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CStone Pharmaceuticals 基石藥業

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

ANNOUNCEMENT OF INTERIM RESULTS FOR THE SIX MONTHS ENDED JUNE 30, 2021

The board (the “**Board**”) of directors (the “**Directors**”) of CStone Pharmaceuticals (the “**Company**”) is pleased to announce the unaudited condensed consolidated results of the Company and its subsidiaries (together, the “**Group**”, “**we**” or “**us**”) for the six months ended June 30, 2021 (the “**Reporting Period**”), together with comparative figures for the six months ended June 30, 2020. Unless otherwise defined herein, capitalized terms used in this announcement shall have the same meanings as those defined in the prospectus of our Company dated February 14, 2019 (the “**Prospectus**”) and our announcement of interim results for the six months ended June 30, 2020 dated August 18, 2020.

FINANCIAL HIGHLIGHTS

International Financial Reporting Standards (“IFRS”) Measures:

- **Revenue** increased from zero for the six months ended June 30, 2020 to RMB79.4 million for the six months ended June 30, 2021, primarily attributable to sales of the Company’s pharmaceutical products (avapritinib and pralsetinib). The revenue of avapritinib and pralsetinib reached RMB33.6 million and RMB45.8 million during the Reporting Period, respectively.
- **Research and development expenses** decreased by RMB31.4 million from RMB544.2 million for the six months ended June 30, 2020 to RMB512.8 million for the six months ended June 30, 2021, primarily due to prioritization of clinical studies, and offset by continued investment in key clinical trials and pre-clinical studies during the Reporting Period.
- **Administrative expenses** decreased by RMB11.1 million from RMB165.2 million for the six months ended June 30, 2020 to RMB154.1 million for the six months ended June 30, 2021, primarily attributable to reduction in professional fees.
- **Selling and marketing expenses** increased by RMB109.5 million from RMB24.1 million for the six months ended June 30, 2020 to RMB133.6 million for the six months ended June 30, 2021, primarily attributable to sales force build-up and marketing activities for product launch.

- **Loss for the period** increased by RMB102.7 million from RMB671.2 million for the six months ended June 30, 2020 to RMB773.9 million for the six months ended June 30, 2021, primarily attributable to the increasing selling and marketing expenses for commercial launch, and offset by the sales income of avapritinib and pralsetinib.

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

- **Research and development expenses** excluding the share-based payment expenses decreased by RMB25.6 million from RMB470.4 million for the six months ended June 30, 2020 to RMB444.8 million for the six months ended June 30, 2021, primarily due to prioritization of clinical studies, and offset by continued investment in key clinical trials and preclinical studies during the Reporting Period.
- **Administrative and selling and marketing expenses** excluding the share-based payment expenses increased by RMB114.0 million from RMB100.3 million for the six months ended June 30, 2020 to RMB214.3 million for the six months ended June 30, 2021, primarily attributable to sales force build-up and marketing activities for product launch.
- **Loss for the period** excluding the share-based payment expenses increased by RMB124.0 million from RMB508.5 million for the six months ended June 30, 2020 to RMB632.5 million for the six months ended June 30, 2021, primarily attributable to the increasing selling and marketing expenses for commercial launch, and offset by the sales income of avapritinib and pralsetinib.

BUSINESS HIGHLIGHTS

In the first half of 2021, CStone continued the tremendous momentum of the prior year, extending a track record of performance as a full-fledged biopharmaceutical company. We delivered six-months of solid execution, maintaining – and where possible, expediting – an ambitious agenda across the business. We further demonstrated our superior clinical development capabilities, with several programs reaching exciting milestones, including three approvals that led to our first product launches. Our commercial team executed a flawless go-to-market strategy for our approved drugs, which achieved an exceptional sales ramp-up. Additionally, we advanced our pre-clinical efforts with progress on multiple first-in-class (“**FIC**”)/best-in-class (“**BIC**”)/first-wave (“**FW**”) candidates in emerging therapeutic modalities and for which we hold global commercial rights. Our efforts have further distinguished our pipeline, which stands out for the distinctiveness of our molecules, balance across stages of development, growing indication coverage, and expanding mix of global and Greater China commercial rights. Altogether, CStone’s performance during the Reporting Period underscores our ability to fully harness the fundamental drivers of our business and brings into clearer view the full commercial and clinical value of our evolving portfolio.

For the six months ended June 30, 2021 and as of the date of this announcement, significant progress has been made with respect to our product pipeline and business operations:

I. Commercial Efforts Lead to Successful Product Launches

The first half of 2021 was the most commercially active period in our history. Through wide and deep engagement with stakeholders in the healthcare community, our growing commercial team set the stage for our first commercial launches, those of GAVRETO[®] (pralsetinib) and AYVAKIT[®] (avapritinib). They engaged healthcare providers, regulators, hospitals, pharmacies and payors, among other groups in the healthcare community, to provide education on our products and expand the number of patients who can access them. As a result, we brought two precision medicines to market with exceptional speed and achieved a rapid sales ramp-up.

Additionally, the commercial team continued their efforts to expand the accessibility of assets on the market to bolster sales while also supporting the broader pipeline of late-stage assets which are on track for commercialization and indication expansions.

Highlights and details on our first-half commercial activity follow below.

- ***Healthcare community engagement supports successful product launches***
 - Active engagement with healthcare community stakeholders expanded our coverage of the market to include over 400 hospitals across more than 130 cities, and deepened our ties to healthcare providers, pharmacies, patient groups and insurers. Our sales team is well on track to establish comprehensive coverage of the market in China for our drugs. They now cover hospitals that account for approximately 70-80% of relevant market of precision medicines. Additionally, they secured inclusion of our precision medicines in 20 of the major commercial and government insurance programs. Through this effort, we established a robust network to support our first two product launches and prepare the pathway for future launches.
 - We launched two precision medicines, reaching a broad swath of patients from the very first day. We successfully launched AYVAKIT[®] (avapritinib) in mainland China and Taiwan, China in May 2021 and June 2021 respectively, achieving net sales of RMB33.6 million in the first half of 2021. In June 2021, we successfully launched GAVRETO[®] (pralsetinib) in mainland China, achieving net sales of RMB45.8 million in the first half of 2021.
- ***Strategic collaboration agreements support product distribution***
 - We established a strategic collaboration agreement with Sinopharm Group Co., Ltd (“**Sinopharm**”). This enabled us to broaden hospital and pharmacy distribution coverage across mainland China for both GAVRETO[®] (pralsetinib) and AYVAKIT[®] (avapritinib). Through the collaboration with China (Shanghai) Pilot Free Trade Zone Lin Gang Special Area (“**Lin Gang**”), we were also able to expedite the process for market entry by clearing customs and completing the port inspection processes within four days, which is significantly earlier than expected.

- We formed strategic collaboration agreements with three of the largest integrated healthcare service platforms in mainland China – Shanghai Meditrust Health Co., Ltd., Beijing Yuanxin Technology Group Co., Ltd., and Medbanks – to leverage each party’s competitive advantages and utilize innovative healthcare payment programs to improve distribution and patient affordability of GAVRETO® (pralsetinib) and AYVAKIT® (avapritinib). These relationships will help to maximize distribution of these drugs and improve patient affordability.
- ***Commercial efforts expand market potential and launch readiness of late-stage assets***
 - We are closely collaborating with our partners Pfizer and EQRx to plan the commercialization of sugemalimab in mainland China, and the global launch (outside Greater China) of sugemalimab. Our work with Pfizer has put us on track to receive new drug application (“NDA”) approval for sugemalimab in mainland China this year, specifically for stage IV non-small cell lung cancer (“NSCLC”). This progress brings us materially closer to full-scale commercial launch of this drug. With EQRx, we are setting the stage for broad distribution of sugemalimab in markets that are forecast to generate approximately US\$30 billion in PD-(L)1 sales in 2026 for the treatment of NSCLC, gastric and esophageal cancers: the U.S., the U.K. and the European Union (“EU”), etc.
 - We took several steps to prepare for the indication expansion of GAVRETO® (pralsetinib) and AYVAKIT® (avapritinib), which will provide greater long-term sales growth potential. For GAVRETO® (pralsetinib), we have submitted NDAs in mainland China for RET-mutant medullary thyroid cancer (“MTC”) and RET fusion-positive thyroid cancer and have been granted priority review. We also expect to submit an NDA in mainland China for the first-line treatment of RET fusion-positive NSCLC in the second half of 2021. In addition, we expect to submit NDAs in Hong Kong and Taiwan, China in the second half of 2021 for the second-line treatment of RET fusion-positive NSCLC. For AYVAKIT® (avapritinib), we have submitted an NDA in Hong Kong for PDGFRA D842V mutant gastrointestinal stromal tumor (“GIST”). Also, we are exploring possible routes to expedite registration in mainland China on the back of U.S. FDA approval for the treatment of adult patients with advanced systemic mastocytosis (“SM”).
 - We advanced the launch readiness of ivosidenib (IDH1 inhibitor) and expect to receive an NDA approval in the fourth quarter of 2021 or first quarter of 2022 for patients with relapsed or refractory acute myeloid leukemia (“R/R AML”).

II. Numerous Clinical Successes Support a Mature Pipeline

We made substantial progress during the first half of 2021 to establish a mature pipeline of late-stage FIC assets across various oncology therapeutic areas and indications, expanding our total potential addressable market. We secured three NDA approvals to support our pralsetinib and avapritinib launches. We submitted four NDA filings covering a third asset, ivosidenib, as well as indication and geographic expansions for pralsetinib, avapritinib and sugemalimab. We also significantly stepped up the volume of planned readouts and presentations relative to prior years.

Of particular significance, we announced several positive developments with sugemalimab that demonstrate its broad applicability and safety as a treatment for both stage III and IV NSCLC, including in an “all-comers” setting, which can give it a unique and potentially enduring market niche.

Details follow below.

- **Sugemalimab** (CS1001, PD-L1 antibody)
 - In May 2021, the phase III trial of sugemalimab in patients with stage III NSCLC as monotherapy in the maintenance setting following concurrent or sequential chemoradiotherapy met its primary endpoint. This innovative trial design reflects real-world clinical practices and demonstrates sugemalimab’s distinct ability to cover a much broader patient population among PD-(L)1 treatments. We submitted an NDA for this indication to the NMPA in August 2021.
 - The final PFS analysis of the phase III trial for stage IV squamous and non-squamous NSCLC showed that sugemalimab combined with chemotherapy as first-line treatment contributed to prolonged PFS and encouraging overall survival. Our NDA for this indication was accepted by the NMPA in November 2020 and we expect to receive the NDA approval by the end of 2021. In addition, we are working closely with EQRx on regulatory discussions for new drug applications for the two indications of stage III and stage IV NSCLC in multiple countries, including the U.S.
- **Pralsetinib** (CS3009, RET inhibitor)
 - On March 24, 2021, we received an NDA approval from the NMPA for the treatment of patients with RET fusion-positive NSCLC previously treated with platinum-based chemotherapy.
 - In April 2021, the NMPA accepted the NDA with Priority Review Designation for the treatment of patients with advanced or metastatic RET-mutant MTC and RET fusion-positive thyroid cancer.

- **Avapritinib** (CS3007, KIT/PDGFR A inhibitor)
 - On March 31, 2021, we received an NDA approval from the NMPA for the treatment of adults with unresectable or metastatic GIST harboring a PDGFR A exon 18 mutation, including PDGFR A D842V mutations.
 - On April 29, 2021, we received the NDA approval license from Taiwan Food and Drug Administration (“**TFDA**”) through an accelerated approval pathway for adults with unresectable or metastatic GIST harboring a PDGFR A D842V mutations.
 - In May 2021, we received the acceptance of the NDA from Hong Kong Department of Health (“**HK DoH**”) for adults with unresectable or metastatic GIST harboring a PDGFR A D842V mutations. We expect a decision on the NDA in the second half of 2022.

- **Ivosidenib** (CS3010, IDH1 inhibitor)
 - The registrational trial of ivosidenib in patients with relapsed or refractory acute myeloid leukemia (“**R/R AML**”) with an isocitrate dehydrogenase 1 (“**IDH1**”) mutation met the pre-specified endpoints. Ivosidenib is the first IDH1 inhibitor in China that has demonstrated efficacy and sustained remission in patients with R/R AML.
 - In August 2021, the NMPA accepted the NDA for the treatment of adults with R/R AML with a susceptible IDH1 mutation and granted priority review. We expect to receive the NDA approval around the end of 2021 or the first quarter of 2022.
 - In August 2021, our partner, Servier, released positive topline data from the global phase III study of ivosidenib in combination with azacitidine in patients with previously untreated IDH1 mutant acute myeloid leukemia. The study recently halted further enrollment due to compelling efficacy data. We expect to file an NDA for this indication with the NMPA in 2022.

III. Strategic Relationships Advance Outlook for Late-Stage Assets and Bolster Development Pipeline

We continue to grow and deepen our relationships with key global strategic partners, Pfizer and EQRx.

With Pfizer, we are preparing sugemalimab for full-scale commercial launch for stage IV NSCLC in mainland China. We are partnering with them in discussions with regulators and working together closely to establish connections with and educate other important healthcare community stakeholders. These efforts are intended to set the stage for broad and rapid market adoption and sales ramp-up of sugemalimab upon commercial launch.

In addition, we broadened our relationship with Pfizer in the first half of the year with the agreement to co-develop Pfizer's late-stage oncology asset lorlatinib in second line c-ros oncogene 1 ("**ROS1**") positive NSCLC in Greater China. This type of collaboration was envisioned in the original partnership that we announced last year. It is a significant development both clinically and in terms of our relationship with Pfizer. The plan for lorlatinib is to assess if this agent can provide benefits to the relapsed ROS1-positive advanced NSCLC after crizotinib, which if positive would add a new therapeutic approach to our lung cancer line-up. This program also bolsters the foundation of our relationship with a global biopharmaceutical leader and sets us up for future collaboration with them.

With EQRx, we have initiated discussions with stakeholders in key global markets – the U.S., the U.K., and the EU – around the registration of sugemalimab for NSCLC indications. Relevant discussions are ongoing. We are collaborating with EQRx to explore the feasibility of extending the range of covered indications for this drug, including gastric cancer and esophageal cancer. In addition, we are working with EQRx to expand a phase III study of CS1003 in HCC in the U.S. and major EU markets.

IV. Pipeline 2.0 Efforts Harness Full Potential of Next-Gen Candidates

We have begun to realize the benefits of the revamp of our research capabilities in order to advance our development of BIC and FIC assets with global commercial rights. We expect this effort to enhance our internal sources of innovation, generate a sustained supply of one to two investigational new drug ("**IND**") application(s) per year, and support development of a globally distinctive and differentiated pipeline.

We are maintaining our near-term Pipeline 2.0 focus on two emerging therapeutic modalities: antibody-drug conjugates ("**ADC**") and multi-specific biologics. In the first half of 2021, we made substantial progress advancing two such assets into the clinical stage this year:

- **CS2006** (NM21-1480, PD-L1×4-1BB×HSA tri-specific molecule): The dose escalation is ongoing and includes sites in the U.S. and Taiwan, China. We have completed dose level 4 enrollment in the U.S. and dose level 5 enrollment is ongoing. We submitted an IND application to the NMPA and received the IND acceptance in July 2021.
- **CS5001** (LCB71, ROR1 ADC): The IND-enabling activities are ongoing and are expected to be completed with an IND/CTA submitted in the U.S./Australia thereafter by the end of 2021.

In addition to CS2006 and CS5001, we are further developing additional FIC/BIC/FW assets for which we hold global commercial rights, including two multi-specific biologics and one ADC.

V. Expanding Capital Markets Access

Due to the strong performance in our shares during the 12 months as of June 2021, our stock has been included in the Hang Seng Composite Index and it is expected to be included in the Hong Kong Stock Connect imminently. This development is significant in that it can foster greater trading in our shares, more efficient price discovery and additional liquidity for investors.

MANAGEMENT DISCUSSION & ANALYSIS

OUR VISION

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

OVERVIEW

CStone is a biopharmaceutical company focused on researching, developing, and commercializing innovative immuno-oncology and precision medicines to address the unmet medical needs of cancer patients in China and worldwide. Established in 2015, CStone has assembled a world-class management team with extensive experience in innovative drug development, clinical research, and commercialization. The company has built an oncology-focused pipeline of 15 drug candidates with a strategic emphasis on immuno-oncology combination therapies. Currently, CStone has received three drug approvals in Greater China, including two in mainland China and one in Taiwan, China. For details of any of the foregoing, please refer to the rest of this announcement and, where applicable, the prospectus of the Company and prior announcements published on the websites of The Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”) and the Company.

Product Pipeline

Drug candidate	Rights	Indication	Pre-clinical	FIH	POC	Pivotal	NDA	Marketed	Approval				Partner		
									CN ⁵	TW	HK	US			
Pralsetinib (RET)		2L NSCLC 1L NSCLC 1L MTC / TC Multiple tumors								✓					
Avapritinib (KIT/PDGFR4)		PDGFR4 exon 18 GIST AdvSM ¹								✓	✓				
Sugemalimab (PD-L1)	Out-licensed	1L Stage IV NSCLC Stage III NSCLC 1L GC 1L ESCC R/R ENKTL R/R ENKTL													Mainland China
Ivosidenib (IDH1)		R/R AML 1L AML											✓		Ex-Greater China
CS1003 (PD-1)		1L HCC													Ex-Greater China
Lorlatinib (ROSI/ALK)		NSCLC											(ALK)		⁴
Fisogatinib (FGFR4)		HCC													
CS1002 (CTLA-4)		Solid tumors													
CS2006² (PD-L1/4-1BB/HSA)		Solid tumors													
CS3002 (CDK4/6)		Solid tumors													
CS3005 (A2aR)		Solid tumors													
CS5001³ (ROR1)		Solid tumors Hematologic malignancies													
CS2007 (Undisclosed Multi-specific)		Solid tumors													
CS2008 (Undisclosed Multi-specific)		Solid tumors													
CS5002 (Undisclosed ADC)		Solid tumors													

Note: Assets status denote progress in the region noted in the column titled “Rights”; CN = Mainland China, TW = Taiwan, China, HK = Hong Kong SAR, US = United States, NSCLC = Non-small Cell Lung Cancer, MTC = Medullary Thyroid Cancer, TC = Thyroid Cancer, GIST = Gastrointestinal Stromal Tumor, AdvSM = Advanced Systemic Mastocytosis, GC = Gastric Cancer, ESCC = Esophageal Squamous Cell Carcinoma, R/R = Relapsed or Refractory, NKTL = Natural KILLER/T Cell Lymphoma, AML = Acute Myeloid Leukemia, HCC = Hepatocellular Carcinoma
 1. POC was conducted in the U.S. and no clinical trials have been conducted in China; 2. CS2006 is currently under PhI dose escalation study in Taiwan & IND preparation in mainland China; 3. CStone obtains the exclusive global right to lead development and commercialization of LCB71/CS5001 outside the Republic of Korea; 4. Co-development in Greater China; 5. Mainland China

Greater China
 Global
 Expedited registration
 Greater China
 Global
 Korea
 Singapore

BUSINESS REVIEW

Commercial Operations

During the first half of 2021, we expanded our commercial team, which includes approximately 300 people currently, and successfully launched two FIC precision medicines: GAVRETO® (pralsetinib) and AYVAKIT® (avapritinib). These drugs were initially made available to patients in 2020 via an early-access pilot program in Bo'ao, enabling Chinese patients to access innovative drugs upon US FDA approval. In the first half of this year, we obtained the regulatory approvals for them and proceeded with their commercial launches in mainland China and Taiwan, China.

In addition, the commercial team continued an aggressive program to broaden and deepen ties to the healthcare community and critical stakeholder groups as part of preparations of launching our drug candidates. Our commercial team has established coverage of over 400 hospitals across more than 130 cities, establishing coverage of hospitals that account for approximately 70-80% of relevant market of precision medicines. They also successfully secured inclusion of our drugs in major commercial and government administered insurance plans as part of an effort to broaden patient access to our drugs by making them more affordable. Details on our full commercial efforts are set out below.

- ***GAVRETO® (pralsetinib)***
 - GAVRETO® (pralsetinib), a FIC RET inhibitor in China, has been approved for the treatment of adults with RET fusion-positive NSCLC previously treated with platinum-based chemotherapy by the NMPA. GAVRETO® (pralsetinib) is the first drug using the Bo'ao Le Cheng pilot program to allow the use of real-world data as support to accelerate the NMPA approval of 6.5 months. The commercialization of GAVRETO® (pralsetinib) reflects our determination to address patients' unmet clinical needs and demonstrates our ability to quickly bring innovative drugs to the market. In the first half of 2021, GAVRETO® (pralsetinib) achieved net sales of RMB45.8 million.
 - On July 3, 2021, we held the national launch meeting of GAVRETO® (pralsetinib) with over 500 oncologists attending in person and more than 13,000 physicians joining online.
 - GAVRETO® (pralsetinib) is recommended by 2021 Chinese Medical Association Guidelines for RET fusion-positive stage IV non-squamous NSCLC as the only therapy for second line and later line treatment.
 - Testing for RET alterations is recommended by 2021 Guidelines on Clinical Practice of Molecular Tests in NSCLC in China with level I recommendation.
 - GAVRETO® (pralsetinib) has been listed in 9 commercial health insurance plans and 11 supplemental insurance plans sponsored by provincial or municipal governments.

- ***AYVAKIT® (avapritinib)***
 - AYVAKIT® (avapritinib), a FIC KIT/PDGFRα inhibitor, has been approved for the treatment of adults with unresectable or metastatic GIST harboring a PDGFRα exon 18 mutation, including PDGFRα D842V mutations by the NMPA. AYVAKIT® (avapritinib) has also been approved for the treatment of patients with PDGFRα D842V mutant GIST by the FDA. AYVAKIT® (avapritinib) took only 4 days to reach distribution partners from the time of arrival in China. In the first half of 2021, AYVAKIT® (avapritinib) achieved net sales of RMB33.6 million.
 - On May 22, 2021, we held the national launch meeting of AYVAKIT® (avapritinib) with over 400 oncologists attending in person and more than 9,600 physicians joining online.
 - AYVAKIT® (avapritinib) has been listed in 9 commercial health insurance plans and 6 supplemental insurance plans sponsored by provincial or municipal governments.
- ***Other Late-stage Assets***
 - Our Commercial platform is also well prepared for pre-launch activities for ivosidenib.
 - In addition, we are working with Pfizer to support the commercialization of sugemalimab in mainland China, and with EQRx to support the global launch (outside Greater China) of sugemalimab.

Clinical Development

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

Pralsetinib (CS3009, RET inhibitor)

- On March 24, 2021, the NMPA approved GAVRETO® (pralsetinib) for the treatment of adults with locally advanced or metastatic RET fusion-positive NSCLC after platinum-based chemotherapy. GAVRETO® was the first approved selective RET inhibitor in China and first approved precision therapy for CStone.
- In April 2021, the NMPA accepted the NDA with Priority Review Designation for the treatment of patients with advanced or metastatic RET-mutant MTC and RET fusion-positive thyroid cancer. In June 2021, we announced China registration-enabling cohort data from the phase I/II ARROW trial of patients with RET-mutant MTC who have not been previously treated with systemic therapy, which was generally consistent with previously announced global clinical data.
 - Primary efficacy data showed deep and durable anti-tumor activity of pralsetinib in Chinese patients with advanced or metastatic RET-mutant MTC, consistent with previously reported results in the global ARROW study. The safety data observed in Chinese patients was similar with results shown in global patients. We plan to present the detailed data at an upcoming international academic conference.

- In June 2021, China registration-enabling cohort from the phase I/II ARROW trial of patients with RET fusion-positive NSCLC who have not been previously treated with systemic therapy showed consistency with global clinical data. We expect to submit an NDA to the NMPA for this indication in the second half of 2021.
 - Primary efficacy data showed deep and durable anti-tumor activity of pralsetinib for first-line treatment in patients with RET fusion-positive NSCLC, which was consistent with the global population. The overall safety was manageable, with no new safety signal detected.
 - This positive clinical data has been accepted as a Late-Breaking Abstract Presentation at the International Association for the Study of Lung Cancer (“IASLC”) 2021 World Conference on Lung Cancer (“WCLC”) in September 2021.
- We expect to submit an NDA to the TFDA in the second half of 2021 for RET fusion-positive NSCLC patients.
- We expect to submit an NDA to HK DoH in the second half of 2021 for RET fusion-positive NSCLC patients.

Avapritinib (CS3007, KIT/PDGFRΑ inhibitor)

- On March 31, 2021, we received an NDA approval from the NMPA for the treatment of adults with unresectable or metastatic GIST harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutations.
- On April 29, 2021, we received the NDA approval license from the TFDA through an accelerated approval pathway for avapritinib for adults with unresectable or metastatic GIST harboring a PDGFRA D842V mutations.
- In May 2021, we received the acceptance of the NDA from HK DoH for adults with unresectable or metastatic GIST harboring a PDGFRA D842V mutations. We expect a decision on the NDA in the second half of 2022.
- The phase I/II bridging study data presented at the 2021 European Society for Medical Oncology (ESMO) World Congress on Gastrointestinal Cancer annual meeting showed avapritinib was generally well-tolerated and had promising anti-tumor activity in Chinese GIST patients with the PDGFRA D842V mutation, and has also shown potential for the treatment of fourth-line and later Chinese GIST patients.
- In June 2021, our partner, Blueprint Medicines announced that the U.S. FDA has approved AYWAKIT™ (avapritinib) for the treatment of adult patients with advanced systemic mastocytosis (“**Advanced SM**”). We plan to communicate with the NMPA about the registrational pathway for this indication in China.

Ivosidenib (CS3010, IDH1 inhibitor)

- In July 2021, the China registrational trial of ivosidenib in patients with R/R AML with an IDH1 mutation met the pre-specified endpoints.
 - The results demonstrated efficacy and manageable safety of ivosidenib, which were consistent with results shown in global patients. This positive clinical data has been accepted as proffered presentation at the ESMO Virtual Congress 2021 in September 2021.
 - Ivosidenib was the first IDH1 inhibitor in China that has demonstrated efficacy and sustained remission in patients with R/R AML.
- In August 2021, the NMPA accepted the NDA of ivosidenib for the treatment of adults with R/R AML with a susceptible IDH1 mutation and granted priority review. We expect to receive the NDA approval around the end of 2021 or the first quarter of 2022.
- In August 2021, our partner, Servier, released positive topline data from the global phase III study of ivosidenib in combination with azacitidine in patients with previously untreated IDH1 mutant acute myeloid leukemia. The study recently halted further enrollment due to compelling efficacy data. We expect to file an NDA for this indication with the NMPA in 2022.

Sugemalimab (PD-L1 antibody)

- Sugemalimab is an investigational monoclonal antibody directed against PD-L1 that is currently under NDA review by the 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 June 30, 2021, we have dosed more than 1,500 patients with sugemalimab in 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 May 2021, the phase III trial of sugemalimab in patients with stage III NSCLC as monotherapy in the maintenance setting following chemoradiotherapy met its primary endpoint. We submitted an NDA for this indication to the NMPA in August 2021.
 - It was the first anti-PD-1/PD-L1 monoclonal antibody worldwide to successfully improve PFS in patients with stage III NSCLC without disease progression after concurrent or sequential chemoradiotherapy. Subgroup analyses demonstrated that sugemalimab was associated with clinical benefit regardless of whether patients received concurrent or sequential chemoradiotherapy prior to sugemalimab. Subgroup analyses showed a clinical benefit across histology subtypes and PD-L1 expression levels. The highly positive clinical data has been accepted as a Late-Breaking Abstract at the ESMO Virtual Congress 2021.

- In July 2021, final PFS analysis of the phase III trial of sugemalimab as a first-line treatment for stage IV squamous and non-squamous NSCLC showed that sugemalimab plus chemotherapy demonstrated further improvement in PFS. In addition, data in longer follow-up further demonstrated that sugemalimab plus chemotherapy brought patients encouraging overall survival. This favorable final PFS data has been accepted as a Late-Breaking Abstract Presentation at the IASLC 2021 WCLC. An NDA for this indication was accepted by the NMPA in November 2020. We expect to receive the NDA approval by end of 2021.
- Sugemalimab was the world’s first anti-PD-1/PD-L1 monoclonal antibody covering both locally advanced/unresectable (stage III) and metastatic (stage IV) NSCLC patients. We are working closely with EQRx on regulatory discussions for new drug applications for the two indications of stage III and stage IV NSCLC in multiple countries including the U.S.
- We completed the enrollment for the phase II registrational trial of sugemalimab as monotherapy for the treatment of ENKTL in May 2021. We received the Breakthrough Therapy Designation (“**BTD**”) from the NMPA in February 2021 for treating patients with R/R ENKTL. We expect to submit an NDA/a biologics license application (“**BLA**”) to the NMPA/U.S. FDA for this indication in the first half of 2022.
- 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. We expect to submit an NDA for this indication in the second half of 2022.
- 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. We expect to submit an NDA for this indication in the second half of 2022.
- 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 hepatocellular carcinoma (“**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. As of the date of this announcement, the trial is ongoing.
 - Sugemalimab with donafenib: We have received an IND approval from the Center for Drug Evaluation of the NMPA in April 2020. The phase I/II trial has initiated with first patient dosed in dose-escalation in October 2020. As of the date of this announcement, the trial is ongoing.

CAUTIONARY STATEMENT REQUIRED BY RULE 18A.08 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. The enrollment is expected to be completed in the first half of 2022. As of the date of this announcement, the trial is ongoing.

Lorlatinib (ROS-1 inhibitor)

- We will work with Pfizer to jointly develop lorlatinib for ROS1-positive advanced NSCLC in Greater China. The upcoming pivotal clinical study in ROS1-positive lung cancer in China will be the world's first pivotal study of lorlatinib in ROS1-positive NSCLC.

Fisogatinib (CS3008, FGFR4 inhibitor)

- 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. As of the date of this announcement, the trial is ongoing.

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 the TFDA in the third quarter of 2020. The dose escalation is ongoing and includes sites in the U.S. and Taiwan, China. We have completed dose level 4 enrollment in the U.S. and dose level 5 enrollment is ongoing.
- We submitted the IND application to the NMPA and received the IND acceptance in July 2021.

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. As of the date of this announcement, the trial is ongoing.
- We submitted an IND application for the combination therapy of CS1002 plus CS1003 in China in the fourth quarter of 2020. As of the date of this announcement, the trial is ongoing.
- In July 2021, the preliminary data of CS1002 in combination with CS1003 was accepted by ESMO 2021.

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. As of the date of this announcement, the trial is ongoing.

Trademarks

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

Research

Research is at the heart of our mission to pioneer breakthroughs in science and translate them into safe and effective therapies. It is where our passion for science intersects with our desire to have a meaningful impact on the lives of suffering patients. It is also a crucial point of distinction from other biotech firms.

Starting last year and continuing into 2021, we took several steps to improve our pre-clinical pipeline and internal sources of innovation. We consolidated leadership of discovery and early development functions under our Chief Scientific Officer, who has over 20 years of experience in translational oncology research spanning cytotoxics, targeted agents and immunotherapies. In addition, we bolstered our team with new research professionals. We formed a dedicated cross-functional innovation sourcing and strategy team to drive the design and selection of candidates. And we have continued to cultivate a strong network of external partners – academic labs, CROs and other commercial partners – that can provide specific resources to advance and operationalize ideas and innovation.

The reinvigoration of our research team has accelerated our Pipeline 2.0 strategy, and is evident in the portfolio of pre-clinical drug candidates we have assembled as well as our progress in developing them. CS5001, which we in-licensed from LegoChem Biosciences in 2020, embodies our Pipeline 2.0 strategy. CS5001 is an ADC composed of a human monoclonal antibody targeting receptor tyrosine kinase-like orphan receptor 1 (“**ROR1**”). The oncofetal gene ROR1 has prevalent expression in a variety of cancers including leukemia, non-Hodgkin lymphoma, breast, lung, and ovarian cancers, and is also as a promising target for the treatment of both hematological and solid malignancies.

The IND-enabling activities for CS5001 are ongoing and expected to be completed with an IND/CTA submitted in the U.S. and Australia by the end of 2021. Also, the pre-clinical data has been submitted as a Late-Breaking Abstract for the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics to be held in October 2021.

In addition to CS2006 and CS5001, we are continuing the development of multiple potential FIC or BIC programs in our Pipeline 2.0, including two multi-specific biologics and an additional ADC.

Business Development and Strategic Partnerships

Our business development team will continue to play a vital strategic role in the growth of our business. They will pursue flexible deal structures for in-licensing and other partnership opportunities to support pipeline development, as well as commercialization efforts in our home market and abroad. In addition, they are supporting the development of our existing strategic partnerships with Pfizer and EQRx.

Our partnerships with Pfizer and EQRx are cornerstones of our near-term commercial plans as well as our global aspirations. Through our successful collaboration with Pfizer, we are demonstrating the merits of our unique approach to clinical development, and our attractiveness to multinational players who may potentially partner with us. Our successful collaboration with EQRx will bring our drugs into the largest global healthcare markets, and ensure they are competitively positioned.

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

- ***Pfizer***

- In November 2020, the NMPA accepted the first NDA submission of sugemalimab for stage IV NSCLC including both squamous and non-squamous patients, with an expected NMPA decision at the end of 2021. CStone and Pfizer have been working closely to prepare for a successful launch for sugemalimab by educating the healthcare community about its BIC clinical results and leveraging Pfizer's leading commercial infrastructure and deep expertise in China.
- In June 2021, CStone and Pfizer jointly announced that they have selected the first late-stage oncology asset for co-development under the strategic collaboration agreement formed in 2020. The two companies will conduct a pivotal clinical trial of lorlatinib for ROS1-positive advanced NSCLC. This step marks another milestone for CStone and Pfizer in their growing strategic partnership, which includes joint efforts to selectively introduce oncology therapies into the Greater China region. Additionally, it bolsters CStone's growing pipeline.

- ***EQRx***

- CStone and EQRx are engaging regulatory authorities in multiple countries and jurisdictions outside of Greater China to discuss regulatory pathways for sugemalimab in multiple indications.
- For the recruitment of CS1003 in HCC, CStone and EQRx are expanding the phase III studies in the U.S. and major EU markets.

- ***LegoChem Biosciences***

- CStone is leading the global development of CS5001, and plans to submit an IND/CTA in the U.S. and Australia by the end of 2021.

In addition to above, we continue to engage potential partners for multiple partnership opportunities that will accelerate our value creation, including in-licensing, out-licensing and strategic partnerships.

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

During the Reporting Period, the impact of COVID-19 on our business operations was immaterial. The Company has followed government mandates and taken various mitigation measures to ensure employees’ safety and undisrupted business operations.

Although the development of vaccines offers the possibility mitigating the scale and impact of COVID-19, the effectiveness of vaccine development, approval, production, distribution and management are still uncertain and unpredictable. The extent of the future impact of COVID-19 on our operating performance, financial condition and cash flows will therefore depend on the development the disease, which is uncertain and may bring potential operational challenges to our businesses. However, the management of the Company currently does not foresee any significant impact of COVID-19 on our business operations in the future.

FUTURE AND OUTLOOK

Active Near-term Agenda

We are working to bring a number of significant clinical and commercial developments to fruition that will be catalysts for our growth in the remainder of the year as well as into 2022.

To begin, we have a clear roadmap for our late-stage assets. We are working to further expand the covered indications for pralsetinib and avapritinib and continue to increase patient accessibility and affordability. As a result of these efforts and rapid adoption of these drugs to date, we expect their strong sales momentum to continue for the remainder of 2021 and beyond. Also, we expect to receive the NDA approval in mainland China for ivosidenib for R/R AML in the fourth quarter of 2021 or the first quarter of 2022. Our commercial team is already mapping out the launch plans to set the stage for rapid ramp-up in sales of these drugs.

Moreover, we are working with our partners Pfizer and EQRx to support the commercialization of sugemalimab in mainland China and other large global markets. We expect to receive the NDA approval in mainland China for sugemalimab for stage IV NSCLC at the end of 2021. We are working with EQRx to engage regulatory authorities in multiple countries and jurisdictions to discuss regulatory pathways for sugemalimab in multiple indications, and expect the first ex-China BLA filing in 2022.

In addition, we have an extensive array of data readouts and presentations planned for our core late-stage drugs, significantly more than in previous years.

In terms of our Pipeline 2.0, we are working to harness the full potential of current suite of molecules and are on track to meet the 1-2 IND filings we are targeting. We expect to submit an IND application for CS5001 in mainland China and achieve first-patient-in in 2022. Additionally, we expect to initiate a phase I bridging study followed by an expansion study for CS2006 in mainland China by 2022. Moreover, our research team is planning IND filings for another one to two highly-differentiated new molecule(s) with FIC/BIC/FW potential and global commercial rights in 2022.

Our commercial team is working rapidly to expand the addressable market for our products and support future launches. They are focusing on various efforts to increase patient accessibility to our drugs, expand the geographic areas in which they will be sold, and promote awareness of them through key opinion leader engagement and inclusion in treatment and diagnosis guidelines.

Finally, the construction of our manufacturing facility in Suzhou remains on track. We expect to reach the ability for pilot operations by the end of this year, as planned, with preparations for full-scale manufacturing continuing into the year ahead.

Looking Beyond 2022 to a Global CStone

Our burgeoning clinical, commercial and research achievements are noteworthy in their own right as well as for what they signify about the future of our business. We can discern from those achievements the elements for maximizing shareholder value as we pursue ground-breaking science.

First, we are continuing to develop high-potential assets in emerging modalities with FIC/BIC potential as part of our Pipeline 2.0 strategy. Our redoubled efforts to improve pre-clinical innovation and development are already bearing fruit as is evident from our current portfolio. We have made substantial progress in fleshing out the clinical development plans for several of these assets. Equally important, as part of this strategy, we are increasing the number of pre-clinical assets to which we have global commercial rights. And we are confident in our ability to generate more sustained volume of INDs that will reach the post proof-of-concept stage.

Second, through a combination of indication expansions for several of our drugs and our growing commercial coverage, we are making steady gains in growing the addressable market for late-stage pipeline. As a result of these efforts, we are poised for successful future launches across a range of indications, including some of the most prevalent cancers.

The third element of our future success is to accelerate the development of the global dimensions of our business. This process is unfolding along several pathways, and overlaps with our Pipeline 2.0 strategy: expanding the number of drugs for which we hold global commercial rights; distributing our drugs in global markets; and forging partnerships with global firms to source new assets to round out our pipeline.

Our business development team will naturally play a central role in supporting our global ambitions. To that end, we are situating the leadership and core of this team in the U.S. There, they will have a clear line of sight into the most promising innovations in oncology as well as more direct access to assets and partners for strategic and multi-dimensional collaboration and in-licensing deals.

We believe that focusing on these aspects of our business will give us significant and powerful levers for unlocking the full potential of our portfolio and realizing sustainable, long-term value creation. We are moving closer to producing a steady volume of commercially viable and clinically differentiated candidate molecules that can generate diverse and recurring revenue streams. As a result, we are actively shortening the pathway to achieving our ultimate vision of clinical success – to provide breakthrough therapies for cancer patients to help them live longer and healthier lives – while realizing the full commercial value of our innovative capacity and distinctive operating model.

FINANCIAL INFORMATION

CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE SIX MONTHS ENDED JUNE 30, 2021

	NOTES	For the six months ended June 30,	
		2021 RMB'000 (Unaudited)	2020 RMB'000 (Unaudited)
Revenue	3	79,449	–
Cost of sales		<u>(31,215)</u>	<u>–</u>
Gross profit		48,234	–
Other income	4	12,315	28,466
Other gains and losses	4	(31,761)	33,967
Research and development expenses		(512,753)	(544,154)
Selling and marketing expenses		(133,584)	(24,055)
Administrative expenses		(154,105)	(165,229)
Finance costs		<u>(2,197)</u>	<u>(238)</u>
Loss for the period	6	<u>(773,851)</u>	<u>(671,243)</u>
Other comprehensive income (expense) for the period:			
<i>Items that may be reclassified subsequently to profit or loss:</i>			
Exchange differences arising on translation of foreign operations		299	518
Fair value gain on investments in debt instruments at fair value through other comprehensive income (“FVTOCI”)		–	31
Reclassified to profit or loss upon redemption of debt instruments at FVTOCI		<u>–</u>	<u>(31)</u>
Other comprehensive income for the period		<u>299</u>	<u>518</u>
Total comprehensive expense for the period		<u><u>(773,552)</u></u>	<u><u>(670,725)</u></u>
Loss per share			
– Basic and diluted (RMB Yuan)	8	<u><u>(0.67)</u></u>	<u><u>(0.66)</u></u>

CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION
AS AT JUNE 30, 2021

	<i>NOTES</i>	June 30, 2021 RMB'000 (Unaudited)	December 31, 2020 RMB'000 (Audited)
Non-current assets			
Property, plant and equipment	<i>9</i>	36,623	39,367
Right-of-use assets	<i>9</i>	24,866	27,175
Deposits for acquisition of property, plant and equipment and intangible assets		51,673	35,411
Other intangible assets		62,453	6,509
Other receivables	<i>11</i>	57,826	81,987
		233,441	190,449
Current assets			
Inventories		30,144	–
Trade receivables	<i>10</i>	50,422	–
Deposits, prepayments and other receivables	<i>11</i>	119,818	178,040
Other investments classified as financial assets measured at fair value through profit or loss (“FVTPL”)	<i>12</i>	10,288	10,125
Restricted bank deposits		–	720
Time deposits	<i>13</i>	–	358,870
Cash and cash equivalents	<i>13</i>	2,447,177	3,024,548
		2,657,849	3,572,303
Current liabilities			
Trade and other payables and accrued expenses	<i>14</i>	445,061	708,525
Borrowings	<i>16</i>	5,052	2,662
Lease liabilities		9,747	8,652
Deferred income	<i>15</i>	7,210	7,210
		467,070	727,049
Net current assets		2,190,779	2,845,254
Total assets less current liabilities		2,424,220	3,035,703
Non-current liabilities			
Borrowings	<i>16</i>	67,615	54,340
Lease liabilities		15,183	18,205
Deferred income	<i>15</i>	8,473	8,698
		91,271	81,243
Net assets		2,332,949	2,954,460
Capital and reserves			
Share capital		793	787
Treasury shares held in the trusts		(16)	(19)
Reserves		2,332,172	2,953,692
Total equity		2,332,949	2,954,460

NOTES

1. GENERAL AND BASIS OF PREPARATION

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

The condensed consolidated financial statements have been prepared in accordance with International Accounting Standard 34 “Interim Financial Reporting” issued by the International Accounting Standards Board (“**IASB**”) as well as the applicable disclosure requirements of Appendix 16 to the Rules Governing the Listing of Securities on the Stock Exchange. The condensed consolidated financial statements do not include all the information required for a complete set of financial statements and should be read in conjunction with the annual consolidated financial statements of the Company and its subsidiaries (the “**Group**”) for the year ended December 31, 2020.

2. PRINCIPAL ACCOUNTING POLICIES

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

Other than additional accounting policies resulting from application of and amendments to International Financial Reporting Standards (“**IFRSs**”) and application of certain accounting policies which became relevant to the Group, the accounting policies and methods of computation used in the condensed consolidated financial statements for the six months ended June 30, 2021 are the same as those presented in the Group’s annual financial statements for the year ended December 31, 2020.

Application of amendments to IFRSs

In the current interim period, the Group has applied the following amendments to IFRSs issued by the IASB, for the first time, which are mandatory effective for the annual periods beginning on or after January 1, 2020 for the preparation of the Group’s condensed consolidated financial statements:

Amendment to IFRS 16	Covid-19-Related Rent Concessions
Amendments to IFRS 9, IAS 39 IFRS 7, IFRS 4 and IFRS 16	Interest Rate Benchmark Reform – Phase 2

The application of the amendments to IFRSs in the current interim period has had no material impact on the Group’s financial position and performance for the current and prior periods and/or on the disclosures set out in these condensed consolidated financial statements.

3. REVENUE AND SEGMENT INFORMATION

Sales of pharmaceutical products

For the sale of pharmaceutical products, revenue is recognized when control of the goods has been transferred, being when the goods have been delivered to the specific location designated by the customers. Following delivery, the customers have the primary responsibility when selling the goods and bear the risks of obsolescence and loss in relation to the goods. Trade receivable is recognized by the Group when the goods are delivered to customers as this represents the point in time at which the right to consideration becomes unconditional, as only the passage of time is required before payment is due. The normal credit term is 60 days upon delivery.

Disaggregation of revenue from contracts with customers

	For the six months ended June 30, 2021 RMB'000 (Unaudited)
Sales of pharmaceutical products	79,449
	<u>79,449</u>
Geographical markets	
Mainland China	79,449
	<u>79,449</u>
Timing of revenue recognition	
A point in time	79,449
	<u>79,449</u>

Segment Information

For the purpose of resource allocation and performance assessment, the Group's chief operating decision maker reviews the overall results and financial position of the Group as a whole which are prepared based on the same accounting policies as set out in Note 3 to the consolidated financial statements included in the Group's annual report for the year ended December 31, 2020.

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").

Information about major customers

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

	For the six months ended June 30, 2021 RMB'000 (Unaudited)
Customer A	73,797
	<u>73,797</u>

4. OTHER INCOME AND OTHER GAINS AND LOSSES

Other income

	For the six months ended June 30,	
	2021	2020
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Bank and other interest income	6,999	20,440
Government grants income (<i>note</i>)	5,316	8,026
	<u>12,315</u>	<u>28,466</u>

Note: Government grants include subsidies from the PRC and Australia governments 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) 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

	For the six months ended June 30,	
	2021	2020
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Gain on fair value changes of other investments classified as financial assets measured at FVTPL (<i>note 12</i>)	163	200
Gain on redemption of debt instruments at FVTOCI	–	31
Changes in fair value of money market funds	6	1,982
Net foreign exchange (losses) gains	(31,936)	31,789
Others	6	(35)
	<u>(31,761)</u>	<u>33,967</u>

5. INCOME TAX EXPENSE

The Company is tax exempted 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 periods.

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 periods.

No provision for taxation for the six months ended June 30, 2021 and 2020 as the Group has no assessable profits derived from the operating entities of the Group.

6. LOSS FOR THE PERIOD

	For the six months ended June 30,	
	2021	2020
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Loss for the period has been arrived at after charging the following items:		
Directors' emoluments (including share-based payment expenses)	80,680	70,292
Staff costs:		
– Salaries and other allowances	131,070	90,825
– Performance-related bonus	24,894	29,198
– Retirement benefit scheme contributions	23,030	6,901
– Share-based payment expenses	64,902	95,507
	324,576	292,723
Amortization for other intangible assets	2,354	1,322
Depreciation for property, plant and equipment	3,399	3,122
Depreciation of right-of-use assets	5,322	2,883
Auditor's remuneration	800	990
Lease payments in respect of short-term and low value leases	1,523	1,826

7. DIVIDENDS

No dividend was paid or declared by the Company during the reporting periods, nor has any dividend been proposed since the end of the Reporting Period.

8. LOSS PER SHARE

The calculation of the basic and diluted loss per share attributable to the owners of the Company is based on the following data:

	For the six months ended June 30,	
	2021	2020
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Loss for the period		
for the purpose of basic and diluted loss per share	(773,851)	(671,243)
	1,154,802,083	1,012,383,724

The calculation of basic and diluted loss per share for the six months ended June 30, 2021 and 2020 has considered the restricted share units that have been vested but not yet registered, and excluded the ordinary shares repurchased but not cancelled yet and the ordinary shares held in a trust which are accounted for as treasury shares of the Company.

The calculation of diluted loss per share for the six months ended June 30, 2021 and 2020 has not considered share options awarded under the employee stock option plan and the unvested restricted share units as their inclusion would be anti-dilutive.

9. PROPERTY, PLANT AND EQUIPMENT AND RIGHT-OF-USE ASSETS

During the current interim period, the Group had additions to property, plant and equipment of approximately RMB655,000 (six months ended June 30, 2020: RMB93,000), in order to construct the facilities in Suzhou for the preparation of commercialization and upgrade its research and development capabilities. The Group entered into a new lease agreement for an office building for 3 years. The Group is required to make fixed monthly payments during the contract period. On lease commencement, the Group recognized RMB3,013,000 (six months ended June 30, 2020: RMB357,000) of right-of-use assets and lease liabilities of RMB3,013,000 (six months ended June 30, 2020: RMB357,000).

10. TRADE RECEIVABLES

The Group allows an average credit period of 60 days to its trade customers.

The following is an analysis of trade receivables by age, presented based on the invoice date at the end of the reporting period.

	June 30, 2021 RMB'000 (Unaudited)	December 31, 2020 RMB'000 (Audited)
Less than 60 days	<u>50,422</u>	<u>–</u>

11. DEPOSITS, PREPAYMENTS AND OTHER RECEIVABLES

	June 30, 2021 RMB'000 (Unaudited)	December 31, 2020 RMB'000 (Audited)
Rental deposits	4,466	4,250
Prepayments	13,481	63,617
Receivables from a director and key management personnel of the Company	76,248	105,288
Value-added tax recoverable	53,360	78,744
Others	<u>30,089</u>	<u>8,128</u>
	<u>177,644</u>	<u>260,027</u>
Analyzed as:		
– Non-current	57,826	81,987
– Current	<u>119,818</u>	<u>178,040</u>
	<u>177,644</u>	<u>260,027</u>

12. OTHER INVESTMENTS CLASSIFIED AS FINANCIAL ASSETS AT FVTPL

	June 30, 2021 RMB'000 (Unaudited)	December 31, 2020 RMB'000 (Audited)
Other investments classified as financial assets measured at FVTPL		
– Wealth management plans (<i>note</i>)	<u>10,288</u>	<u>10,125</u>

Note: The Group entered into contracts in respect of wealth management plans managed by financial institutions. The principal is unguaranteed by the relevant financial institutions with expected return as stated in the contracts at 3.6% per annum as at June 30, 2021 (December 31, 2020: 3.6% per annum). All investments have maturity dates within one year and are classified as other investments classified as financial assets measured at FVTPL.

13. TIME DEPOSITS AND CASH AND CASH EQUIVALENTS

Time deposits

	June 30, 2021 RMB'000 (Unaudited)	December 31, 2020 RMB'000 (Audited)
Time deposits	–	358,870

The time deposits are placed with a bank in the PRC with a term of 1 year upon placement.

During the six months ended June 30, 2021, all the original time deposits as at December 31, 2020 have been withdrawn.

Cash and cash equivalents

	June 30, 2021 RMB'000 (Unaudited)	December 31, 2020 RMB'000 (Audited)
Cash at banks	1,493,127	2,084,307
Cash on hand	90	–
Cash equivalents (<i>note</i>)		
– Money market funds	200,066	204,885
– Time deposits	753,894	735,356
	<u>2,447,177</u>	<u>3,024,548</u>

Note: Cash equivalents represent (1) investments 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.

14. TRADE AND OTHER PAYABLES AND ACCRUED EXPENSES

	June 30, 2021 RMB'000 (Unaudited)	December 31, 2020 RMB'000 (Audited)
Trade payables	<u>11,519</u>	<u>28,030</u>
Accrued expenses		
– Research and development (<i>Note a</i>)	338,420	460,384
– Selling, marketing and royalties expenses	27,471	–
– Legal and professional fees	1,185	4,815
– Others	11,799	26,194
	<u>378,875</u>	<u>491,393</u>
Other payables	9,481	26,368
Other tax payable (<i>Note b</i>)	6,297	102,938
Accrued bonus	<u>38,889</u>	<u>59,796</u>
	<u>445,061</u>	<u>708,525</u>

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:

	June 30, 2021 RMB'000 (Unaudited)	December 31, 2020 RMB'000 (Audited)
Less than 30 days	11,519	28,030

Notes:

- (a) Amounts mainly included accrued service fees to outsourced service providers including contract research organizations and clinical trial sites.
- (b) Included in the balances as at December 31, 2020 are withholding tax payable for employee's individual income tax associated with vested restricted share units, which are fully settled during the six months period ended June 30, 2021.

15. DEFERRED INCOME

	June 30, 2021 RMB'000 (Unaudited)	December 31, 2020 RMB'000 (Audited)
Subsidies related to property, plant and equipment (<i>note a</i>)	1,923	2,148
Other subsidies (<i>note b</i>)	13,760	13,760
	15,683	15,908
Analyzed as:		
Non-current	8,473	8,698
Current	7,210	7,210
	15,683	15,908

Notes:

- (a) The Group received government subsidies for capital expenditure incurred for the plant, machineries and spare parts. The amounts are deferred and amortized over the estimated useful lives of the respective assets.
- (b) The Group received government subsidies towards research and development projects to compensate the research and development expenses incurred by the Group. Certain conditions have to be fulfilled until these subsidies can be regarded as fully granted. As at June 30, 2021 and December 31, 2020, the relevant conditions have not been fully fulfilled and therefore, the government subsidies were deferred.

16. BORROWINGS

	June 30, 2021 RMB'000 (Unaudited)	December 31, 2020 RMB'000 (Audited)
Unsecured and unguaranteed	17,398	17,680
Secured and unguaranteed	<u>55,269</u>	<u>39,322</u>
	<u>72,667</u>	<u>57,002</u>
The carrying amounts of the above borrowings are repayable*:		
Within 1 year	5,052	2,662
Within a period of more than 1 year but not exceeding 2 years	18,568	1,877
Within a period of more than 2 years but not exceeding 5 years	<u>49,047</u>	<u>52,463</u>
	72,667	57,002
Current	<u>(5,052)</u>	<u>(2,662)</u>
Non-current	<u>67,615</u>	<u>54,340</u>

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

Financial Review

Six Months Ended June 30, 2021 Compared to Six Months Ended June 30, 2020

	For the six months ended June 30,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Revenue	79,449	–
Cost of sales	<u>(31,215)</u>	<u>–</u>
Gross profit	48,234	–
Other income	12,315	28,466
Other gains and losses	(31,761)	33,967
Research and development expenses	(512,753)	(544,154)
Selling and marketing expenses	(133,584)	(24,055)
Administrative expenses	(154,105)	(165,229)
Finance costs	<u>(2,197)</u>	<u>(238)</u>
Loss for the period	<u>(773,851)</u>	<u>(671,243)</u>
Other comprehensive income (expense) for the period:		
<i>Items that may be reclassified subsequently to profit or loss:</i>		
Exchange differences arising on translation of foreign operations	299	518
Fair value gain on investments in debt instruments at fair value through other comprehensive income (“FVTOCI”)	–	31
Reclassified to profit or loss upon redemption of debt instruments at FVTOCI	<u>–</u>	<u>(31)</u>
Other comprehensive income for the period	<u>299</u>	<u>518</u>
Total comprehensive expense for the period	<u><u>(773,552)</u></u>	<u><u>(670,725)</u></u>
Non-IFRS measures:		
Adjusted loss for the period	<u><u>(632,488)</u></u>	<u><u>(508,471)</u></u>

Other Income. Our other income decreased by RMB16.2 million from RMB28.5 million for the six months ended June 30, 2020 to RMB12.3 million for the six months ended June 30, 2021. This was primarily attributable to reduced government grants received and interest income.

Other Gains and Losses. Our other gains and losses decreased by RMB65.8 million from gains of RMB34.0 million for the six months ended June 30, 2020 to losses of RMB31.8 million for the six months ended June 30, 2021. This decrease was primarily attributable to foreign exchange losses as of June 30, 2021.

Research and Development Expenses. Our research and development expenses decreased by RMB31.4 million from RMB544.2 million for the six months ended June 30, 2020 to RMB512.8 million for the six months ended June 30, 2021. This decrease was primarily attributable to (i) a decrease of RMB5.7 million third party contracting cost from RMB381.6 million for the six months ended June 30, 2020 to RMB375.9 million for the six months ended June 30, 2021 for different phases of our clinical trials; and (ii) Share-based payment expenses decreased by RMB5.8 million and other employee cost decreased by RMB13.0 million.

	For the six months ended June 30,	
	2021	2020
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Employee cost	135,019	153,785
Milestone fee and third party contracting cost	375,853	381,574
Others	1,881	8,795
	<u>135,019</u>	<u>153,785</u>
	<u>375,853</u>	<u>381,574</u>
	<u>1,881</u>	<u>8,795</u>
Total	<u>512,753</u>	<u>544,154</u>

Administrative Expenses. Our administrative expenses decreased by RMB11.1 million from RMB165.2 million for the six months ended June 30, 2020 to RMB154.1 million for the six months ended June 30, 2021. This was primarily attributable to the decrease of RMB9.6 million in professional fee from RMB30.0 million for the six months ended June 30, 2020 to RMB20.4 million for six months ended June 30, 2021.

	For the six months ended June 30,	
	2021	2020
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Employee cost	103,451	119,957
Professional fees	20,425	30,041
Rental expenses	1,688	1,317
Depreciation and amortization	9,767	6,694
Others	18,774	7,220
	<u>103,451</u>	<u>119,957</u>
	<u>20,425</u>	<u>30,041</u>
	<u>1,688</u>	<u>1,317</u>
	<u>9,767</u>	<u>6,694</u>
	<u>18,774</u>	<u>7,220</u>
Total	<u>154,105</u>	<u>165,229</u>

Selling and marketing Expenses. Our selling and marketing expenses increased by RMB109.5 million from RMB24.1 million for the six months ended June 30, 2020 to RMB133.6 million for the six months ended June 30, 2021. The increase was primarily attributable to sales force build-up and marketing activities for product launch.

	For the six months ended June 30,	
	2021	2020
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Employee cost	86,106	18,982
Professional fees	11,401	3,572
Others	36,077	1,501
	<hr/>	<hr/>
Total	133,584	24,055
	<hr/> <hr/>	<hr/> <hr/>

Finance Costs. The finance costs increased by RMB2.0 million from RMB0.2 million for the six months ended June 30, 2020 to RMB2.2 million for the six months ended June 30, 2021.

Other Comprehensive Income. Our other comprehensive income decreased by RMB0.2 million from RMB0.5 million for the six months ended June 30, 2020 to RMB0.3 million for the six months ended June 30, 2021.

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

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

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

	For the six months ended June 30,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Loss for the period	(773,851)	(671,243)
Added:		
Share-based payment expenses	<u>141,363</u>	<u>162,772</u>
Adjusted loss for the period	<u><u>(632,488)</u></u>	<u><u>(508,471)</u></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 the six months ended June 30,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Research and development expenses for the period	(512,753)	(544,154)
Added:		
Share-based payment expenses	<u>67,984</u>	<u>73,796</u>
Adjusted research and development expenses for the period	<u><u>(444,769)</u></u>	<u><u>(470,358)</u></u>

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

	For the six months ended June 30,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Administrative and selling and marketing expenses for the period	(287,689)	(189,284)
Added:		
Share-based payment expenses	<u>73,379</u>	<u>88,976</u>
Adjusted administrative and selling and marketing expenses for the period	<u><u>(214,310)</u></u>	<u><u>(100,308)</u></u>

Employees and Remuneration Policies

The following table sets forth a breakdown of our employees as at June 30, 2021 by function:

Function	Number of employees	% of total number of employees
Research and Development	166	28.97
Sales, General and Administrative	407	71.03
Total	573	100.0

As of June 30, 2021, we had 264 employees in Shanghai, 69 employees in Beijing, 51 employees in Suzhou and 189 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.

As of June 30, 2021, our time deposits and cash and cash equivalents were RMB2,447.2 million, as compared to RMB3,383.4 million as of December 31, 2020. The decrease was mainly due to the research and development expenses, as well as the administrative and selling expenses.

Gearing Ratio

Gearing ratio is calculated using total liabilities divided by total assets and multiplied by 100%. As at June 30, 2021, our gearing ratio was 19.3% (as at December 31, 2020: 21.5%).

Charge on Assets

As of June 30, 2021, the Group did not pledge any group assets.

OTHER FINANCIAL INFORMATION

Significant Investments, Material Acquisitions and Disposals

As at June 30, 2021, we did not hold any significant investments. For the six months ended June 30, 2021, 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

On January 7, 2020, the Group obtained two new bank loan facilities amounting to RMB175 million and RMB25 million, respectively, for the purpose of the construction of the facilities. During the six months ended June 30, 2021, the Group has drawn down RMB17,277,000 and repaid RMB3,052,000 of principal and interest in accordance with the payment schedules.

Contingent Liabilities

As of June 30, 2021, 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 Reporting Period, the Company has complied with all the code provisions as set out in the Corporate Governance Code (the “**CG Code**”) contained in Appendix 14 to the Listing Rules, except for the deviation explained below.

In accordance with Code Provision A.2.1 of the CG Code, the roles of the chairman and chief executive should be separate and should not be performed by the same individual. 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.

Model Code for Securities Transactions by Directors of Listed Issuers

We have adopted our own code of conduct regarding Directors' securities transactions, namely the policy on management of securities transactions by directors (the "**Securities Transactions Code**"), 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 Model Code during the Reporting Period.

Purchase, Sale or Redemption of Listed Securities

Neither the Company nor any of its subsidiaries purchased, sold or redeemed any of the Company's listed securities during the Reporting Period.

Material Litigation

The Company was not involved in any material litigation or arbitration during the Reporting Period. The Directors are also not aware of any material litigation or claims that were pending or threatened against the Group during the Reporting Period.

Material Events after the Reporting Period

As at the date of this announcement, there were no materials event after the Reporting Period.

Use of Net Proceeds

Our Shares were listed on the Main Board of the Stock Exchange on February 26, 2019. The Group received net proceeds (after deduction of underwriting commissions and related costs and expenses) from the initial public offering in Hong Kong (the “**HK IPO**”, initial public offering, “**IPO**”) and the exercise of over-allotment option of approximately RMB2,090.16 million. There was no change in the intended use of net proceeds as previously disclosed in the Prospectus 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 June 30, 2021:

	% of use of proceeds <i>(Approximately)</i>	Net proceeds from the HK IPO <i>(RMB million)</i>	Actual usage up to June 30, 2021 <i>(RMB million)</i>	Unutilized net proceeds as of June 30, 2021 <i>(RMB million)</i>
Fund ongoing and planned clinical trials, preparation for registration filings and commercial launches of CS1001	30.0%	627.04	566.24	60.80
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	836.06	–
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	2,029.36	60.80

Notes:

- (1) Net IPO proceeds were received in Hong Kong dollars and translated to Renminbi for application planning.
- (2) The unutilized net proceeds of RMB60.80 million as of June 30, 2021 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 June 30, 2021:

	% of use of proceeds <i>(Approximately)</i>	Proceeds from the subscription <i>(RMB million)</i>	Actual usage up to June 30, 2021 <i>(RMB million)</i>	Unutilized net proceeds as of June 30, 2021 <i>(RMB million)</i>
Fund the development activities under the collaboration agreement	<u>100.0%</u>	<u>1,355.9</u>	<u>218.4</u>	<u>1,137.5</u>

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

Audit Committee

The Company has established an audit committee (the “**Audit Committee**”) with written terms of reference in accordance with the Listing Rules. The Audit Committee currently comprises three independent non-executive Directors, namely, Mr. Hongbin Sun (Chairman), Dr. Paul Herbert Chew and Mr. Ting Yuk Anthony Wu.

Review of Interim Results

The independent auditors of the Company, namely Deloitte Touche Tohmatsu, have carried out a review of the interim financial information in accordance with the Hong Kong Standard on Review Engagement 2410 “Review of Interim Financial Information Performed by the Independent Auditor of the Entity” issued by the Hong Kong Institute of Certified Public Accountants. The Audit Committee has jointly reviewed with the management of the Company, the accounting principles and policies adopted by the Company and discussed internal control and financial reporting matters (including the review of the unaudited interim results for the six months ended June 30, 2021) of the Group. The Audit Committee considered that the interim results are in compliance with the applicable accounting standards, laws and regulations, and the Company has made appropriate disclosures thereof. The Audit Committee has also discussed matters with respect to the accounting policies and practices adopted by the Company and internal control with senior management of the Company.

INTERIM DIVIDEND

The Board does not recommend the payment of a dividend for the six months ended June 30, 2021 (2020: Nil).

PUBLICATION OF INTERIM RESULTS ANNOUNCEMENT AND INTERIM REPORT

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

The interim report for the six months ended June 30, 2021 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, August 26, 2021

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. Xianghong Lin and Mr. Edward Hu as non-executive Directors, and Dr. Paul Herbert Chew, Mr. Ting Yuk Anthony Wu and Mr. Hongbin Sun as independent non-executive Directors.