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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, 2020

The board (the “**Board**”) of directors (the “**Directors**”) 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, 2020 (the “**Reporting Period**”), together with comparative figures for the year ended December 31, 2019. Unless otherwise defined herein, capitalised terms used in this announcement shall have the same meanings as those defined in the prospectus of our Company dated February 14, 2019 (the “**Prospectus**”) and our announcement of annual results for the year ended December 31, 2019 dated March 26, 2020.

FINANCIAL HIGHLIGHTS

International Financial Reporting Standards (“IFRS”) Measures:

- **Revenue** increased from zero for the year ended December 31, 2019 to RMB1,038.8 million for the year ended December 31, 2020, primarily attributable to the license fee income.
- **Other gains and losses** decreased by RMB458.0 million from losses of RMB637.4 million for the year ended December 31, 2019 to losses of RMB179.4 million for the year ended December 31, 2020, primarily attributable to the elimination of losses in fair value of derivative financial liabilities as the Group had no preferred shares outstanding as of December 31, 2020.
- **Research and development expenses** increased by RMB9.1 million from RMB1,395.6 million for the year ended December 31, 2019 to RMB1,404.7 million for the year ended December 31, 2020, primarily attributable to our pipeline advancement.

- **Administrative expenses** increased by RMB1.0 million from RMB341.5 million for the year ended December 31, 2019 to RMB342.5 million for the year ended December 31, 2020, primarily attributable to the combination impact of change in employee cost and professional fees.
- **Selling expenses** increased from zero for the year ended December 31, 2019 to RMB142.2 million for the year ended December 31, 2020, primarily attributable to increase in employee cost and professional fees incurred for activities associated with marketing and sales prior to product launch.
- **Loss for the year** decreased by RMB1,087.4 million from RMB2,308.4 million for the year ended December 31, 2019 to RMB1,221.0 million for the year ended December 31, 2020, primarily attributable to license fee income, elimination of losses in fair value of derivative financial liabilities, while partially offset by increase in selling expenses.

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

- **Research and development expenses** excluding the share-based payment expenses increased by RMB57.0 million from RMB1,188.7 million for the year ended December 31, 2019 to RMB1,245.7 million for the year ended December 31, 2020, primarily attributable to our pipeline advancement.
- **Administrative and selling expenses** excluding the share-based payment expenses increased by RMB150.0 million from RMB137.6 million for the year ended December 31, 2019 to RMB287.6 million for the year ended December 31, 2020, primarily attributable to increase in employee cost and professional fees.
- **Loss for the year** excluding the effect of the fair value changes of the conversion feature of preferred shares and share-based payment expenses decreased by RMB276.3 million from RMB1,141.3 million for the year ended December 31, 2019 to RMB865.0 million for the year ended December 31, 2020, primarily due to license fee income and offset by increase in selling expenses.

BUSINESS HIGHLIGHTS

The past year was rich with material developments for CStone. We continued to execute and implement a systematic growth strategy, achieving significant objectives across all aspects of our business, from pipeline development to the buildout of our commercialization capabilities. Among our business development achievements, we formed agreements that maximize the commercial potential of our two lead immuno-oncology (“**IO**”) assets and expand the opportunities for combination strategies globally. As a result, we have reached an inflection point in our transition to a commercial stage company with global partnerships and business development opportunities, a revamped R&D direction and portfolio focused on promising new drug categories and combo therapies, and a commercial infrastructure with a demonstrated ability to market our products.

For the year ended December 31, 2020 and as of the date of this announcement, significant progress has been made with respect to our product pipeline and business operations:

I. Secured Approval for First-in-Class Precision Medicines; Second Expected Imminently

On March 24, 2021, the National Medical Products Administration (“**NMPA**”) of the People’s Republic of China (“**China**”) approved GAVRETO[®] (pralsetinib, RET inhibitor) for the treatment of adults with locally advanced or metastatic RET fusion-positive non-small cell lung cancer (“**NSCLC**”) after platinum-based chemotherapy. GAVRETO[®] is the first approved selective RET inhibitor in China and first approved precision therapy for CStone.

We expect the NMPA of China will soon approve AYVAKIT[®] (avapritinib, KIT/PDGFR α inhibitor) for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (“**GIST**”) harboring a PDGFR α exon 18 mutation, including PDGFR α D842V mutations. Once approved, AYVAKIT[®] is expected to be China’s first approved precision therapy for patients with PDGFR α exon 18 mutant GIST.

II. Filed Multiple NDAs for Key Late-stage Assets

We continued to advance our pipeline of by positioning multiple late-stage first-in-class assets across various oncology therapeutic areas and indications for commercial readiness through successful New Drug Application (“**NDA**”) submissions.

- **Pralsetinib** (CS3009, RET inhibitor)
 - In September 2020, an NDA was accepted by the NMPA for the treatment of patients with RET fusion-positive NSCLC previously treated with platinum-based chemotherapy. The Priority Review Designation was granted by the NMPA in September 2020. We received an NDA approval on March 24, 2021.
 - In December 2020, a Breakthrough Therapy Designation (“**BTD**”) was granted by the NMPA for the patients with advanced or metastatic RET-mutant medullary thyroid cancer (“**MTC**”). We submitted an NDA to the NMPA in March 2021 for the treatment of patients with advanced or metastatic RET-mutant MTC and RET fusion-positive thyroid cancer.

- **Avapritinib** (CS3007, KIT/PDGFR α inhibitor)
 - We submitted an NDA to the NMPA for avapritinib for adults with unresectable or metastatic GIST harboring a PDGFR α exon 18 mutation, including PDGFR α D842V mutations, which was accepted in April 2020. The Priority Review Designation was granted by the NMPA in July 2020. We expect to receive the NDA approval imminently.
 - We submitted an NDA to Taiwan Food and Drug Administration (“**TFDA**”) for the same indication in March 2020. We expect to receive the NDA approval in the first half of 2021.
- **Sugemalimab** (CS1001, PD-L1 antibody)
 - The Phase III trial of sugemalimab as first-line treatment for Stage IV squamous and non-squamous NSCLC met its primary endpoint in August 2020. An NDA for this indication was accepted by NMPA in November 2020. We expect to receive the NDA approval in the second half of 2021.
 - Sugemalimab demonstrated best-in-class potential among PD-1 and PD-L1 monoclonal antibodies for the treatment of patients with stage IV squamous and non-squamous NSCLC, and is the only PD-L1 proven efficacious for both NSCLC histologies. When combined with chemotherapy, it reduced the risk of cancer progression or death by 50% over chemotherapy alone. These results are among the best of published data for competitor PD-1 and PD-L1 monoclonal antibodies. Furthermore, sugemalimab demonstrated a more favorable safety profile with lower incidences of severe immune related adverse events such as pneumonitis.

III. Additional Significant Late-stage Pipeline Achievements

We achieved significant milestones in 2020 with additional core late-stage molecules, and are advancing their development.

- **Sugemalimab** (CS1001, PD-L1 antibody)
 - We received the Orphan Drug Designation (“**ODD**”) for treating patients with T-cell lymphoma and the BTD for treating adult patients with relapsed or refractory (“**R/R**”) extranodal natural killer/T cell lymphoma (“**ENKTL**”) from the United States (“**U.S.**”) Food and Drug Administration (“**FDA**”) in October 2020, following the Investigational New Drug (“**IND**”) approval in August 2020. BTD was granted by the NMPA for the treatment of patients with R/R ENKTL in February 2021.
 - We are conducting a phase III trial of sugemalimab in patients with stage III NSCLC as monotherapy in the maintenance setting following chemoradiation. The enrollment was completed in December 2020. We expect the top-line results readout in the first half of 2021.

- We have completed proof of concept clinical studies for sugemalimab in several cancer types and presented data at international conferences in 2020. These results demonstrated sugemalimab is highly active in esophageal cancer and gastric cancer, and provided strong supporting evidence to the ongoing phase III trials in these cancers.
- **CS1003** (PD-1 antibody)
 - We are conducting a global phase III trial of CS1003 in combination with LENVIMA® (lenvatinib), a standard-of-care TKI in patients with advanced hepatocellular carcinoma (“HCC”). CS1003 was granted an ODD by U.S. FDA for the treatment of patients with HCC in July 2020.

IV. Further Built Out Robust Commercialization Capabilities

We invested in – and achieved in developing – robust and highly efficient commercialization capabilities to support the successful launch of global breakthrough therapies in 2021. We demonstrated our capabilities with the successful launch of two late-stage drugs via the Bo’ao pilot zone.

- In 2020, our commercial team laid the groundwork for four 2021 commercial launches: pralsetinib (RET inhibitor), avapritinib (KIT/PDGFRα inhibitor) and ivosidenib (IDH1 inhibitor) in mainland China and avapritinib in Taiwan. Specific achievements include:
 - Built a full-fledged commercial team: We built strong commercial capabilities with a seasoned leadership team and overall team size reaching approximately 200 employees including sales staff, with plans to reach 300 by the end of 2021. The rapid ramp-up of our commercial capabilities has resulted in comprehensive coverage of 4 key oncology areas, over 400 hospitals and approximately 100 cities. This coverage represents hospitals that account for over 80% of the sales generated from prescriptions of precision medicines. With this coverage and our first-mover advantage in precision medicines, we believe we are building a commercial workforce that will fully reach our commercial aspirations.
 - Successful brand development initiatives: We proactively engaged key opinion leaders (“KOL”) and participated in activities of reputable local cancer societies to secure important recognition and recommendations, while launching various programs to position CStone as a source of information for healthcare professionals’ (“HCP”) on topics related to diseases, treatment paradigms and diagnostics standards. Avapritinib and ivosidenib were formally recommended in the Chinese Society of Clinical Oncology (“CSCO”) guidelines for the treatment of GIST and hematological malignancies, respectively. Meanwhile, we leveraged innovative digital tools and channels to further broaden CStone’s profile and brand awareness within the healthcare information ecosystem. Our digital platforms attracted tens of thousands of virtual participants and visitors for CStone’s R&D day and CSCO virtual booth. Also, we launched a WeChat platform to serve as an education and information portal for future patient education.

- Removal of drug adoption barriers: We proactively collaborated with multiple gene testing companies to build up testing standards and perceptions by providing molecular diagnostics training to pathologists, among other efforts. Additionally, we entered a collaboration agreement with MediTrust to launch an early bird program for avapritinib and pralsetinib. And, we have initiated discussions and negotiations with different partners on developing a multilayer payment system to improve patient affordability.
- Expanding product accessibility: In the third quarter of 2020, we successfully launched avapritinib and pralsetinib in the Bo’ao pilot zone, allowing Chinese patients to have early access to an innovative precision medicine prior to the NDA approval by the NMPA of China. This program has been record-breaking with fastest approval timeline in Bo’ao, and has generated tremendous interest from HCP and patients. In an effort to increase the possibility of including our drugs in basic medical insurance, we have initiated an external consulting project and formed an internal taskforce to develop a strategy and implementation roadmap to ensure the widest accessibility for CStone products via National Reimbursement Drug List (“**NRDL**”) listing. Also, we have entered into strategic collaboration agreement with Sinopharm Group Co., Ltd. to establish access to distribution channels, making sure prescribed medicines can be delivered quickly to patients.

V. Executed Transformative Business Development Initiatives

2020 was a breakout year for CStone’s business development achievements. The Company forged strategic partnerships to commercialize two lead IO assets, and materially advance our innovation and commercialization capabilities. In particular, these achievements provided capital for growth investments, opened global markets for our products, engaged new partners for co-development and licensing initiatives, and supported the development of our portfolio around emerging therapeutics such as antibody drug conjugates (“**ADC**”) and multi-specific antibodies.

- In September 2020, we entered into a multi-dimensional strategic collaboration with Pfizer that met several immediate objectives and enhanced the Company’s ability to invest in its growth strategy and development initiatives. Pfizer invested US\$200 million in CStone shares at a price of HK\$13.37 per share and was licensed CStone’s late-stage oncology asset sugemalimab in mainland China, maximizing the domestic revenue-generating potential of this core late-stage asset. By harnessing Pfizer’s vast commercial platform for sugemalimab, this partnership has allowed CStone to focus its commercialization capabilities around other key late-stage assets. In addition, CStone and Pfizer will together select late-stage assets for co-development in the Greater China market. Both parties expect to announce the updates for such co-development this year.
- In October 2020, we entered into an exclusive out-licensing agreement with EQRx, INC. (“**EQRx**”) for exclusive rights to our sugemalimab and CS1003 for development and commercialization outside of Greater China. This agreement provides a pathway to bring these important late-stage assets to global patient communities by partnering with a firm that has unique capabilities to shepherd them through global development and position them competitively for commercialization against established alternative treatments. Additionally, we retained the rights to develop and commercialize CS1003 in Greater China, where we can continue to pursue development as a monotherapy or as part of its combination strategy for this drug.

- In October 2020, we entered into an exclusive licensing agreement with LegoChem Biosciences, Inc. (“**LegoChem Biosciences**”) to lead global development and commercialization of LCB71, an ADC targeting receptor tyrosine kinase-like orphan receptor 1 (“**ROR1**”), outside the Republic of Korea. The agreement bolsters CStone’s precision medicine franchise with a new modality, and provides a potential best-in-class asset in an emerging and promising course of therapeutics.

VI. Elevated of Research Capabilities and Advanced Pipeline 2.0

We are undertaking a strategic effort to elevate our research capabilities to focus on developing best-in-class and first-in-class assets, and enhancing our internal sources of innovation. We expect this effort to translate breakthrough science and clinical insights into differentiated products, and position CStone in emerging therapeutic modalities and mechanisms of action with 1-2 IND filings per year. Our near-term focus is on assets in two modalities: ADC and multi-specific biologics. We are preparing two assets for IND filings this year:

- **CS2006** (NM21-1480, PD-L1×4-1BB×HSA tri-specific molecule)
 - In the second quarter of 2020, our partner, Numab Therapeutics AG (“**Numab**”), received a “may proceed” letter from the U.S. FDA for the IND application for NM21-1480. We received an IND approval for CS2006 from TFDA in the third quarter of 2020. The dose escalation is ongoing and includes sites in the US and Taiwan. We have completed dose level 4 enrollment in US, no dose limiting toxicity (“**DLT**”) identified so far. We expect to submit an IND application to the NMPA in the second half of 2021.
- **CS5001** (LCB71, ROR1 ADC)
 - In the fourth quarter of 2020, we in-licensed CS5001 (LCB71) from LegoChem Biosciences. CS5001 is a highly differentiated ADC targeting ROR1, a promising ADC target for multiple solid and hematological malignancies. ROR1 is highly expressed across a variety of cancers including various forms of leukemia and non-Hodgkin lymphoma, and breast, lung, and ovarian cancers. We expect to submit IND/CTA applications for CS5001 by the end of 2021.

In addition to CS2006 and CS5001, multiple potentially first-in-class or best-in-class programs including two multi-specific biologics and one ADC are under development.

For more details of the progress on our pipeline assets, please refer to the section headed “Management Discussion & Analysis” in this announcement.

MANAGEMENT DISCUSSION & ANALYSIS

OUR VISION

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

OVERVIEW

Established at the end of 2015, CStone is a biopharmaceutical company focused on the development and commercialization of innovative tumor immunotherapy and precision medicines to meet the acute medical needs of cancer patients in China and worldwide. The Company has built an oncology-focused pipeline of 14 innovative assets with a strategic emphasis on IO combination therapies and precision medicines. As of the date of this announcement, 1 drug candidate has been granted NDA approval, 1 drug candidate is expected to receive NDA approval imminently, 2 candidates are in the process of NDA review or NDA preparation, and 2 candidates are in pivotal trials. 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 and the Company.

Product Pipeline

	Drug Candidate	Lead Indication(s) and Line(s) of Therapies	Rights	Pre-clinical	Dose Escalation	POC	Pivotal	NDA	Partner
Commercial stage	Pralsetinib (RET)	1L / 2L NSCLC, MTC / TC		Mainland China NDA approved					
	Avapritinib (KIT / PDGFRA)	PDGFRA exon 18 GIST, AdvSM, ISM		Mainland China NDA approval expected imminently; Taiwan NDA submitted					
Late-stage	Sugemalimab (CS1001, PD-L1)	NSCLC, GC, ESCC R/R NKTL	Out-licensed	Mainland China NDA submitted					Mainland China Ex-Greater China
	Ivosidenib (IDH1)	R/R AML, 1L AML, Cholangiocarcinoma		Expecting to submit NDA in mainland China in 2021					
	CS1003 (PD-1)	HCC							Ex-Greater China
	Fisogatinib (FGFR4)	1L / 2L HCC							
Clinical/IND	CS1002 (CTLA-4)	Solid tumors							
	CS2006 (PD-L1/4-1BB/HSA)	Solid tumors							
	CS3002 (CDK4/6)	Solid tumors							
	CS3005 (A2aR)	Solid tumors							
Pre-clinical	CS5001 (ROR1)	Solid tumors, hematologic cancers							
	CS2007 (Multi-Specific)	Undisclosed							
	CS2008 (Multi-Specific)	Undisclosed							
	CS5002 (ADC)	Undisclosed							

Source: Company

Note: Assets status denote progress in the region noted in the column titled "Rights".

* CStone obtains the exclusive global right to lead development and commercialization of LCB71 outside the Republic of Korea

POC = Proof of Concept, NSCLC = Non-small Cell Lung Cancer, MTC = Medullary Thyroid Cancer, TC = Thyroid Cancer,

GIST = Gastrointestinal Stromal Tumor, AdvSM = Advanced Systemic Mastocytosis, ISM = Indolent Systemic Mastocytosis,

GC = Gastric Cancer, ESCC = Esophageal Squamous Cell Carcinoma, R/R = Relapsed or Refractory,

NKTL = Natural KILLER/T Cell Lymphoma, AML = Acute Myeloid Leukemia, HCC = Hepatocellular Carcinoma



BUSINESS REVIEW

Commercial Progress

A key achievement for CStone in 2020 was entering into commercial arrangements with partners who will lead commercialization of sugemalimab and CS1003. First, CStone licensed to Pfizer commercialization rights for sugemalimab in mainland China. Second, CStone licensed global development and commercialization rights (outside Greater China) to a US biotech firm, EQRx, for sugemalimab and CS1003. As a result of these arrangements, CStone has freed resources to focus its own commercialization efforts around the remainder of its late-stage portfolio.

In 2020, we implemented the following initiatives to ensure successful product launches in 2021.

Commercial Team Ramp-up: In the past year, we rounded out our commercial team with strategic hires and now have on board a seasoned leadership team for key commercial functions.

- All leaders have over 15 years of working experience in the pharmaceutical industry at different multinational corporations and biotech start-ups.
- By the end of 2020, we had approximately 200 commercial employees including sales staff, and we project the commercial team will grow to over 300 by end of 2021.
- The rapid ramp-up of our commercial capabilities resulted in comprehensive coverage of 4 key oncology therapeutic areas, over 400 hospitals and approximately 100 cities.

Successful Brand Development Initiatives

- Brand awareness
 - We engaged KOLs and participated in activities of reputable local cancer societies (e.g. CSCO, China Anti-Cancer Association and Chinese Thoracic Oncology Group) to secure important recognition and recommendations.
 - We launched various programs through different channels and platforms, such as CSCO guideline roadshows, to position CStone as a source of information for HCPs on treatment paradigms and diagnostics standards.
 - By the end of 2020, more than 500 activities were held or sponsored to enhance HCPs' understanding of CStone products.
- Guideline listing: AYVAKIT[®] (avapritinib) and TIBSOVO[®] (ivosidenib) were formally included in the 2020 CSCO guideline for the treatment of GIST and hematological malignancies, respectively.

- Expanded use of digital tools to broaden CStone’s recognition among HCPs. Examples include:
 - CStone R&D day: Online viewership exceeded 31,000 counts through our digital platform.
 - Digital campaign at CSCO: Digital amplification achieved more than 15,000 views of the CStone virtual booth; lung cancer and GIST satellite meeting viewership volume was far beyond the industry average.
 - We developed and launched a WeChat platform to provide convenient access to disease and treatment information, and guidance on adherence to prescription medication regimens.

Removal of Adoption Barriers

- Gene testing enhancement: We are taking steps to increase awareness of the benefits of gene-driven therapy. In 2020, we collaborated with multiple gene testing companies to provide molecular diagnostics training to pathologists, among other efforts.
- Early bird program: We entered a collaboration agreement with MediTrust to launch an early bird program for avapritinib and pralsetinib.
- Innovative payment scheme: We have initiated discussions and negotiations with different partners on developing a multilayered payment system to improve drug affordability for patients.

Numerous Efforts to Expand Product Accessibility

- Named-patient early access program: In the third quarter of 2020, we launched avapritinib and pralsetinib via the early access program in the Bo’ao pilot zone. We achieved several objectives:
 - Pralsetinib became the first innovative drug launched in mainland China within the same month as its global launch.
 - The prescription of pralsetinib in Bo’ao is the first one outside the US.
 - CStone will leverage the real world data generated by this program to support further adoption of avapritinib and pralsetinib after official NDA approval.
 - We demonstrated CStone’s implementation and execution capabilities, and enhanced the readiness of entire organization for 2021 product launches.

- Basic medical insurance inclusion: We have initiated an external consulting project and formed an internal taskforce to develop a strategy and implementation roadmap to ensure widest accessibility to CStone products via NRDL listing.
- Access to key distribution channels: We have entered into strategic collaboration agreement with Sinopharm Group Co., Ltd. to establish access to distribution channels for our drugs.

Business Development

We successfully completed several milestone transactions in 2020 that entail wide-reaching strategic benefits for our business. First, we forged a multi-dimensional partnership with Pfizer that included an equity investment in our business, a pathway to commercialize sugemalimab in mainland China, and a framework to pursue joint business development initiatives. Second, we secured a pathway to global commercialization of sugemalimab and CS1003 through a partnership with EQRx, a US-based biotech firm with an industry-renowned executive team and unique commercialization model. And third, we licensed exclusive global development and commercialization rights to a highly differentiated, potential best-in-class ADC from LegoChem Biosciences, a Korean firm with established expertise in this exciting modality of oncology therapeutics. Details are below.

- In September 2020, we entered into a multi-component strategic collaboration with Pfizer to address oncological needs in China. Pfizer invested US\$200 million in CStone shares and licensed CStone's late-stage oncology asset sugemalimab in mainland China. CStone will receive up to US\$280 million in milestone payments for sugemalimab, and additional royalties. In addition, CStone and Pfizer will together select late-stage (post proof-of-concept) oncology assets for co-development in the Greater China market. These assets may come either from Pfizer's pipeline or through joint in-licensing. Both parties expect to announce the updates for such co-development this year. This collaboration provided financing to support CStone's development of sugemalimab and other strategic imperatives, and also positioned CStone and Pfizer to develop and commercialize additional oncology assets for the Greater China market.
- In October 2020, we entered into an out-licensing agreement with EQRx for exclusive rights to our sugemalimab and CS1003 for development and commercialization outside of Greater China. Under the terms of the agreement, we received an upfront payment of US\$150 million and are entitled to receive up to US\$1.15 billion in milestone payments for both drugs as well as separate tiered royalties. EQRx obtained exclusive rights to lead global development and commercialization worldwide, excluding mainland China, Taiwan, Hong Kong and Macau. We retained the rights to CS1003 in Greater China, where we can continue to pursue development as a monotherapy or as part of a combination strategy for this drug. This collaboration provides a pathway to bring our two late-stage IO assets to global patient communities by partnering with a company with an innovative business model and unique ability to commercialize these two assets competitively against established treatments.

- In October 2020, we entered into an exclusive licensing agreement with LegoChem Biosciences to lead global development and commercialization of LCB71 outside the Republic of Korea. LCB71 is a potential best-in-class ROR1 ADC with monotherapy and combination applications for a range of cancer indications. Under the agreement, LCB will receive an upfront payment of US\$10 million, and up to US\$353.5 million in cumulative milestone payments, plus tiered royalties. The agreement adds the first ADC to CStone’s development pipeline, and bolsters our precision medicine franchise with a new modality.
- We continue to engage potential partners for multiple partnership opportunities that will accelerate our value creation, including in-licensing, out-licensing and strategic partnerships.

Clinical Development

Our current clinical development activities mainly relate to the clinical advancement of our 10 clinical and IND stage drug candidates. By the end of 2021, we expect to have more than 30 ongoing and/or completed trials in China and globally.

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

Late-stage Assets Progress

Pralsetinib (CS3009, RET inhibitor)

- We obtained an exclusive license from Blueprint Medicines Corporation (NASDAQ: BPMC) (“**Blueprint Medicines**”) for the development and commercialization of pralsetinib in mainland China, Hong Kong, Macau, and Taiwan in June 2018.
- In July 2020, the clinical data from phase 1/2 ARROW trial of pralsetinib in Chinese RET fusion-positive NSCLC patients previously treated with platinum-based chemotherapy showed consistency with global clinical data previously disclosed. In September 2020, the NDA was accepted by the NMPA for the treatment of patients with RET fusion-positive NSCLC previously treated with platinum-based chemotherapy. The Priority Review Designation was granted by the NMPA in September 2020. We received an NDA approval on March 24, 2021.
 - Primary efficacy data showed deep and durable anti-tumor activity of pralsetinib in RET fusion-positive NSCLC previously treated with platinum-based chemotherapy. Pralsetinib was well-tolerated in the Chinese patient population. Overall, the data showed that the efficacy and safety profile in Chinese patients with RET fusion-positive NSCLC were consistent with previously reported data from the global patient population in the ARROW trial.
 - This positive clinical data was submitted and accepted as an oral presentation at the IASLC 2020 WCLC in January 2021.

- We completed enrollment in China for the registration-enabling cohort from the phase 1/2 ARROW trial of patients with RET-mutant MTC who have not been previously treated with systemic therapy. A BTD was granted by the NMPA for the treatment of patients with advanced or metastatic RET-mutant MTC in December 2020. We submitted an NDA to the NMPA in March 2021 for the treatment of patients with advanced or metastatic RET-mutant MTC and RET fusion-positive thyroid cancer.
- We completed enrollment in China for the registration-enabling cohort from the phase 1/2 ARROW trial of patients with RET fusion-positive NSCLC who have not been previously treated with systemic therapy. We expect to submit an NDA to the NMPA for this patient population in the second half of 2021.
- We expect to submit an NDA to TFDA in the second half of 2021 for RET fusion-positive NSCLC patients previously treated with platinum-based chemotherapy.
- Blueprint Medicines and Genentech, a member of the Roche Group, received accelerated approval from the U.S. FDA for the treatment of adult patients with metastatic RET fusion-positive NSCLC as detected by an FDA approved test in September 2020 as well as for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant MTC who require systemic therapy, or with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate) in December 2020.
- Blueprint Medicines announced a global (excluding mainland China, Hong Kong, Macau and Taiwan) collaboration with Roche to develop and commercialize pralsetinib for patients with RET-altered cancers in July 2020.

Avapritinib (CS3007, KIT/PDGFR α 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.
- We submitted an NDA to the NMPA for avapritinib for adults with unresectable or metastatic GIST harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutations, which was accepted in April 2020. The Priority Review Designation was granted by the NMPA in July 2020. We expect to receive an NDA approval imminently.
- We submitted an NDA to TFDA for the same indication in March 2020. We expect an NDA approval in the first half of 2021.
- In the phase 1/2 bridging study data presented at the 2020 American Society of Clinical Oncology annual meeting and the 2020 CSCO annual meeting, avapritinib was generally well-tolerated and had promising preliminary anti-tumor activity in Chinese GIST patients with the PDGFRA D842V mutation.

- Blueprint Medicines received U.S. FDA approval of avapritinib for the treatment of adults with unresectable or metastatic GIST harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutations in January 2020.
- Blueprint Medicines announced that the European Commission granted conditional marketing authorization to avapritinib as a monotherapy for the treatment of adult patients with unresectable or metastatic GIST harboring the PDGFRA D842V mutation in September 2020.

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, and in Singapore in March 2020.
- Ivosidenib was acknowledged as urgent need medicine by the Center for Drug Evaluation (“CDE”) in China and included in the List of Overseas Drugs with Urgent Clinical Needs in November 2020.
- We completed enrollment in China for ivosidenib for the treatment of patients with IDH1 mutant relapsed or refractory acute myeloid leukemia (“AML”) in November 2020, and we expect to submit an NDA to the NMPA in the second half of 2021.
- We expect to complete enrollment for ivosidenib for the treatment of patients with newly diagnosed IDH1 mutant AML who are not eligible for intensive therapy by the end of 2021.

Sugemalimab (PD-L1 antibody)

- Sugemalimab is an investigational monoclonal antibody directed against PD-L1 that is currently under NDA review by NMPA in China. 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 December 31, 2020, we have dosed more than 1,600 patients in sugemalimab clinical trials.
- As of the date of this announcement, we are currently conducting five registrational trials for sugemalimab, three of which were initiated in 2018, including stage III NSCLC, stage IV NSCLC and ENKTL, and the other two were initiated in 2019, including advanced gastric cancer and esophageal cancer.
 - In August 2020, the phase III trial of sugemalimab as a first-line treatment for stage IV squamous and non-squamous NSCLC met its primary endpoint. An NDA for this indication was accepted by NMPA in November 2020. We expect to receive the NDA approval in the second half of 2021.
 - It was the first anti-PD-L1 monoclonal antibody worldwide to demonstrate overwhelming efficacy as a first line treatment for stage IV squamous and non-squamous NSCLC in a randomized, double-blind phase III trial.

- Interim analysis showed that sugemalimab combined with chemotherapy had a statistically significant prolongation of PFS compared with chemotherapy, reducing the risk of disease progression or death by 50%. The median PFS was 7.8 months vs. 4.9 months for sugemalimab combined with chemotherapy and for a placebo combined with chemotherapy, respectively. Subgroup analyses showed a clinical benefit across histology subtypes and PD-L1 expression levels. Sugemalimab in combination with chemotherapy was well tolerated.
- The highly positive clinical data was disclosed in an oral presentation at the European Society for Medical Oncology (“**ESMO**”) Asia Virtual Congress 2020 in November 2020.
- A phase II registrational clinical trial of sugemalimab as monotherapy for the treatment of ENKTL. We presented promising clinical data for ENKTL at the CSCO annual meeting in September 2020. We received the ODD for treating patients with T-cell lymphoma and the BTD for treating adult patients with R/R ENKTL from the FDA in October 2020, following the IND approval in August 2020. The BTD was granted by the NMPA for the treatment of patients with R/R ENKTL in February 2021.
- A phase III trial of sugemalimab in patients with stage III NSCLC as monotherapy in the maintenance setting following chemoradiation. The enrollment was completed in December 2020 and we expect the top-line results readout in the first half of 2021.
- A phase III trial of sugemalimab in combination with standard-of-care chemotherapies for first-line treatment in patients with unresectable or metastatic gastric cancer. The enrollment is expected to be completed by the end of 2021.
- A phase III trial of sugemalimab in combination with standard-of-care chemotherapies for first-line treatment in patients with unresectable or metastatic esophageal squamous cell cancer. The enrollment is expected to be completed by the end of 2021.
- To capitalize on the significant market opportunity in China, we are strategically developing multiple combination therapies of sugemalimab with candidates from our internal pipeline and external partners.
 - Sugemalimab with fisogatinib (CS3008, FGFR4 inhibitor) in HCC: Phase Ib part was completed with the recommended phase II dose (“**RP2D**”) declared in June 2020. The first patient was dosed in dose-expansion of the phase II part in July 2020.
 - Sugemalimab with donafenib: We have received an IND approval from CDE in April 2020. The phase I/II trial has initiated with first patient dosed in dose-escalation in October 2020.

**CAUTIONARY STATEMENT REQUIRED BY RULE 18A.05 OF THE LISTING RULES:
WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET SUGEMALIMAB
SUCCESSFULLY.**

CS1003 (PD-1 antibody)

- We are conducting a global phase III trial of CS1003 in combination with LENVIMA® (lenvatinib), a standard-of-care TKI in patients with advanced HCC.
- CS1003 was granted an ODD by U.S. FDA for the treatment of patients with HCC in July 2020.
- We published the preliminary pharmacokinetics, safety and efficacy data of two dosing regimens-200mg once every 3 weeks and 400mg once every 6 weeks dosing of CS1003 in solid tumors at 2020 ESMO virtual annual meeting in September 2020.
- We released the clinical data of a phase Ib study of CS1003 plus lenvatinib in Chinese patients with the first-line unresectable HCC at 2020 ESMO virtual annual meeting in September 2020.
- A scientific paper describing the full characterization of CS1003 and its pre-clinical data was published on Acta Phamacologica Sinica in May 2020 (Fu et al, 2020 online).

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.
- The phase Ib study for the combination therapy of fisogatinib plus sugemalimab in HCC was completed with the RP2D declared in June 2020. The first patient was dosed in dose-expansion of the phase II part in July 2020.
- We released the phase I clinical data of fisogatinib monotherapy in Chinese patients with advanced HCC expressing FGF19 at the 2020 CSCO virtual annual meeting in September 2020.

Early-stage Assets Progress

CS1002 (CTLA-4 antibody)

- The first patient for the study of a combination therapy of CS1002 plus CS1003 was dosed for dose-escalation in the first quarter of 2020 and for dose-expansion in the second quarter of 2020 in Australia.
- We submitted an IND application for the combination therapy of CS1002 plus CS1003 in China in the fourth quarter of 2020.

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

- In the second quarter of 2020, our partner, Numab, received a “may proceed” letter from the U.S. FDA for the IND application for NM21-1480. We received an IND approval for CS2006 from TFDA in the third quarter of 2020. The dose escalation is ongoing and includes sites in the US and Taiwan. We have completed dose level 4 enrollment in US, no DLT identified so far.
- We expect to submit an IND application to the NMPA in the second half of 2021.

CS3002 (CDK4/6 inhibitor)

- In the first quarter of 2020, the first patient was dosed in Australia in a phase I trial of CS3002 as a single agent for the treatment of patients with solid tumors in Australia and China. We also received an IND approval from the NMPA for the treatment of patients with solid tumors in the same quarter.

CS3005 (A2aR antagonist)

- In the first quarter of 2020, the first patient was dosed in Australia in a phase I trial of CS3005 as a single agent for the treatment of patients with solid tumors in Australia and China. In the second quarter of 2020, we received an IND approval from the NMPA for the treatment of patients with solid tumors.

Research

In 2020, CStone initiated a strategic effort to elevate its research capabilities with several goals in mind: first, to support CStone’s Pipeline 2.0 strategy with a focus on first-in-class/best-in-class drug candidates rather than “fast follow-on” or “me-better” products; second, to enhance internal innovation, in part by harnessing more clinical-stage insights; and third, to generate a steady flow of INDs that reach the proof-of-concept (“**PoC**”) stage.

As part of this effort, we have consolidated leadership of discovery and early development functions under the Chief Scientific Officer. This consolidation provides a single line-of-sight from discovery to the PoC stage. Also, we have recruited additional research professionals to form a dedicated cross-functional innovation sourcing and strategy team to drive the design and selection of Pipeline 2.0 candidates.

CStone will continue to work with external partners – academic labs, innovative biotechnology companies, and contract research organizations (“**CROs**”) – that can provide specific resources to advance and operationalize ideas and innovation.

Early results from the shift to our Pipeline 2.0 strategy are evident in the potential drug candidates we have already assembled. In particular, we in-licensed CS5001 (LCB71) from LegoChem Biosciences in the fourth quarter of 2020. CS5001 is a highly differentiated ADC targeting ROR1, a promising ADC target for multiple solid and hematological malignancies. ROR1 is highly expressed across a variety of cancers including various forms of leukemia and non-Hodgkin lymphoma, and breast, lung, and ovarian cancers. We expect to submit IND/CTA applications for CS5001 by the end of 2021.

In addition to CS2006 and CS5001, multiple potentially first-in-class or best-in-class programs including two multi-specific biologics and one ADC are under development.

The Impact of the Novel Coronavirus (“COVID-19”)

Our business operations in China have only been impacted slightly by the outbreak of COVID-19 since the latter half of January 2020. The Company, following government mandates, has taken various mitigation measures including arranging for delivery of drug candidates via courier services, to ensure that patient protocols continues to be followed in those regions heavily impacted by the outbreak. The management of the Company currently does not foresee significant disruption in the ongoing trials and delays in the initiation of additional clinical trials due to COVID-19 going forward.

EVENTS AFTER THE REPORTING PERIOD

On March 24, 2021, the NMPA of China approved GAVRETO[®] (pralsetinib) for the treatment of adults with locally advanced or metastatic RET fusion-positive NSCLC after platinum-based chemotherapy. GAVRETO[®] is the first approved selective RET inhibitor in China and first approved precision therapy for CStone.

FUTURE AND OUTLOOK

At CStone, we endeavour to make a meaningful contribution to the biopharmaceutical value chain in China, lead the development of new classes of innovative treatments, and most important, measurably improve the lives and wellbeing of cancer patients worldwide.

Despite challenges posed by COVID-19, the past year was a pivotal time for CStone. We demonstrated our scientific and clinical expertise with significant advancements in our pipeline. We forged strategic collaboration agreements with globally renowned partners who are uniquely positioned to maximize the commercial potential of our two lead IO assets in China and globally. We bolstered our capital base and ability to fund development initiatives. And we positioned key products for a successful commercial launch. As we look to the year ahead, we will harness these and other strengths in order to invigorate our innovative capabilities, secure the successful commercial launch of our late-stage pipeline assets, and pursue development of global first-in-class/best-in-class assets in emerging therapeutic categories.

In 2021, we have set clearly defined business priorities and initiatives, which we describe below.

Imminent and Robust Commercialization Activity

A principal commercial objective for 2021 is to carve out a definitive leadership position in the growing market for precision medicines. To support this goal, our commercial team is building its network of trusted relationships across the entire healthcare ecosystem, including physicians, patients, payors, pharmacies and patient advocacy groups. In addition, we continue to deepen our connections to the information network of industry bodies and key industry opinion leaders. This approach will provide maximal support to our sales and distribution efforts at the moment of a new drug launch.

We expect to receive five NDA approvals in total this year, including four approvals for pralsetinib, avapritinib, ivosidenib and sugemalimab in mainland China, as well as one approval for avapritinib in Taiwan. We have just received NMPA approval for pralsetinib, and we expect approval of avapritinib imminently. With our strong and growing commercial platform, we are confident in our ability to maximize the commercial potential of these late-stage clinical drug candidates.

To ensure our ability to execute successful launches, we are undertaking a vigorous expansion of our commercial team and its geographic coverage. By year-end, we expect to have a commercial force of approximately 300 employees, and coverage of four key oncology therapeutic areas, and more than 400 target hospitals in approximately 100 cities. This expansion will allow us to cover the hospitals that account for over 80% of the market for precision medicines as measured by sales.

In addition, we are working with Pfizer to support the commercialization of sugemalimab in mainland China, and EQRx to support the global launch (outside Greater China) of sugemalimab and CS1003. By harnessing Pfizer's extensive commercialization infrastructure in mainland China, where Pfizer has licensed commercial rights to sugemalimab, we will ensure that patients across a vast number of markets in this country have quicker access to our highly differentiated PD-L1 treatment. By partnering with EQRx, a company uniquely capable of reducing costs in the drug distribution chain, we will help bring sugemalimab and CS1003 to a broad swath of patients in the United States and worldwide.

Expediting a Full Slate of Clinical Development Programs

We have a robust clinical development agenda for 2021, and believe we are poised for unprecedented growth in this area. The agenda includes: at least five NDA filings for three key products; four data readouts for three products; and 30 ongoing trials, including 15 registrational trials, by the end of 2021.

In addition, we will supplement our in-house pipeline by working with Pfizer to identify late-stage (post PoC) oncology assets for joint in-licensing and co-development efforts in Greater China as part of the partnership we signed last year. This may encompass co-development of Pfizer assets, including some already on the market in the United States.

Elevating Research and Bolstering Pipeline 2.0

We are making substantial progress in elevating our research capabilities in order to curate a portfolio of first-in-class and best-in-class assets to which we have global rights, and further develop robust internal sources of innovation.

As a result, we expect to achieve meaningful increases in our ability to discover and develop assets in emerging classes of therapeutics. The tangible outcomes will include an increase in the number of innovative, internally designed assets, and greater quantity and quality of INDs that reach the PoC stage.

Our current early-stage portfolio includes ADCs and multi-specific biologics. We have five candidates in development. We are preparing two for INDs in mainland China this year: ROR1 ADC, a potential best-in-class molecule targeting multiple solid and hematological malignancies, and PD-L1x4-1BBxHSA tri-specific antibody, a potential best-in-class 4-1BB agonist and next generation PD-(L)1 inhibitor.

Near-term Launch of Pilot Manufacturing Operations

An important aspect of our transition to a commercial stage biopharmaceutical company is establishing in-house manufacturing capabilities. We are on track with the construction of a state-of-the-art facility in Suzhou, and anticipate launching pilot operations this year.

FINANCIAL INFORMATION

The Board announces the audited consolidated results of the Group for the year ended December 31, 2020, with comparative figures for the previous year as follows:

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE YEAR ENDED DECEMBER 31, 2020

		For the year ended December 31,	
	NOTES	2020 RMB'000 (Audited)	2019 RMB'000 (Audited)
Revenue	4	1,038,832	–
Cost of revenue		(241,421)	–
Gross profit		797,411	–
Other income	5	51,671	83,962
Other gains and losses	5	(179,419)	(637,365)
Research and development expenses		(1,404,684)	(1,395,624)
Selling expenses		(142,150)	–
Administrative expenses		(342,508)	(341,476)
Listing expenses		–	(17,638)
Finance costs	6	(1,320)	(303)
Loss for the year	7	(1,220,999)	(2,308,444)
Other comprehensive (expense) income:			
<i>Items that may be reclassified subsequently to profit or loss:</i>			
Exchange differences arising on translation of foreign operations		(1,274)	(1,802)
Fair value gain on investments in debt instruments at fair value through other comprehensive income (“FVTOCI”)		31	408
Reclassified to profit or loss upon disposal of debt instruments at FVTOCI		(31)	(758)
Other comprehensive expense for the year		(1,274)	(2,152)
Total comprehensive expense for the year		(1,222,273)	(2,310,596)

		For the year ended	
		December 31,	
		2020	2019
	<i>NOTES</i>	RMB'000	RMB'000
		(Audited)	(Audited)
Loss for the year attributable to:			
Owners of the Company			
– ordinary shareholders		(1,220,999)	(2,068,740)
– preferred shareholders		–	(239,704)
		<u>–</u>	<u>(239,704)</u>
		<u>(1,220,999)</u>	<u>(2,308,444)</u>
Total comprehensive expense for the year attributable to:			
Owners of the Company			
– ordinary shareholders		(1,222,273)	(2,070,824)
– preferred shareholders		–	(239,772)
		<u>–</u>	<u>(239,772)</u>
		<u>(1,222,273)</u>	<u>(2,310,596)</u>
		<i>RMB</i>	<i>RMB</i>
Loss per share	<i>9</i>		
– Basic		<u>(1.17)</u>	<u>(2.39)</u>
– Diluted		<u>(1.17)</u>	<u>(2.39)</u>

CONSOLIDATED STATEMENT OF FINANCIAL POSITION
AS AT DECEMBER 31, 2020

	<i>NOTES</i>	December 31, 2020 RMB'000 (Audited)	December 31, 2019 RMB'000 (Audited)
Non-current assets			
Property, plant and equipment		39,367	14,185
Right-of-use assets		27,175	4,469
Deposits for acquisition of property, plant and equipment and intangible assets		35,411	3,572
Other intangible assets		6,509	1,305
Other receivables	11	81,987	40,271
		<u>190,449</u>	<u>63,802</u>
Current assets			
Deposits, prepayments and other receivables	11	178,040	143,599
Other investments classified as financial assets measured at fair value through profit or loss (“FVTPL”)		10,125	11,946
Debt instruments at FVTOCI		–	4,811
Restricted bank deposit		720	620
Time deposits	12	358,870	1,599,431
Cash and cash equivalents	12	3,024,548	1,126,436
		<u>3,572,303</u>	<u>2,886,843</u>
Current liabilities			
Trade and other payables and accrued expenses	14	708,525	449,440
Deferred income		7,210	4,180
Lease liabilities		8,652	4,344
Borrowings	13	2,662	–
		<u>727,049</u>	<u>457,964</u>
Net current assets		<u>2,845,254</u>	<u>2,428,879</u>
Total assets less current liabilities		<u>3,035,703</u>	<u>2,492,681</u>
Non-current liabilities			
Lease liabilities		18,205	–
Deferred income		8,698	11,099
Borrowings	13	54,340	–
		<u>81,243</u>	<u>11,099</u>
Net assets		<u>2,954,460</u>	<u>2,481,582</u>
Capital and reserves			
Share capital		787	687
Treasury shares held in the trusts		(19)	(30)
Reserves		2,953,692	2,480,925
Total equity		<u>2,954,460</u>	<u>2,481,582</u>

NOTES

1. GENERAL

CStone Pharmaceuticals (the “**Company**”) is an exempted company incorporated in the Cayman Islands and its shares are listed on the Main Board of The Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”) since February 26, 2019.

The Company is an investment holding company. The Company’s subsidiaries are principally engaged in research and development of highly complex biopharmaceutical products.

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

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

Amendments to IFRSs that are mandatorily effective for the current year

The Company and its subsidiaries (the “**Group**”) have applied the *Amendments to References to the Conceptual Framework in IFRS Standards* and the following amendments to IFRSs issued by the International Accounting Standards Board (the “**IASB**”) for the first time, which are mandatorily effective for the annual period beginning on or after January 1, 2020 for the preparation of the consolidated financial statements:

Amendments to IAS 1 and IAS 8	Definition of Material
Amendments to IFRS 3	Definition of a Business
Amendments to IFRS 9, IAS 39 and IFRS 7	Interest Rate Benchmark Reform

The application of the *Amendments to References to the Conceptual Framework in IFRS Standards* and the amendments to IFRSs in the current year had no material impact on the Group’s financial positions and performance for the current and prior years and/or on the disclosures set out in these consolidated financial statements.

New and amendments to IFRSs in issue but not yet effective

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

IFRS 17	<i>Insurance Contracts and the related Amendments¹</i>
Amendment to IFRS 16	<i>Covid-19-Related Rent Concessions⁴</i>
Amendments to IFRS 3	<i>Reference to the Conceptual Framework²</i>
Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16	<i>Interest Rate Benchmark Reform – Phase 2⁵</i>
Amendments to IFRS 10 and IAS 28	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture³</i>
Amendments to IAS 1	<i>Classification of Liabilities as Current or Non-current¹</i>
Amendments to IAS 1 and IFRS Practice Statement 2	<i>Disclosure of Accounting Policies¹</i>
Amendments to IAS 8	<i>Disclosure of Accounting Estimate¹</i>
Amendments to IAS 16	<i>Property, Plant and Equipment: Proceeds before Intended Use²</i>
Amendments to IAS 37	<i>Onerous Contracts - Cost of Fulfilling a Contract²</i>
Amendments to IFRSs	<i>Annual Improvements to IFRS Standards 2018-2020²</i>

- ¹ Effective for annual periods beginning on or after 1 January 2023.
- ² Effective for annual periods beginning on or after 1 January 2022.
- ³ Effective for annual periods beginning on or after a date to be determined.
- ⁴ Effective for annual periods beginning on or after 1 June 2020.
- ⁵ Effective for annual periods beginning on or after 1 January 2021.

The directors of the Company anticipate that the application of all the new and amendments to IFRSs will have no material impact on the consolidated financial statements in the foreseeable future.

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.

Geographical information

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

4. REVENUE

Disaggregation of revenue from contracts with customers

	For the year ended December 31, 2020
	<i>License fee RMB'000 (Audited)</i>
License fee income	<u>1,038,832</u>
Geographical markets	
Mainland China	4,717
United States of America	<u>1,034,115</u>
Total	<u>1,038,832</u>
Timing of revenue recognition	
A point in time	<u><u>1,038,832</u></u>

License fee income

The Group provides licence of its patented intellectual property (“IP”) or commercialisation licence to customers and revenue is recognised when the customers obtain rights to access or use the underlying IP or licence. Licence fee income is recognised at a point of time upon the customer obtains the right to use the IP. The consideration for licence comprises a fixed element (the upfront payment) and variable elements (including but not limited to development milestones and royalties).

Information about major customers

Revenue from the following customers contributed over 10% of the total sales of the Group:

	For the year ended	
	December 31,	
	2020	2019
	RMB'000	RMB'000
	(Audited)	(Audited)
Customer A	<u>1,034,115</u>	<u>–</u>

5. OTHER INCOME AND OTHER GAINS AND LOSSES

Other income

	For the year ended	
	December 31,	
	2020	2019
	RMB'000	RMB'000
	(Audited)	(Audited)
Bank and other interest income	24,161	67,287
Government grants income (note a)	23,891	16,675
Income from pharmaceutical products (note b)	<u>3,619</u>	<u>–</u>
	<u>51,671</u>	<u>83,962</u>

Notes:

- (a) Government grants include subsidies from the PRC government which are specifically for (i) the capital expenditure incurred for plant and machinery and is recognised over the useful life of the related assets; (ii) the incentive and subsidies for research and development activities which are recognised 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 recognised in profit or loss in the period in which they become receivable.

- (b) Income from pharmaceutical products primarily relates to the sales contract with a pre-approved medical institution located in Boao Hope City International Medical Tourism Pilot Zone in the PRC. It is recognised at the point in time when the medicine are delivered and accepted by the customer. The credit term is 40 days upon invoiced. The Group applies the practical expedient of not disclosing the transaction price allocated to performance obligations that were unsatisfied in respect of the sales contract as the Group's contract has original duration of less than one year.

Other gains and losses

	For the year ended	
	December 31,	
	2020	2019
	<i>RMB'000</i>	<i>RMB'000</i>
	(Audited)	(Audited)
Gain on fair value changes of other investments classified as financial assets measured at FVTPL	396	457
Changes in fair value of money market funds	1,990	7,265
Gain on disposal of debt instruments at FVTOCI	31	758
Loss on disposal of property, plant and equipment	–	(104)
Loss on fair value changes of derivative financial liabilities	–	(756,464)
Net foreign exchange (losses) gains	(181,836)	110,723
	<u>(179,419)</u>	<u>(637,365)</u>

6. FINANCE COSTS

	For the year ended	
	December 31,	
	2020	2019
	<i>RMB'000</i>	<i>RMB'000</i>
	(Audited)	(Audited)
Interest on lease liabilities	241	303
Interest on bank borrowings	1,079	–
	<u>1,320</u>	<u>303</u>

7. LOSS FOR THE YEAR

	For the year ended December 31,	
	2020	2019
	<i>RMB'000</i>	<i>RMB'000</i>
	(Audited)	(Audited)
Loss for the year has been arrived at after charging:		
Depreciation of property, plant and equipment	6,446	6,397
Depreciation of right-of-use assets	5,580	4,890
Amortisation of other intangible assets	2,775	293
	<hr/>	<hr/>
Total depreciation and amortisation	14,801	11,580
	<hr/>	<hr/>
Directors' emoluments	164,101	167,245
Other staff costs:		
Salaries and other allowances	194,880	129,198
Performance related bonus	62,934	31,749
Retirement benefit scheme contributions	16,534	18,643
Share-based payment expenses	199,219	250,659
	<hr/>	<hr/>
Total staff costs	637,668	597,494
	<hr/>	<hr/>
Auditors' remuneration	1,900	1,900
	<hr/> <hr/>	<hr/> <hr/>

8. INCOME TAX EXPENSE

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

Under the two-tiered profits tax rates regime in Hong Kong, the first HK\$2 million of profits sourced in Hong Kong 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 as the Group has no profit 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. ("CStone Australia") is qualified as small business entity and is subject to a corporate tax rate of 27.5% for both years.

As at December 31, 2020, the Group has unused tax losses of approximately RMB4,149,230,000 (2019: RMB2,576,877,000) available for offset against future profits. No deferred tax asset has been recognised in respect of the tax losses due to the unpredictability of future profit streams.

At December 31, 2020, the Group has deductible temporary differences related to deferred government grants income of RMB15,908,000 (2019: RMB15,279,000). No deferred tax asset has been recognised 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 utilised.

9. LOSS PER SHARE

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

	For the year ended December 31,	
	2020	2019
	RMB'000	RMB'000
	(Audited)	(Audited)
Loss		
Loss for the year attributable to owners of the Company	(1,220,999)	(2,308,444)
Add: Loss attributable to preferred shareholders	—	239,704
	<u> </u>	<u> </u>
Loss for the purpose of basic and diluted loss per share	<u><u>(1,220,999)</u></u>	<u><u>(2,068,740)</u></u>
	For the year ended December 31,	
	2020	2019
	(Audited)	(Audited)
Number of shares		
Weighted average number of ordinary shares for the purpose of basic and diluted loss per share	<u><u>1,046,032,298</u></u>	<u><u>866,728,184</u></u>

10. DIVIDENDS

No dividend was paid or declared by the Company during the years ended December 31, 2020 and 2019 nor has any dividend been proposed since the end of the reporting period.

11. DEPOSITS, PREPAYMENTS AND OTHER RECEIVABLES

	December 31, 2020	December 31, 2019
	RMB'000	RMB'000
	(Audited)	(Audited)
Rental deposits	4,250	2,840
Prepayments	63,617	41,835
Other receivables	8,128	496
Receivables from a director and key management personnel of the Company	105,288	96,977
Value-added tax recoverable	78,744	41,722
	<u> </u>	<u> </u>
	<u><u>260,027</u></u>	<u><u>183,870</u></u>
Analyzed as:		
– Non-current	81,987	40,271
– Current	178,040	143,599
	<u> </u>	<u> </u>
	<u><u>260,027</u></u>	<u><u>183,870</u></u>

12. TIME DEPOSITS AND CASH AND CASH EQUIVALENTS

Time deposits

	December 31, 2020 <i>RMB'000</i> (Audited)	December 31, 2019 <i>RMB'000</i> (Audited)
Times deposits	<u>358,870</u>	<u>1,599,431</u>

The time deposits presented above are placed with a bank in the PRC with a term of 6 months to 1 year upon placement. Since the time deposits will be matured in the coming financial year, the time deposits are classified as current assets.

Cash and cash equivalents

	December 31, 2020 <i>RMB'000</i> (Audited)	December 31, 2019 <i>RMB'000</i> (Audited)
Cash at banks	2,084,307	504,681
Cash equivalents (<i>note</i>)		
– Money market funds	204,885	217,104
– Time deposits	<u>735,356</u>	<u>404,651</u>
	<u>3,024,548</u>	<u>1,126,436</u>

Note:

Cash equivalents represent (1) investment in a public debt constant net asset value money market fund, and low volatility net asset value money market fund; and (2) time deposits with maturity date within three months on the initial placement date.

Time deposits and cash at banks carry interests at market rates per annum ranging as follows:

	December 31, 2020 (Audited)	December 31, 2019 (Audited)
Time deposits	0.91% - 3.30%	2.84% - 3.30%
Cash at banks	<u>0.00% - 0.30%</u>	<u>0.00% - 0.30%</u>

The carrying amounts of the Group's time deposits and cash and cash equivalents denominated in currencies other than functional currencies of the relevant group entities at the end of the reporting period are as follows:

	December 31, 2020 <i>RMB'000</i> (Audited)	December 31, 2019 <i>RMB'000</i> (Audited)
United States Dollar (“US\$”)	3,147,325	1,877,293
Hong Kong Dollar (“HK\$”)	<u>207,700</u>	<u>795,428</u>

13. BORROWINGS

	December 31, 2020 <i>RMB'000</i> (Audited)	December 31, 2019 <i>RMB'000</i> (Audited)
Bank loans		
Unsecured and unguaranteed (<i>note</i>)	17,680	–
Secured and unguaranteed (<i>note</i>)	39,322	–
	<u>57,002</u>	<u>–</u>
The carrying amounts of the above borrowings are repayable*:		
Within 1 year	2,662	–
Within a period of more than 1 year but not exceeding 2 years	1,877	–
Within a period of more than 2 years but not exceeding 5 years	52,463	–
	<u>57,002</u>	<u>–</u>
Current	(2,662)	–
	<u>54,340</u>	<u>–</u>

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

Note:

On January 7, 2020, the Group obtained two new bank loan facilities amounting to RMB175,000,000 and RMB25,000,000 respectively, for the purpose of working capital improvement and the construction of the factory and facilities. During the year ended December 31, 2020, the Group has drawn down RMB58,582,000 and repaid RMB1,580,000 of principal in accordance with the payment schedules.

The new bank borrowings are denominated in RMB and carry the variable interest rate at Loan Prime Rate (“LPR”) plus 10 basis points per annum.

14. TRADE AND OTHER PAYABLES AND ACCRUED EXPENSES

	December 31, 2020 RMB'000 (Audited)	December 31, 2019 RMB'000 (Audited)
Trade payables	<u>28,030</u>	<u>37,304</u>
Accrued expenses		
– Research and development (<i>Note a</i>)	460,384	270,099
– Legal and professional fees	4,815	3,723
– Others	<u>26,194</u>	<u>8,121</u>
	<u>491,393</u>	<u>281,943</u>
Other payables	26,368	2,131
Other tax payable (<i>Note b</i>)	102,938	97,589
Staff payroll payable	<u>59,796</u>	<u>30,473</u>
	<u>708,525</u>	<u>449,440</u>

Notes:

- (a) Amounts mainly included service fees paid to outsourced service providers including contract research organisation and outsourced service providers.
- (b) Amounts represent withholding tax payable (2019: RMB96,845,000) for employee's individual income tax associated with vested restricted share units which were fully paid subsequently settled to the tax bureau in January 2021.

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

	December 31, 2020 RMB'000 (Audited)	December 31, 2019 RMB'000 (Audited)
Less than 30 days	28,030	26,471
31 – 60 days	<u>–</u>	<u>10,833</u>
	<u>28,030</u>	<u>37,304</u>

Financial Review

Year Ended December 31, 2020 Compared to Year Ended December 31, 2019

	For the year ended	
	December 31,	
	2020	2019
	RMB'000	RMB'000
	(Audited)	(Audited)
Revenue	1,038,832	–
Cost of revenue	(241,421)	–
Gross profit	797,411	–
Other income	51,671	83,962
Other gains and losses	(179,419)	(637,365)
Research and development expenses	(1,404,684)	(1,395,624)
Selling expenses	(142,150)	–
Administrative expenses	(342,508)	(341,476)
Listing expenses	–	(17,638)
Finance costs	(1,320)	(303)
Loss for the year	(1,220,999)	(2,308,444)
Other comprehensive (expense) income:		
<i>Items that may be reclassified subsequently to profit or loss:</i>		
Exchange differences arising on translation of foreign operations	(1,274)	(1,802)
Fair value gain on investments in debt instruments at FVTOCI	31	408
Reclassified to profit or loss upon disposal of debt instruments at FVTOCI	(31)	(758)
Other comprehensive expense for the year	(1,274)	(2,152)
Total comprehensive expense for the year	(1,222,273)	(2,310,596)
Non-IFRS measures:		
Adjusted loss for the year	(864,976)	(1,141,263)

Revenue. Revenue increased from zero for the year ended December 31, 2019 to RMB1,038.8 million for the year ended December 31, 2020, primarily attributable to the license fee income.

Other Income. Other income decreased by RMB32.3 million from RMB84.0 million for the year ended December 31, 2019 to RMB51.7 million for the year ended December 31, 2020, primarily attributable to less interest income.

Other Gains and Losses. Other gains and losses decreased by RMB458.0 million from losses of RMB637.4 million for the year ended December 31, 2019 to losses of RMB179.4 million for the year ended December 31, 2020, primarily attributable to the elimination of losses in fair value of derivative financial liabilities as the Group had no preferred shares outstanding as of December 31, 2020.

Research and Development Expenses. Our research and development expenses increased by RMB9.1 million from RMB1,395.6 million for the year ended December 31, 2019 to RMB1,404.7 million for the year ended December 31, 2020. This increase was primarily attributable to our pipeline advancement.

	For the year ended	
	December 31,	
	2020	2019
	RMB'000	RMB'000
Employee cost	313,402	337,857
Milestone fee and third party contracting cost	1,088,706	1,056,042
Others	2,576	1,725
	<hr/>	<hr/>
Total	<u>1,404,684</u>	<u>1,395,624</u>

Administrative Expenses. Our administrative expenses increased by RMB1.0 million from RMB341.5 million for the year ended December 31, 2019 to RMB342.5 million for the year ended December 31, 2020. This was primarily attributable to the combination impact of (i) a decrease of RMB21.6 million in employee cost from RMB259.6 million for the year ended December 31, 2019 to RMB238.0 million for year ended December 31, 2020 due to decreased share-based payment expenses; and (ii) an increase of RMB17.6 million in professional fees from RMB40.3 million for the year ended December 31, 2019 to RMB57.9 million for the year ended December 31, 2020.

	For the year ended December 31,	
	2020	2019
	RMB'000	RMB'000
Employee cost	238,022	259,637
Professional fees	57,927	40,264
Rental expenses	3,160	2,859
Depreciation and amortization	14,594	10,390
Others	28,805	28,326
	<u>342,508</u>	<u>341,476</u>
Total	<u>342,508</u>	<u>341,476</u>

Selling Expenses. Our selling expenses increased from zero for the year ended December 31, 2019 to RMB142.2 million for the year ended December 31, 2020. The increase was primarily attributable to the increase in employee cost and professional fees incurred for activities associated with marketing and sales prior to product launch.

	For the year ended December 31,	
	2020	
	RMB'000	
Employee cost	86,244	
Professional fees	24,486	
Others	31,420	
	<u>142,150</u>	
Total	<u>142,150</u>	

Finance Costs. The finance costs increased by RMB1.0 million from RMB0.3 million for year ended December 31, 2019 to RMB1.3 million for the year ended December 31, 2020.

Listing Expenses. We did not incur any listing expenses for year ended December 31, 2020. 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.

Other Comprehensive Expense. Our other comprehensive expense decreased from RMB2.2 million for year ended December 31, 2019 to RMB1.3 million for year ended December 31, 2020.

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 onetime 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 compensation 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 periods indicated:

	For year ended	
	December 31,	
	2020	2019
	RMB'000	RMB'000
Loss for the year	(1,220,999)	(2,308,444)
Added:		
Loss on changes in fair value of derivative financial liabilities	–	756,464
Share-based payment expenses	<u>356,023</u>	<u>410,717</u>
Adjusted loss for the year	<u>(864,976)</u>	<u>(1,141,263)</u>

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

	For year ended	
	December 31,	
	2020	2019
	RMB'000	RMB'000
Research and development expenses for the year	(1,404,684)	(1,395,624)
Added:		
Share-based payment expenses	<u>158,972</u>	<u>206,881</u>
Adjusted research and development expenses for the year	<u>(1,245,712)</u>	<u>(1,188,743)</u>

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

	For year ended December 31,	
	2020	2019
	RMB'000	RMB'000
Administrative and selling expenses for the year	(484,658)	(341,476)
Added:		
Share-based payment expenses	<u>197,051</u>	<u>203,836</u>
Adjusted administrative and selling expenses for the year	<u>(287,607)</u>	<u>(137,640)</u>

Employees and Remuneration Policies

The following table sets forth a breakdown of our employees as at December 31, 2020 by function:

Function	Number of employees	% of total number of employees
Research and Development	212	45.11
Sales, General and Administrative	<u>258</u>	<u>54.89</u>
Total	<u>470</u>	<u>100.0</u>

As of December 31, 2020, we had 247 employees in Shanghai, 37 employees in Suzhou, 66 employees in Beijing and 120 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 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 December 31, 2020, our time deposits, bank balances and cash were RMB3,383.4 million, as compared to RMB2,725.9 million as of December 31, 2019. The increase was mainly due to license fee income and equity investment.

Gearing Ratio

Gearing ratio is calculated using total liabilities divided by total assets and multiplied by 100%. As at December 31, 2020, our gearing ratio was 21.5% (as at December 31, 2019: 15.9%).

Other Financial Information

Significant Investments, Material Acquisitions and Disposals

As at December 31, 2020, we did not hold any significant investments. For year ended December 31, 2020, we did not have material acquisitions or disposals of subsidiaries, associates and joint ventures.

Foreign Exchange Risk

Certain time deposits, cash and cash equivalents, other receivables, debt instruments measured at FVTOCI, other investments classified as financial assets at FVTPL and trade and other payables are denominated in foreign currencies of the respective group entities which are exposed to foreign currency risk.

The Group currently does not have a foreign currency hedging policy. However, the management of the Group monitors foreign exchange exposure and will consider hedging of 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 working capital improvement and the construction of the factory and facilities. During year ended December 31, 2020, the Group has drawn down RMB58,582,000 and repaid RMB1,580,000 of principal in accordance with the payment schedules.

Contingent Liabilities

As of December 31, 2020, we did not have any material contingent liabilities.

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 year ended December 31, 2020, we had 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 year ended December 31, 2020, the Board is of the opinion that we have 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 constitutes 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.

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.

Securities Transactions by Directors

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 on terms not less exacting than the required standard indicated by the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix 10 to the Listing Rules (the “**Model Code**”).

Specific enquiries have been made to all the Directors and they have confirmed that they have complied with the Securities Transactions Code during the year ended December 31, 2020. 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

For the year ended December 31, 2020, the Company repurchased a total of 3,025,500 Shares through the Stock Exchange, details of which are set out below:

Month/Year	Number of Shares purchased	Highest price per Share (HK\$)	Lowest price per Share (HK\$)	Aggregate Price Paid (excluding expenses) (HK\$)
May 2020	2,187,500	8.16	7.05	16,328,535
June 2020	838,000	9.00	8.57	7,480,390

2,403,000 repurchased Shares were cancelled on June 17, 2020 and 622,500 repurchased Shares were cancelled on July 10, 2020. The purchase of the Company's shares during the year was effected by the Directors, pursuant to the mandate from shareholders received at the last annual general meeting, with a view to benefiting shareholders as a whole by enhancing the net asset value per share and earnings per share of the Group. Save as disclosed above, neither the Company nor any of its subsidiaries purchased, sold or redeemed any of the Company's listed securities (whether on the Stock Exchange or otherwise) for the year ended December 31, 2020.

Material Litigation

The Company was not involved in any material litigation or arbitration during the year ended December 31, 2020. The Directors are also not aware of any material litigation or claims that were pending or threatened against the Group during the year ended December 31, 2020.

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 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 as follows and the Company will gradually utilize the residual amount of the net proceeds in accordance with such intended purposes depending on actual business needs.

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, 2020:

	% of use of proceeds (Approximately)	Net proceeds from the IPO (RMB million)	Actual usage up to December 31, 2020 (RMB million)	Unutilized net proceeds as of December 31, 2020 (RMB million)
Fund ongoing and planned clinical trials, preparation for registration filings and commercial launches of sugemalimab	30.0%	627.04	558.31	68.73
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	40.0%	836.06	702.14	133.92
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	20.0%	418.04	418.04	-
For working capital and general corporate purposes	10.0%	209.02	209.02	-
Total	100.0%	2,090.16	1,887.51	202.65

Notes:

- (1) Net IPO proceeds were received in Hong Kong dollars and translated to Renminbi for application planning.
- (2) The unutilized net proceeds of RMB202.65 million as of December 31, 2020 is expected to be completely used by December 31, 2021.

On September 30, 2020 (before trading hours), the Company entered into the share subscription agreement with Pfizer, pursuant to which Pfizer has conditionally agreed to subscribe for an aggregate of 115,928,803 subscription shares at the subscription price of approximately HK\$13.37 per Share. The gross proceeds from the allotment and issue of the subscription shares were approximately US\$200.0 million (equivalent to approximately RMB1,355.9 million), which will be used for the funding of the development activities under the collaboration agreement. All the conditions of the subscription have been fulfilled and the closing of the subscription took place on October 9, 2020. The use of these proceeds is in line with the planned use and there is no significant change or delay.

The table below sets out the planned applications of the proceeds and actual usage up to December 31, 2020:

	% of use of proceeds <i>(Approximately)</i>	Proceeds from the subscription <i>(RMB million)</i>	Actual usage up to December 31, 2020 <i>(RMB million)</i>	Unutilized net proceeds as of December 31, 2020 <i>(RMB million)</i>
Fund the development activities under the collaboration agreement	<u>100%</u>	<u>1,355.9</u>	<u>59.5</u>	<u>1,296.4</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.

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, 2020 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, 2020 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 final dividend for the year ended December 31, 2020.

PUBLICATION OF ANNUAL RESULTS ANNOUNCEMENT AND ANNUAL REPORT

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

The annual report for the year ended December 31, 2020 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 25, 2021

As of the date of this announcement, the Board comprises Dr. Frank Ningjun Jiang as Chairman and Executive Director, Dr. Wei Li, Mr. Qun Zhao, Mr. Yanling Cao, Mr. Xianghong Lin 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.