341,476)	(190,991)
Listing expenses	(17,638)	(30,459)
Finance costs	(303)	–
Loss for the year	<u>(2,308,444)</u>	<u>(1,793,129)</u>
<b>Other comprehensive (expense) income:</b>		
<i>Items that may be reclassified subsequently to profit or loss:</i>		
Exchange differences arising on translation of foreign operations	(1,802)	–
Fair value gain on investments in debt instruments at fair value through other comprehensive income (“FVTOCI”)	408	3,125
Reclassified to profit or loss upon redemption of debt instruments at FVTOCI	(758)	(1,298)
Other comprehensive (expense) income for the year	<u>(2,152)</u>	<u>1,827</u>
Total comprehensive expense for the year	<u><u>(2,310,596)</u></u>	<u><u>(1,791,302)</u></u>
<b>Non-IFRS measures:</b>		
Adjusted loss for the year	<u><u>(1,141,263)</u></u>	<u><u>(672,598)</u></u>

**Other Income.** Our other income increased by RMB63.5 million from RMB20.5 million for the year ended December 31, 2018 to RMB84.0 million for the year ended December 31, 2019. This was primarily attributable to the increase in interest income from bank deposits and time deposits.

**Other Gains and Losses.** Our other gains and losses decreased by RMB104.6 million from losses of RMB742.0 million for the year ended December 31, 2018 to losses of RMB637.4 million for the year ended December 31, 2019. The decrease in other losses was primarily attributable to a narrowed loss on fair value changes of derivative financial liabilities.

Such loss on the fair value changes of conversion features of Preferred Shares was a non-cash and non-recurring adjustment recognized as of Listing Date, as the fair value of the conversion features was deemed to be increased upon the completion of the IPO of the Company. As all the Preferred Shares were converted to ordinary shares upon the Listing Date, the Group will not incur any additional losses related to the fair value changes of the conversion features.



**Research and Development Expenses.** Our research and development expenses increased by RMB545.4 million from RMB850.2 million for the year ended December 31, 2018 to RMB1,395.6 million for the year ended December 31, 2019. This increase was primarily attributable to the combination impact of (i) additional trials which increased the clinical development costs. More specifically, third party contracting costs increased by RMB599.2 million from RMB323.1 million for the year ended December 31, 2018 to RMB922.3 million for the year ended December 31, 2019, while employee costs increased by RMB160.5 million from RMB177.4 million for the year ended December 31, 2018 to RMB337.9 million for the year ended December 31, 2019; and (ii) the decrease in payment of licensing fees by RMB214.9 million from RMB348.7 million for the year ended December 31, 2018 to RMB133.8 million for the year ended December 31, 2019, due to significant milestone payment incurred for the several collaboration and licensing agreements entered with third-party partners in the year ended December 31, 2018.

	<b>Year ended December 31,</b>	
	<b>2019</b>	<b>2018</b>
	<b>RMB'000</b>	<b>RMB'000</b>
Employee costs	337,857	177,437
Depreciation and amortization	1,190	938
Licensing fees	133,792	348,749
Third party contracting costs	922,250	323,073
Rental and management fee expense*	535	—
<b>Total</b>	<b>1,395,624</b>	<b>850,197</b>

\* Include short-term lease and lease of low value assets.

**Administrative Expenses.** Our administrative expenses increased by RMB150.5 million from RMB191.0 million for the year ended December 31, 2018 to RMB341.5 million for the year ended December 31, 2019. This was primarily attributable to an increase of RMB127.6 million in employee costs from RMB132.0 million for the year ended December 31, 2018 to RMB259.6 million for the year ended December 31, 2019.

	<b>Year ended December 31,</b>	
	<b>2019</b>	<b>2018</b>
	<b>RMB'000</b>	<b>RMB'000</b>
Employee costs	259,637	131,982
Professional fees	40,264	25,898
Rental and management fee expenses*	2,859	3,752
Depreciation and amortization	10,390	4,336
Others	28,326	25,023
<b>Total</b>	<b>341,476</b>	<b>190,991</b>

\* Include short-term lease and lease of low value assets.

**Finance Costs.** The RMB0.3 million finance costs during the year ended December 31, 2019 were attributable to the interest expenses on lease liabilities.

**Listing Expenses.** The RMB17.6 million listing expenses for the year ended December 31, 2019 were mainly attributable to legal and professional fees in relation to the IPO. We incurred listing expenses of RMB30.5 million for the year ended December 31, 2018.

**Other Comprehensive (Expense) Income.** Our other comprehensive (expense) income changed from income of RMB1.8 million for the year ended December 31, 2018 to expense of RMB2.2 million for the year ended December 31, 2019. This change was primarily attributable to the exchange differences arising on translation of foreign operations and the decreased fair value gain on investments in debt instruments at fair value through other comprehensive income.

### Non-IFRS Measure

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

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

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

	<b>Year ended December 31,</b>	
	<b>2019</b>	<b>2018</b>
	<b>RMB'000</b>	<b>RMB'000</b>
Loss for the year	<b>(2,308,444)</b>	(1,793,129)
Added:		
Loss on fair value changes of the conversion feature of preferred shares	<b>756,464</b>	885,569
Share-based payment expenses	<b>410,717</b>	234,962
Adjusted loss for the year	<b><u>(1,141,263)</u></b>	<b><u>(672,598)</u></b>

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

	<b>Year ended December 31,</b>	
	<b>2019</b>	<b>2018</b>
	<b>RMB'000</b>	<b>RMB'000</b>
Research and development expenses for the year	(1,395,624)	(850,197)
Added:		
Share-based payment expenses	<u>206,881</u>	<u>123,267</u>
Adjusted research and development expenses for the year	<u><u>(1,188,743)</u></u>	<u><u>(726,930)</u></u>

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

	<b>Year ended December 31,</b>	
	<b>2019</b>	<b>2018</b>
	<b>RMB'000</b>	<b>RMB'000</b>
Administrative expenses for the year	(341,476)	(190,991)
Added:		
Share-based payment expenses	<u>203,836</u>	<u>111,695</u>
Adjusted administrative expenses for the year	<u><u>(137,640)</u></u>	<u><u>(79,296)</u></u>

### **Employees and Remuneration Policies**

The following table sets forth a breakdown of our employees as at December 31, 2019 by function:

<b>Function</b>	<b>Number of employees</b>	<b>% of total number of employees</b>
Research and Development	204	70.59
Sales, General and Administrative	<u>85</u>	<u>29.41</u>
<b>Total</b>	<u><u>289</u></u>	<u><u>100.0</u></u>

As of December 31, 2019, we had 195 employees in Shanghai, 26 employees in Suzhou and 68 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**

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 March 21, 2019, the international underwriters of the Global Offering exercised the over-allotment option in full, pursuant to which the Company is required to allot and issue 27,959,000 Shares at HK\$12 per Share, representing approximately 15% of the maximum number of Shares initially available under the Global Offering, at the offer price under the Global Offering. The net proceeds from the exercise of the over-allotment option were approximately HK\$325.42 million (after deducting the commissions and other offering expenses payable by the Company in relation to the exercise of the over-allotment option). The option shares were listed on the Stock Exchange on March 26, 2019.

As of December 31, 2019, our time deposits and cash and cash equivalents were RMB2,725.9 million, as compared to RMB1,462.6 million as of December 31, 2018. The increase was mainly due to the proceeds we received from our IPO. Our primary uses of cash are to fund research and development efforts, in-licensing of new drug candidates and working capital and other general corporate purposes.

### ***Gearing Ratio***

Gearing ratio is calculated using total liabilities divided by total assets and multiplied by 100%. As at December 31, 2019, our gearing ratio was 15.9% (as at December 31, 2018: 68.4%).

### **Other Financial Information**

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

As of December 31, 2019, we did not hold any significant investments. For the year ended December 31, 2019, we did not have material acquisitions or disposals of subsidiaries, associates and joint ventures.

#### ***Foreign Exchange Risk***

Our financial statements are expressed in RMB, but certain of our cash and cash equivalents, restricted bank deposits, time deposits, other receivables, other investments classified as financial assets measured at fair value through profit or loss 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 monitors foreign exchange exposure and will consider hedging significant foreign currency exposure should the need arise.

### ***Bank Loans and Other Borrowings***

As at December 31, 2019, we had RMB200.0 million banking facilities of which nil has been drawn down as at the same date.

Save as disclosed above, we did not have any material mortgages, charges, debentures, loan capital, debt securities, loans, unutilized banking facilities, bank overdrafts or other similar indebtedness, liabilities under acceptances (other than normal trade bills), acceptance credits, which are either guaranteed, unguaranteed, secured or unsecured, or guarantees.

### ***Lease Liabilities***

We have applied IFRS 16 and recognized lease liabilities since January 1, 2019. As at December 31, 2019, our lease liabilities amounted to RMB4.3 million.

### ***Contingent Liabilities***

As of December 31, 2019, we did not have any material contingent liabilities.

## **CORPORATE GOVERNANCE AND OTHER INFORMATION**

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

The Company has applied the principles and code provisions as set out in the Corporate Governance Code and Corporate Governance Report (the “**CG Code**”) contained in Appendix 14 to the Listing Rules. During the period from the Listing Date to December 31, 2019, the Board is of the opinion that the Company has complied with all the code provisions apart from the deviation below.

We do not have a separate chairman and chief executive officer and Dr. Frank Ningjun Jiang currently performs these two roles. While this will constitute a deviation from Code Provision A.2.1 of the CG Code, our Board believes that this structure will not impair the balance of power and authority between our Board and the management of our Company, given that: (i) decision to be made by our Board requires approval by at least a majority of our Directors and that our Board comprises three independent non-executive Directors out of nine Directors, and we believe there is sufficient check and balance in our Board; (ii) Dr. Frank Ningjun Jiang and other Directors are aware of and undertake to fulfill their fiduciary duties as Directors, which require, among other things, that they act for the benefit and in the best interests of our Company and will make decisions for our Group accordingly; and (iii) the balance of power and authority is 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. Finally, our Board believes that vesting the roles of both chairman and chief executive officer in the same person has the benefit of ensuring consistent leadership within our Group and enables more effective and efficient overall strategic planning for and communication within our Group. Our Board will continue to review the effectiveness of the corporate governance structure of our Group in order to assess whether separation of the roles of chairman and chief executive officer is necessary.

## Model Code for Securities Transactions by Directors of Listed Issuers

We have also adopted our own code of conduct regarding securities transactions, namely the policy on management of securities transactions by directors (the “**Securities Transactions Code**”), which applies to all directors of the Company 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 of all the Directors and they have confirmed that they have complied with the relevant Securities Transactions Code throughout the period from the Listing Date to the date of this announcement.

The Company’s employees, who are likely to be in possession of unpublished inside information of the Company, are subject to the Model Code. No incident of noncompliance of the Model Code by the employees was noted by the Company as at 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 throughout the period from the Listing Date to the date of this announcement.

## Use of Net Proceeds

The Shares were listed on the Main Board of the Stock Exchange on the Listing Date. The Group received net proceeds (after deduction of underwriting commissions and related costs and expenses) from the IPO and the exercise of over-allotment option of approximately RMB2,090.16 million.

The net proceeds from the Listing (adjusted on a pro rata basis based on the actual net proceeds) have been and will be utilized in accordance with the purposes set out in the Prospectus. The table below sets out the planned applications of the net proceeds and actual usage up to December 31, 2019:

	<b>% of use of proceeds (Approximately)</b>	<b>Net proceeds from the HK IPO RMB million</b>	<b>Actual usage up to December 31, 2019 RMB million</b>	<b>Unutilized net proceeds as of December 31, 2019 RMB million</b>
Fund ongoing and planned clinical trials, preparation for registration filings and commercial launches of CS1001	30%	627.04	236.96	390.08
Fund ongoing and planned clinical trials, preparation for registration filings and commercial launches eight of our other clinical and IND stage candidates in our pipeline	40%	836.06	319.88	516.18
Fund the R&D of five of the remaining drug candidates in our pipeline and the R&D and in-licensing of new drug candidates	20%	418.04	50.35	367.69
For working capital and general corporate purposes	10%	209.02	59.77	149.25
<b>Total</b>	<b>100%</b>	<b>2,090.16</b>	<b>666.96</b>	<b>1,423.20</b>

*Notes:*

- (1) Net IPO proceeds were received in Hong Kong dollar and translated to Renminbi for application planning.
- (2) The unutilized net proceeds of RMB1,423.20 million as of December 31, 2019 is expected to be completely used by December 31, 2021.

### **Audit Committee**

The audit committee of the Company (the “**Audit Committee**”) has three members (who are all independent non-executive directors), being Mr. Hongbin Sun (chairman), Mr. Ting Yuk Anthony Wu, and Dr. Paul Herbert Chew with terms of reference in compliance with the Listing Rules.

The Audit Committee has considered and reviewed the accounting principles and practices adopted by the Group and discussed matters in relation to internal control and financial reporting with the management. The Audit Committee reviewed and considered that the annual financial results for the year ended December 31, 2019 are in compliance with the relevant accounting standards, rules and regulations and appropriate disclosures have been duly made.

### **Scope of work of Messrs. Deloitte Touche Tohmatsu**

The figures in respect of the Group’s consolidated statement of financial position, consolidated statement of profit or loss and other comprehensive income and the related notes thereto for the year ended December 31, 2019 as set out in the preliminary announcement have been agreed by the Group’s auditor, Messrs. Deloitte Touche Tohmatsu to the amounts set out in the Group’s audited consolidated financial statements for the year. The work performed by Messrs. Deloitte Touche Tohmatsu in this respect did not constitute an assurance engagement in accordance with Hong Kong Standards on Auditing, Hong Kong Standards on Review Engagements or Hong Kong Standards on Assurance Engagements issued by the Hong Kong Institute of Certified Public Accountants and consequently no assurance has been expressed by Messrs. Deloitte Touche Tohmatsu on the preliminary announcement.

### **FINAL DIVIDEND**

The Board does not recommend the payment of a dividend for the year ended December 31, 2019.

### **PUBLICATION OF ANNUAL RESULTS ANNOUNCEMENT AND ANNUAL REPORT**

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

The annual report for the year ended December 31, 2019 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.

## **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. Frank Ningjun Jiang**  
*Chairman*

Suzhou, PRC, March 26, 2020

*As at the date of this announcement, the Board of Directors of the Company comprises Dr. Frank Ningjun Jiang as Chairman and Executive Director, Dr. Wei Li, Mr. Qun Zhao, Mr. Yanling Cao, Mr. Guobin Zhang and Dr. Lian Yong Chen as non-executive Directors, and Dr. Paul Herbert Chew, Mr. Ting Yuk Anthony Wu and Mr. Hongbin Sun as independent non-executive Directors.*