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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, 2021 AND RESUMPTION OF TRADING

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, 2021 (the "**Reporting Period**"), together with comparative figures for the year ended December 31, 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 annual results for the year ended December 31, 2020 dated March 25, 2021.

FINANCIAL HIGHLIGHTS

International Financial Reporting Standards ("IFRS") Measures:

- **Revenue** was RMB243.7 million for the year ended December 31, 2021, composed of RMB162.8 million in sales of pharmaceutical products, representing sales of the Company's newly launched pharmaceutical products (avapritinib and pralsetinib), and RMB80.9 million in license fee income, representing a decrease of RMB957.9 million from RMB1,038.8 million in the previous year as a result of decrease in the one-off license fee income.

- **Research and development expenses** were RMB1,304.9 million for the year ended December 31, 2021, representing a decrease of RMB99.8 million from RMB1,404.7 million for the year ended December 31, 2020, primarily due to lower spending on approved products, and offset by continued investment in key clinical trials and pre-clinical studies during the Reporting Period. In particular, we received the approval of sugemalimab in mainland China for stage IV non-small cell lung cancer ("**NSCLC**") and met the primary endpoint of progression-free survival ("**PFS**") in patients with stage III NSCLC during the Reporting Period.

- **Administrative expenses** were RMB297.6 million for the year ended December 31, 2021, representing a decrease of RMB44.9 million from RMB342.5 million for the year ended December 31, 2020, primarily due to the decrease in share-based payment expenses.

- **Selling and marketing expenses** were RMB363.8 million for the year ended December 31, 2021, representing an increase of RMB221.6 million from RMB142.2 million for the year ended December 31, 2020, primarily attributable to sales force build-up and marketing activities for product launches.

- **Loss for the year** was RMB1,920.1 million for the year ended December 31, 2021, representing an increase of RMB699.1 million from RMB1,221.0 million for the year ended December 31, 2020, primarily attributable to the decrease in the license fee income, increase in selling and marketing expenses for commercial launch, and offset by the increase in sales income of avapritinib and pralsetinib.

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

- **Research and development expenses** excluding the share-based payment expenses were RMB1,182.1 million for the year ended December 31, 2021, representing a decrease of RMB63.6 million from RMB1,245.7 million for the year ended December 31, 2020, primarily due to lower spending on approved products, and offset by continued investment in key clinical trials and pre-clinical studies during the Reporting Period. In particular, we received the approval of sugemalimab in mainland China for stage IV NSCLC and met the primary endpoint of PFS in patients with stage III NSCLC during the Reporting Period.

- **Administrative and selling and marketing expenses** excluding the share-based payment expenses were RMB561.5 million for the year ended December 31, 2021, representing an increase of RMB273.9 million from RMB287.6 million for the year ended December 31, 2020, primarily attributable to sales force build-up and marketing activities for product launches.

- **Loss for the year** excluding the share-based payment expenses was RMB1,697.4 million, representing an increase of RMB832.4 million from RMB865.0 million for the year ended December 31, 2020, primarily attributable to the decrease in the one-off license fee income, increase in selling and marketing expenses for commercial launch and offset by the increase in revenue of avapritinib and pralsetinib.

BUSINESS HIGHLIGHTS

2021 was a breakout year in CStone's history marked by the launch of two first-in-class precision medicines and multiple additional milestones across our pipeline and business. For the year ended December 31, 2021 and as of the date of this announcement, significant progress has been made with respect to our product pipeline and business operations. A shortlist of our achievements over this period includes:

- RMB243.7 million in total revenue, including RMB162.8 million of product revenue within eight months
- 7 NDA approvals obtained for 4 products
- 3 products launched: avapritinib, pralsetinib, and sugemalimab, and a fourth, ivosidenib, to launch imminently
- 6 NDAs filed for additional indications or territories
- 4 IND approvals for Pipeline 2.0 assets with best-in-class potential: CS5001 (ROR1 ADC) in the U.S., Australia and mainland China, and CS2006 (PD-L1/4-1BB/HSA) in mainland China
- Over 10 discovery projects in progress, including multi-specifics, antibody drug conjugates, and a proprietary platform for drugging intractable intracellular targets
- 2 strategic partnerships formed, one with Jiangsu Hengrui Pharmaceuticals Co., Ltd. to support product commercialization and the second with an early-stage biotech company to support pre-clinical asset development
- Co-development of Pfizer's lorlatinib initiated to further our lung cancer offering
- Launched pilot operations of our state-of-the-art manufacturing facility

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

We have fully developed our commercial capabilities, making rapid and significant progress in building the team, infrastructure, and industry network over the past year. Our commercial team has executed a clearly defined strategy and achieved successful launches of three products. We have shaped the treatment paradigm for the target diseases of our precision medicines with broad physician education, collaboration with industry associations on diagnostic and treatment standardization, and collaboration with diagnostics companies. As a result, we have seen continuous improvement in diagnostic rates for the approved indications for avapritinib and pralsetinib since their launch. Currently, our precision medicines have been included in over 10 national guidelines, up from 7 at the time we released our 2021 interim results announcement. In addition, they have been listed in over 60 supplemental insurance plans, up from 20, covering an urban population of approximately 60 million people, up from 40 million at the time we released our 2021 interim results.

Our clinical team has demonstrated the ability to translate our advantages in innovation, speed, and quality into tangible results for patients and our business. We successfully obtained approval of four products within 12 months, including three first-in-class precision medicines as well as our flagship immuno-oncology backbone drug. We have also advanced a number of trials through significant clinical milestones. For one, sugemalimab met the primary endpoint in a study of patients with stage III NSCLC without disease progression after concurrent or sequential chemoradiotherapy in our one-of-a-kind GEMSTONE-301 trial, making it the world's only anti-PD-1/PD-L1 monoclonal antibody to achieve this outcome. The broader spectrum of our clinical development success is reflected in the fact that CStone was invited to present data via seven (7) oral presentations at global academic conferences, a rare accomplishment among Chinese biotech companies. These presentations covered study results of sugemalimab in stage III NSCLC and stage IV NSCLC patients, pralsetinib in first-line NSCLC and MTC patients in China and ivosedinib in R/R AML patients in China as well as first-line AML patients in a global trial. In the latter, the global phase III AGILE trial was halted for further enrolment due to overwhelmingly compelling efficacy and the results were published in *The New England Journal of Medicine*. Moreover, the results of the unique sugemalimab trials for both stage III NSCLC and stage IV NSCLC have been published in the oncology journal *The Lancet Oncology*.

Our research team has made transformational changes to its capacity for early-stage innovation and efficiency. In 2021, we refined our research strategy to harness the modular nature of biologics to accelerate internal drug discovery around new modalities. Additionally, we established a new global R&D center, expanding our capacities in critical areas such as antibody discovery and development, systems pharmacology, and bioinformatics. These initiatives bolster our immuno-oncology and precision medicine franchises and enhance our capacity to meet our long-term target of filing 1-2 INDs per year.

Our latest business development partnerships will maximize the commercial value of our CTLA-4 antibody and bring access to proprietary technology to generate new pre-clinical assets with BIC/FIC potential.

Lastly, we launched pilot operations of our manufacturing facility as expected. We are steadily advancing our readiness for full-scale operations to produce our products for clinical trials as well as commercial sales. We are also in the process of technology transfer for multiple products which will reduce costs and improve long-term profitability of our products.

These achievements give us the potential to finish 2022 with the launch of ivosidenib, additional launches for in-market products across a range of indications and geographies, new IND filings, new preclinical development programs, and further the maturation of our business into a full-fledged biopharmaceutical company with end-to-end capabilities.

For the year ended December 31, 2021 and as of the date of this announcement, significant progress has been made with respect to our product pipeline and business operations:

I. Multiple Product Launches and Continued Robust Commercial Efforts

We have maintained a significantly accelerated level of commercial activity with the launch of two first-in-class precision medicines, AYVAKIT® (avapritinib) and GAVRETO® (pralsetinib), which we brought to market over the course of May and June 2021. We continued our success into the beginning of 2022 with the commercial launch of CEJEMLY® (sugemalimab), in partnership with Pfizer. Most recently, we have received NDA approval for another first-in-class product, TIBSOVO® (ivosidenib), and expect to launch soon in mainland China.

Our growing commercial team continued its rapid execution of pre-launch and post-launch efforts to set the stage for market adoption of our products. They have kept up robust efforts to engage the healthcare community, including healthcare providers, academic societies, patient groups, hospitals, pharmacies, payors, and other stakeholders, to provide education on our products and demonstrate our scientific leadership. In addition, they have expanded access and affordability of our products through various patient identification programs and by working with payors to promote coverage of them in insurance programs.

Lastly, they are supporting the broader pipeline of late-stage assets by mapping out commercialization plans for those coming to market in the near-term, including in close collaboration with our commercial partners.

Highlights and details on our 2021 commercial activity follow below.

- ***Achieved Significant Sales Ramp Up of Our First Products to Market***

  We achieved a rapid sales ramp up of AYVAKIT® (avapritinib) and GAVRETO® (pralsetinib), our first two drugs to market, generating combined net sales of RMB162.8 million within the first eight months following their launch.

- ***Achieved Successful Launches***

  Our comprehensive commercial efforts resulted in successful launches of our approved products.

  – AYVAKIT® (avapritinib): Launched in mainland China and Taiwan, China. Prescribed in approximately 50 hospitals and available in 50 direct-to-patient pharmacies ("**DTPs**") within one month of launch.

  – GAVRETO® (pralsetinib): Launched in mainland China. Available in 80 DTPs in approximately 70 cities within one month of launch.

  – CEJEMLY® (sugemalimab): Launched in mainland China within 18 days of receiving NDA approval, thanks to close collaboration with our commercial partner Pfizer.

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

  – We have established a full-fledged commercial organization with the capabilities and executional sophistication of multinational company. The leadership team is composed of seasoned industry executives whose track record include over 30 successful drug launches in oncology and hematology. The team is currently focused on market development for CStone's approved precision medicines and the broader pipeline of late-stage assets to support CStone's oncology franchise.

  – We have specifically focused our efforts on ensuring dedicated sales coverage and expanded to approximately 600 hospitals in the second half of 2021, up from 400 at midyear, accounting for approximately 70-80% of the relevant market for precision medicines where we believe we can maximize the return on our sales efforts.

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

  – We established GAVRETO® (pralsetinib), AYVAKIT® (avapritinib) and TIBSOVO® (ivosidenib) in over 10 of China's national guidelines, including CSCO NSCLC/GIST Guidelines, Chinese Medical Association Guidelines, and Guidelines on Clinical Practice of Molecular Tests in NSCLC, for treatment paradigms for multiple therapeutic areas (NSCLC, thyroid cancer, gastrointestinal stromal tumors and acute myeloid leukemia).

  – We collaborated with several industry associations – Chinese Society of Clinical Oncology, China Anti-Cancer Association, and Chinese Medical Doctor Association – on diagnostic and treatment standardization projects for gastrointestinal stromal tumors, NSCLC and hematological malignancies, further strengthening our industry connections and demonstrating our expertise.

- We enhanced awareness of our products among physicians and key opinion leaders ("**KOLs**") via proactive engagement and constant education. In 2021, we participated in over 1,500 activities and events reaching over 10,000 leading KOLs and healthcare professionals ("**HCPs**"), resulting in an enhanced awareness within the healthcare community of our treatments.

- We sponsored leading KOLs in post-approval clinical projects such as investigator-initiated trials and real-world studies to generate additional data in multiple cancer indications which may support the adoption of our drugs, and funded research in collaboration with non-profit academic institutions.

• ***Launched anchor projects to facilitate patient identification and support prescription and retention ratios***

- We are collaborating with gene sequencing companies to strengthen the diagnostic capabilities of hospitals and improve testing rates.

- We have launched disease management programs for patients and physicians, including an online platform, to provide education and process inquiries on our drugs, encourage follow up visits and manage adverse events that may arise during the course of treatment, among other topics. This patient-centric approach is intended to increase prescription and retention ratios.

• ***Developing a range of approaches to promote access to and affordability of our drugs***

- We established a patient assistance program (PAP) for AYVAKIT® (avapritinib) and GAVRETO® (pralsetinib) with a charitable foundation.

- We secured inclusion of AYVAKIT® (avapritinib) and GAVRETO® (pralsetinib) in over 60 of the major commercial and government insurance programs, up from 20 as disclosed in our 2021 interim results announcement. Our efforts have expanded the availability of reimbursement for our drugs for approximately 60 million people.

- We established a strategic collaboration agreement with Sinopharm Group Co., Ltd ("**Sinopharm**") to broaden hospital and pharmacy distribution coverage for both GAVRETO® (pralsetinib) and AYVAKIT® (avapritinib). By the end of 2021, AYVAKIT® (avapritinib) and GAVRETO® (pralsetinib) have been listed in approximately 100 hospitals and DTPs.

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

- ***Establishing commercial plans for new indications to expand the addressable market for precision medicines***

  – We are actively preparing for the launch readiness of several new indications for late-stage drugs, which can greatly expand their market potential. For three of our precision medicines, GAVRETO® (pralsetinib), AYVAKIT® (avapritinib) and TIBSOVO® (ivosidenib), we estimate the potential addressable patient population to expand from approximately 10,000 for second-line NSCLC and GIST launched in 2021 to approximately 90,000 for these and other indications, including first-line NSCLC, thyroid cancer, acute myeloid leukemia, cholangiocarcinoma, and myelodysplastic syndromes, among others.

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

  – We are closely collaborating with our partners Pfizer and EQRx on the development and commercialization of sugemalimab in mainland China and outside of Greater China, respectively. On December 21, 2021, we received the approval of sugemalimab in mainland China for stage IV NSCLC and the drug has been launched successfully in early January 2022. We worked with Pfizer to set up all commercial agreements, ordering process and commercial/PAP goods supply. In addition, we have opened distributor accounts and supported bidding progress to ensure patient accessibility upon the NDA approval.

  – With EQRx, we are working closely on global development and regulatory strategies for sugemalimab, including the U.S., the U.K. and the European Union ("**EU**"), as well as territories beyond these such as the Middle East, Turkey and Africa. The global market size of PD-(L)1 for the treatment of NSCLC, gastric and esophageal cancers is forecasted to be approximately US$30 billion in 2026.

II. Innovation, High Quality and Rapid Execution Lead to Advances across a Maturing Pipeline

CStone followed through on an aggressive clinical agenda with further developments across its pipeline. In total, we secured seven NDA approvals and submitted six NDA filings as we rounded out our diverse and maturing pipeline of in-market and near-commercial ready drugs. In doing so, our clinical engine once again distinguished itself in terms of four key dimensions:

– **Innovation in drug development to broaden addressable patient populations and target unmet medical needs:**

  ▪ Our sugemalimab trials simultaneously covered different pathologies and treatment modalities to establish efficacy for stage III and stage IV NSCLC.

  ▪ We achieved breakthrough therapy designation from China National Medical Products Administration ("**NMPA**") and the U.S. Food and Drug Administration ("**U.S. FDA**") for the treatment of relapsed or refractory extranodal natural killer/T-cell lymphoma (R/R ENKTL), demonstrating our ability to target patient populations with significant unmet needs.

    - We made seven oral presentations at prestigious global conferences in 2021, including the American Society for Clinical Oncology (ASCO), the European Society for Medical Oncology (ESMO), and the World Conference on Lung Cancer (WCLC). And two manuscripts were published in the Lancet Oncology on our trials with sugemalimab in stage III and stage IV NSCLC, with commentary from the journal recognizing the high degree of similarity between progression-free-survival and overall-survival and those of previously approved trials by global regulatory bodies such as the U.S. FDA.

– **Exceptional speed leading to consecutive launches:** We secured approval of four products within 12 months, reaching the commercial stage of our development within just over five years since the company's inception; and we achieved approval of our sugemalimab in its first large indication, NSCLC, within four years from the first patient dosed.

– **World class quality to support our global partnerships:** Our global quality has been validated by our global strategic partners such as Pfizer, Bayer, Blueprint, Servier, and EQRx. Our clinical trials have generated data that is highly consistent with that achieved by our global partners.

– **Efficiency and cost effectiveness:** Our abilities across all of these dimensions will ultimately shorten the route to commercialization for our products and allow us to do so with fewer costs and resources. We believe this capability gives us a significant competitive advantage.

Details follow below.

• **Sugemalimab** (CS1001, PD-L1 antibody), in 2021 became the first PD-(L)1 in the world to demonstrate efficacy for both stage III and stage IV NSCLC in randomized, double-blind phase III trials.

  – In September 2021, the NMPA accepted the NDA for sugemalimab as a consolidation therapy in patients with unresectable stage III NSCLC without disease progression after concurrent or sequential chemoradiotherapy, addressing a significant unmet need in the patient population. The final PFS analysis of the registrational study further demonstrates sugemalimab's robust efficacy and significant clinical benefits shown in interim analysis. We expect to receive the NDA approval in the first half of 2022. This would cement sugemalimab's global first-in-class stature for treatment of the sequential population, which accounts for approximately 70% of the clinical practice in China.

  – In December 2021, we received the NDA approval of sugemalimab from the NMPA for the first-line treatment of both squamous and non-squamous stage IV NSCLC. This is the first trial to show a benefit when combining a PD-L1 inhibitor with chemotherapy for patients with metastatic squamous and non-squamous NSCLC. In January 2022, the drug was launched in mainland China by our partner, Pfizer.

- In January 2022, the registrational trial for relapsed or refractory extranodal natural killer/T-cell lymphoma (R/R ENKTL) met the primary endpoint and demonstrated a complete response (CR) rate significantly exceeding that of the currently available targeted monotherapy for these patients. This gives it the potential to set a new standard of care in this indication. We plan to submit an NDA to the NMPA for this indication in the near term.

- In January 2022, two key phase III registrational clinical trials completed patient enrollment, one for the first-line treatment of metastatic gastric adenocarcinoma (GC)/gastro-esophageal junction (GEJ) adenocarcinoma, and the other for the first-line treatment of metastatic esophageal squamous cell carcinoma (ESCC).

- For the markets outside of Greater China, we are working closely with EQRx on regulatory discussions for regulatory submissions for indications in stage III NSCLC, stage IV NSCLC, and ENKTL in multiple countries and regions, including the U.S., the U.K., and the EU. For stage IV NSCLC, we expect the first NDA filing outside of the U.S. in the second half of 2022. Meanwhile, constructive conversations with the U.S. FDA are ongoing to gain greater clarity on the regulatory path. For ENKTL, sugemalimab has received Breakthrough Therapy Designation ("**BTD**") from the U.S. FDA and we expect the Biologics License Application ("**BLA**") filing in 2023.

• **Pralsetinib** (CS3009, RET inhibitor) – We have secured two (2) NDA approvals and have two (2) NDA filings currently under review.

- On March 24, 2021, we received the NDA approval from the NMPA for the treatment of patients with locally advanced or metastatic 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 medullary thyroid cancer (MTC) and RET fusion-positive thyroid cancer (TC).

- On March 11, 2022, we received the NDA approval from the NMPA for the treatment of patients with advanced or metastatic RET-mutant MTC and RET fusion-positive TC.

- In February 2022, the Taiwan Food and Drug Administration ("**TFDA**") accepted the NDA for the treatment of patients with RET fusion-positive locally advanced or metastatic NSCLC, RET-mutant MTC and RET fusion-positive TC.

- In March 2022, the Hong Kong Department of Health ("**HK DoH**") accepted the NDA for the treatment of patients with RET fusion-positive locally advanced or metastatic NSCLC.

- **Avapritinib** (CS3007, KIT/PDGFRA inhibitor) – We have secured three (3) NDA approvals for this product.

  – On March 31, 2021, we received an NDA approval from the NMPA for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutation.

  – On April 29, 2021, we received the NDA approval license from the TFDA through an accelerated approval pathway for adults with unresectable or metastatic GIST harboring a PDGFRA D842V mutation.

  – On December 28, 2021, we received the NDA approval from the HK DoH for adults with unresectable or metastatic GIST harboring a PDGFRA D842V mutation.

  – In June 2021, our partner Blueprint Medicines announced that the U.S. FDA approved avapritinib for the treatment of adult patients with advanced systemic mastocytosis ("**Advanced SM**"), including aggressive SM, SM with an associated hematologic neoplasm and mast cell leukemia. We reached agreement with the NMPA about the registrational pathway for this indication in mainland China.

- **Ivosidenib** (CS3010, IDH1 inhibitor) – We have secured our first NDA approval for this product and achieved a positive topline readout.

  – On January 31, 2022, we received an NDA approval from the NMPA for the treatment of adults with relapsed or refractory acute myeloid leukemia ("**R/R AML**") with an isocitrate dehydrogenase 1 ("**IDH1**") mutation.

  – In August 2021, our partner, Servier, released positive topline data from the global phase III AGILE trial of ivosidenib for previously untreated IDH1 mutant acute myeloid leukemia ("**AML**"). The trial halted further enrolment due to compelling efficacy data. Servier announced the U.S. FDA approval for this indication in May 2022. We plan to submit an NDA for this indication to the NMPA in 2022.

- **Lorlatinib** (ROS-1 inhibitor)

  – We are working with Pfizer to jointly develop lorlatinib for c-ros oncogene 1 ("**ROS1**")-positive advanced NSCLC in Greater China. In December 2021, we received the IND approval from the NMPA. In May 2022, the first patient was enrolled in the pivotal study of lorlatinib for the treatment of ROS1-positive advanced NSCLC.

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

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

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

In 2021, we made significant progress developing two high-potential pre-clinical assets and advancing them toward clinical development. We received IND approval for our ROR1 antibody drug conjugate ("**ADC**") (CS5001) in the U.S., Australia and mainland China, and announced the commencement of the first-in-human ("**FIH**") clinical trial in the U.S.. Our PD-L1/4-1BB/HSA tri-specific molecule, CS2006, also received approval of its IND application and is proceeding toward first-in-human study in China in the near-term.

Beside these two molecules, we are developing additional Pipeline 2.0 assets. Precision medicine and immuno-oncology combinations remain our strategic focus. In the near-term, we will pursue developments in these areas using two emerging therapeutic modalities: ADCs which deliver cytotoxic agents to tumor with precision, and multi-specific biologics which are combinations of themselves. Additionally, we have systemically revised our research strategy to take advantage of the modular nature of biologics that allows "plug-and-play" of various modules into an antibody backbone to provide different specificity and functionality. This research strategy offers an efficient and streamlined approach to create a suite of FIC/BIC/FW molecules via collective efforts of in-house research and platform partner collaborations. In support of this effort, we recently recruited new talent with expertise in protein engineering, structural biology, and quantitative systems pharmacology.

Following this modular research framework, which we have fully implemented, we initiated and have in progress a total of over 10 discovery projects in 2021 that are currently in progress, including multi-specifics, ADCs, antibody-cytokine fusion molecules, and a proprietary platform for targeting otherwise undruggable intracellular proteins. Additionally, we are working with our new strategic partner, Singapore-based DotBio, to harness the company's proprietary technology platform to co-develop preclinical multi-specific assets. CStone will lead the design of the target combination based on the intended mechanism of action while DotBio will be responsible for engineering the molecules.

To further strengthen our in-house discovery research capability, we are establishing the CStone Global R&D Center, a brand-new research facility located adjacent to the manufacturing plant in Suzhou. The Center will be a cutting-edge discovery and translational research institute where state-of-the-art technical and functional platforms such as antibody discovery and development, systems pharmacology, and bioinformatics drive CStone's Pipeline 2.0 forward.

This new R&D facility will occupy approximately 16,000 square-meters of research and office space, an approximately six-fold increase from our current facilities. We have completed the design, begun construction and expect to commence operations by the fourth quarter of 2022.

In a further effort to spur innovation, we will dedicate space within this facility to house an incubator to foster the growth of biotech startups developing promising molecules and technological platforms to which we can have early access. We will broadly select candidates for the incubator based on their potential to contribute molecules for discovery platforms that would be highly complementary to our Pipeline 2.0 efforts. We are currently in active discussions with several incubator candidates, with DotBio slated to be the first among them, and expect to announce additional candidates soon.

Details of our progress are below.

- **CS2006** (NM21-1480, PD-L1/4-1BB/HSA tri-specific molecule): The FIH study is ongoing and includes sites in the U.S. and Taiwan, China. We anticipate the completion of monotherapy dose-escalation in the first half of 2022. We received the IND approval from the NMPA in September 2021.The enrolment for FIH studies of CS2006 in China is expected to commence in the second half of 2022.

- **CS5001** (LCB71, ROR1 ADC): We submitted an IND application to the U.S. FDA and received the SAFE TO PROCEED ("**STP**") letter in December 2021, and commenced the FIH study in March 2022. In addition, the Australia Ethics Committee ("**EC**") submission has also been achieved in December 2021. Additionally, we submitted IND application to the NMPA in March 2022 and received the approval in May 2022.

IV. Strategic Relationships Advance Commercialization Activities and Pipeline Development

We continue to grow and deepen relationships with key global strategic partners and to forge new partnerships to expand commercialization of our in-market and late-stage drugs, bolster our early-stage pipeline of potential First-in-Class (FIC)/Best-in-Class (BIC) molecules, and access technologies that complement our research and development efforts.

In November 2021, we formed a strategic collaboration agreement with Singapore-based DotBio to pursue joint design and engineering of up to three pre-clinical assets with BIC/FIC potential, harnessing DotBio's proprietary technology platform for prefabricating antibody modules. This collaboration, which includes CStone making an equity investment in DotBio, represents the first project to be settled at CStone Global R&D Headquarters and Industrialization Base in Suzhou. CStone will lead the design of target combination based on the intended mechanism of action and DotBio will lead the molecular design and engineering. It will become a source of innovative preclinical candidates to support CStone's Pipeline 2.0 strategy, further accelerating drug discovery with de novo design.

In November 2021, we established a new strategic partnership with Jiangsu Hengrui Pharmaceuticals Co., Ltd. ("**Hengrui**"). This strategic partnership marks another milestone in CStone's mission to introduce innovative oncology therapies in China after the commercial launch of two first-in-class drugs this year. CStone granted the exclusive rights to Hengrui for research, development, registration, manufacturing and commercialization of anti-CTLA-4 mAb (CS1002), a backbone immuno-oncology asset, in Greater China. CStone will retain the rights to develop and commercialize CS1002 outside of Greater China. CStone and Hengrui will partner respective R&D and commercial expertise to accelerate the development and commercialization of CS1002 to fully unleash its commercial value.

In addition, we broadened our relationship with Pfizer in 2021 with the agreement to co-develop Pfizer's late-stage oncology asset lorlatinib in second line ROS1-positive NSCLC in Greater China. This type of collaboration was envisioned in the original partnership that we announced in 2020. It is a significant advancement which not only expands our partnership with Pfizer, but also provides validation of our clinical and research strength. The plan for lorlatinib is to assess if this agent can provide benefits to the patients with relapsed ROS1-positive advanced NSCLC, which if positive would add a new therapeutic approach to our lung cancer pipeline. 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 are advancing discussions with regulatory bodies in multiple countries and jurisdictions all around the world – the U.S., the U.K., and the EU – regarding the registration of sugemalimab for NSCLC and ENKTL indications. We are collaborating with EQRx to explore the feasibility of extending indications for this drug in the global market including gastric cancer and esophageal cancer. In addition, we are working with EQRx on a global phase III study of nofazinlimab in hepatocellular carcinoma ("**HCC**") in the U.S. and major EU markets.

V. Other Business Updates

Capital Markets Access. Due to the strong performance in our shares during the 12 months by the end of 2021, our stock has been included in the Hang Seng Composite Index and the Hong Kong Stock Connect. This development is significant as it makes our shares accessible to investors in mainland China, and can foster greater trading in our shares, more efficient price discovery and additional liquidity for investors.

Manufacturing. Additionally, we have completed construction of our state-of-the-art manufacturing facility and began running pilot operations at the end of 2021 as projected. The manufacturing facility has a capacity of 26,000 liters for biologics and 1 billion tablets/capsules for small molecule drugs. We are also in the process of technology transfer for multiple products which will reduce costs and improve long-term profitability of our products.

FUTURE AND OUTLOOK

We are working to bring a number of significant clinical and commercial developments to fruition that will be catalysts for our growth in the rest of 2022. Additionally, to further strengthen CStone's in-house research capability, we anticipate the grand opening of the new global R&D center in the second half of 2022.

A detailed breakdown of expected developments for the remainder of 2022 is below.

Commercial Developments

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

- Improving market coverage organically by maximizing deployment effectiveness and leveraging digital platform.
- Improving diagnosis rate and accuracy via collaboration with next generation sequencing companies and National Pathology Quality Control Center.
- Strengthening physician education with focus on differentiation in clinical and safety profile.
- Strengthening accessibility with continued efforts in hospitals and DTPs listing.
- Improving affordability through pricing strategy optimization, commercial insurance/ innovative payment plans and strategically considering National Reimbursement Drug List potential.

Research & Development

NDA approvals expected:

- Sugemalimab: NDA approval in mainland China for stage III NSCLC.

NDA filings expected:

- Sugemalimab: NDA submission in mainland China for R/R ENKTL.
- Pralsetinib: NDA submission in mainland China for 1L RET fusion-positive NSCLC.
- Ivosidenib: NDA submission in mainland China for IDH1-mutant 1L AML.
- Sugemalimab: first NDA filing outside of China.

Topline readouts expected:

- Sugemalimab: first-line GC/GEJ.

First-in-human study initiation:

- CS2006: Commencement of first-in-human study in China.

Research catalysts:

- Advancing several of the compounds in our discovery projects into preclinical development.
- Completing the transfer of all laboratory work to the new CStone Global R&D Center.
- Launching our biotech incubator and selecting our first slate of candidate startups.

Manufacturing

Having launched pilot operations, in the current year we are progressing with the preparations for commercial-scale operations that will give us the ability to control the supply of our own products, whether for use in clinical trials or for commercial sales. The facility will have a production capacity of 26,000 litres for biologics and 1 billion tablets for small molecules. For 2022, we will continue the technology transfer for multiple products which will reduce costs and improve long-term profitability of our products.

Looking Beyond 2022

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

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

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

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

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.

MANAGEMENT DISCUSSION & ANALYSIS

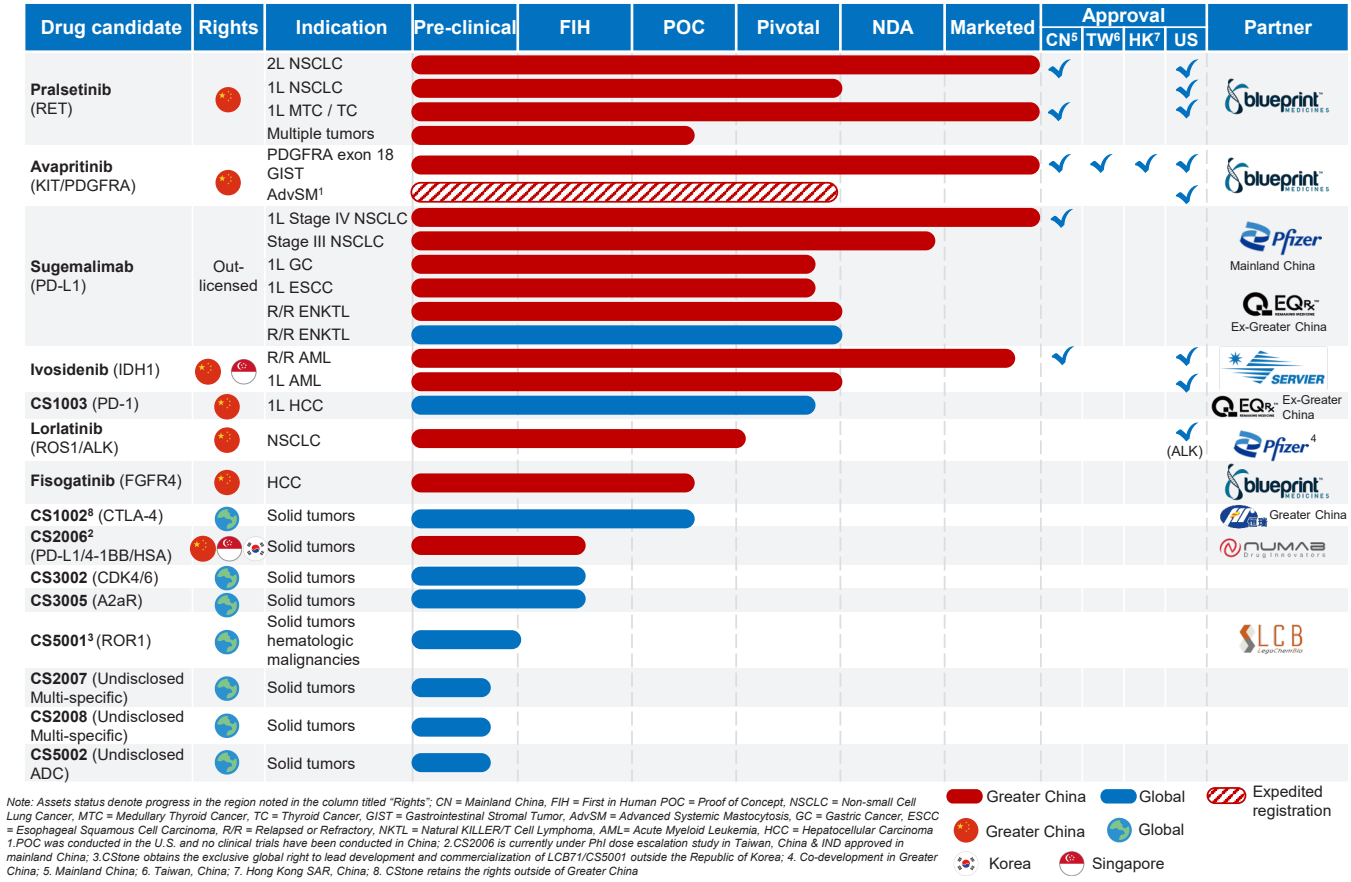
OUR VISION

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 seven drug approvals in Greater China, including five in mainland China, one in Taiwan, China and one in Hong Kong, 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



Note: Assets status denote progress in the region noted in the column titled "Rights"; CN = Mainland China, FIH = First in Human POC = Proof of Concept, NSCLC = Non-small Cell Lung Cancer, MTC = Medullary Thyroid Cancer, TC = Thyroid Cancer, GIST = Gastrointestinal Stromal Tumor, AdvSM = Advanced Systemic Mastocytosis, GC = Gastric Cancer, ESCC = Esophageal Squamous Cell Carcinoma, R/R = Relapsed or Refractory, NKTL = Natural KILLER/T Cell Lymphoma, AML= Acute 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, China & IND approved in mainland China; 3.CStone obtains the exclusive global right to lead development and commercialization of LCB71/CS5001 outside the Republic of Korea; 4. Co-development in Greater China; 5. Mainland China; 6. Taiwan, China; 7. Hong Kong SAR, China; 8. CStone retains the rights outside of Greater China

BUSINESS REVIEW

Commercial Operations

CStone has made a great leap forward in commercialization of its products over the past year with three product launches: GAVRETO® (pralsetinib), AYVAKIT® (avapritinib), and CEJEMLY® (sugemalimab). The rapid commercialization of products following regulatory approvals was made possible by the strong execution of our continuously growing commercial team, which includes approximately 300 people currently.

Our commercial team's efforts have enhanced the accessibility and affordability of our products on the market to bolster sales. They have continued a proactive engagement program to broaden and deepen ties to the healthcare community and critical stakeholder groups as part of preparations for launching our drug candidates. Our commercial team has established coverage of over 600 hospitals across more than 130 cities, building coverage of hospitals that account for approximately 70-80% of the relevant market of precision medicines. They also successfully secured the inclusion of our drugs in major commercial and government-administered insurance plans as part of an effort to broaden patient access to our drugs by making them more affordable. As a result of these efforts, we achieved a rapid sales ramp up of AYVAKIT® (avapritinib) and GAVRETO® (pralsetinib), generating combined net sales of RMB162.8 million within the first eight months following their launch.

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 clinical development capabilities, and our attractiveness to multinational players who may potentially partner with us. Our successful collaboration with EQRx will bring our drugs into the largest global healthcare markets, and ensure they are competitively positioned.

Details on our full commercial efforts are set out below.

- ***GAVRETO® (pralsetinib)***

  – GAVRETO® (pralsetinib), an FIC RET inhibitor in China, has been approved by the NMPA for the treatment of adults with locally advanced or metastatic RET fusion-positive NSCLC previously treated with platinum-based chemotherapy. GAVRETO® 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, which occurred within 6.5 months of the NDA's acceptance.

  – On July 3, 2021, we held the national launch meeting of GAVRETO with over 500 oncologists attending in person and more than 13,000 physicians joining online.

  – On November 21, 2021, we held a lung cancer symposium for Taiwan, Hong Kong and mainland China that engaged more than 7,000 HCPs to emphasize the importance of gene testing and the efficacy and safety data of GAVRETO in advanced RET fusion-positive NSCLC patients.

  – GAVRETO is recommended by 2021 CSCO NSCLC Guidelines for the second-line treatment of RET fusion-positive NSCLC with level II recommendation and 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. It is also recommended by 2022 China Anti-Cancer Association Guidelines for Thyroid Cancer.

  – Testing for RET alterations is recommended by 2021 CSCO NSCLC Guidelines with level I recommendation and by 2021 Guidelines on Clinical Practice of Molecular Tests in NSCLC in China with level I recommendation.

  – In Taiwan, China, we have strategically leveraged diagnostic companies for joint educational events to increase share of voice in lung cancer area, and for to have pralsetinib's first named patient program ("**NPP**") usage before license approval.

- ***AYVAKIT® (avapritinib)***

  – AYVAKIT® (avapritinib), an FIC KIT/PDGFRA inhibitor, has been approved by the NMPA for the treatment of adults with unresectable or metastatic GIST harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutations. AYVAKIT has also been approved by the TFDA for the treatment of patients with unresectable or metastatic PDGFRA D842V mutant GIST. AYVAKIT took only 4 days to reach distribution partners from the time of arrival in China.

- On May 22, 2021, we held the national launch meeting of AYVAKIT with over 400 oncologists attending in person and more than 9,600 physicians joining online.

- We collaborated with the Chinese Medical Doctor Association Chinese College of Surgeons and the Chinese Society of Clinical Oncology Experts Committee on GIST to shape the paradigm of precision medicine and the ability to diagnose and treat GIST.

- AYVAKIT is recommended by 2021 CSCO GIST Guidelines for neoadjuvant therapy for PDGFRA exon18 GIST.

- AYVAKIT received approval for National Health Insurance application in Taiwan, China, which will be effective from June 1, 2022.

• ***Ivosidenib***

- Our commercial platform is also well prepared for pre-launch activities for ivosidenib.

- We held the advisory board meeting for ivosidenib to exchange clinical data with the top key opinion leaders from hematology and to convey our post-marketing strategy.

- We established a combo sales team focused on avapritinib and ivosidenib to optimize our leveraged focus on gastrointestinal cancer and hematology.

- Ivosidenib is recommended by 2021 Chinese Medical Association Guidelines for the diagnosis and treatment of adult acute myeloid leukemia.

• ***Sugemalimab***

- We are working with Pfizer to support the commercialization in mainland China, and with EQRx to support the global launch (outside Greater China).

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

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 pralsetinib for the treatment of adults with locally advanced or metastatic RET fusion-positive NSCLC after platinum-based chemotherapy. Pralsetinib was the first approved selective RET inhibitor in China and the first approved precision therapy for CStone.

- In June 2021, the 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 previously announced global clinical data. We reached an agreement with the NMPA for the registration strategy for this indication, and we plan to submit a new NDA in 2022.

  – Primary efficacy data showed deep and durable anti-tumor activity for pralsetinib for the first-line treatment of patients with RET fusion-positive NSCLC, which was consistent with the global population. The overall safety was manageable, with no new safety signals detected.

  – These positive clinical data have been presented as a Late-Breaking Abstract Oral Presentation at the International Association for the Study of Lung Cancer ("**IASLC**") 2021 World Conference on Lung Cancer ("**WCLC**") in September 2021.

- On March 11, 2022, we received NDA approval from the NMPA for the treatment of patients with advanced or metastatic RET-mutant MTC and RET fusion-positive TC.

  – In 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 TC. 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 for 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 to results shown in global patients. These positive clinical data have been presented as a Late-Breaking Oral Presentation at the 90th Annual Meeting of the American Thyroid Association ("**ATA**") in October 2021.

- In February 2022, the TFDA accepted the NDA for the treatment of patients with RET fusion-positive locally advanced or metastatic NSCLC, RET-mutant MTC and RET fusion-positive TC.

- In March 2022, the HK DoH accepted the NDA for the treatment of patients with RET fusion-positive locally advanced or metastatic NSCLC.

Avapritinib (CS3007, KIT/PDGFRA 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.

  – The phase I/II bridging study data presented at the 2021 European Society for Medical Oncology ("**ESMO**") World Congress on Gastrointestinal Cancer showed avapritinib was generally well-tolerated and had promising anti-tumor activity in Chinese patients with advanced GIST harboring a PDGFRA D842V mutation, and avapritinib has also shown potential for the treatment of fourth-line and later Chinese GIST patients.

- On April 29, 2021, we received the NDA approval license from the TFDA through an accelerated approval pathway for adults with unresectable or metastatic GIST harboring a PDGFRA D842V mutation.

- On December 28, 2021, we received the NDA approval from the HK DoH for adults with unresectable or metastatic GIST harboring a PDGFRA D842V mutation.

- In June 2021, our partner, Blueprint Medicines announced that the U.S. FDA has approved avapritinib for the treatment of adult patients with Advanced SM. We reached an agreement with the NMPA of China about the registrational pathway for this indication in China. We plan to submit an IND to the NMPA in 2022.

Ivosidenib (CS3010, IDH1 inhibitor)

- On January 31, 2022, we received an NDA approval from the NMPA for the treatment of adults with R/R AML with an IDH1 mutation. Ivosidenib was the first IDH1 inhibitor approved in China for the treatment of patients with R/R AML.

  – In 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 presented as a proffered presentation at the ESMO Virtual Congress 2021 in September 2021.

  – 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.

- In August 2021, our partner, Servier, released positive topline data from the global phase III AGILE study of ivosidenib in combination with azacitidine in patients with previously untreated IDH1 mutant AML. The trial halted further enrollment due to compelling efficacy data. We plan to submit an NDA for this indication to the NMPA in 2022.

  – The phase III data from the global AGILE study presented at the 2021 American Society of Hematology ("**ASH**") Annual Meeting showed that ivosidenib in combination with the chemotherapy azacitidine significantly improved event-free survival and overall survival in adults with previously untreated IDH1-mutated AML compared to azacitidine plus placebo.

  – In May 2022, Servier announced the U.S. FDA approval of ivosidenib in combination with azacitidine for patients with newly diagnosed IDH1-mutated AML.

Sugemalimab (CS1001, PD-L1 antibody)

- Sugemalimab is an investigational monoclonal antibody directed against PD-L1 that has been approved by the NMPA in China. As a fully-human, full-length anti-PD-L1 monoclonal antibody, sugemalimab mirrors the natural G-type IgG4 human antibody, which may potentially reduce the risk of immunogenicity and toxicity in patients, a potential unique advantage and differentiation factor compared to similar drugs. As of the date of this announcement, we are conducting five registrational trials for sugemalimab, including one phase II registrational study for lymphoma and four phase III registrational studies in stage IV NSCLC, stage III NSCLC, gastric cancer, and esophageal cancer, respectively.

- In December 2021, we received the NDA approval from the NMPA for sugemalimab in combination with pemetrexed and carboplatin as first-line treatment of patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations, and in combination with paclitaxel and carboplatin as first-line treatment of patients with metastatic squamous NSCLC. In January 2022, the first prescription of sugemalimab was issued.

  – In June 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 was presented as a Late-Breaking Abstract at the IASLC 2021 WCLC. The data was also published in the world-leading oncology journal *The Lancet Oncology*, of which the impact factor is 41.3.

  – In January 2022, the pre-specified OS interim analysis showed that sugemalimab in combination with chemotherapy significantly and clinical meaningfully improved the overall survival in stage IV NSCLC patients, and the data will be presented in a poster session at 2022 ASCO Annual Meeting. The positive OS data will be used for ex-China filling for sugemalimab.

- In September 2021, the China NMPA accepted the NDA for sugemalimab as a consolidation therapy in patients with unresectable stage III NSCLC without disease progression after concurrent or sequential chemoradiotherapy. We expected to receive the NDA approval in the first half of 2022.

  – 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.

  – Sugemalimab 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 was presented as a Late-Breaking Abstract at the ESMO Virtual Congress 2021. The data was also published in the world-leading oncology journal *The Lancet Oncology*.

– In May 2022, we announced that the final PFS analysis of the registrational study further demonstrates sugemalimab's robust efficacy and significant clinical benefits shown in interim analysis. Subgroup analysis demonstrated clinical benefits in patients receiving either concurrent or sequential chemoradiotherapy prior to sugemalimab. Sugemalimab had a well-tolerated safety profile and no new safety signals were observed. The detailed results will be presented at an upcoming international academic conference.

- If the NDA is approved in China for stage III NSCLC, sugemalimab will become 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 the indications of stage III NSCLC, stage IV NSCLC, and ENKTL in multiple territories, including the U.S., the U.K. and the EU. For stage IV NSCLC, we expect the first NDA filing outside of the U.S. in the second half of 2022. Meanwhile, constructive conversations with the U.S. FDA are ongoing to gain greater clarity on the regulatory path. For ENKTL, sugemalimab has received the BTD from the U.S. FDA and we expect the BLA filing in 2023.

- In January 2022, the registrational trial of sugemalimab in patients with R/R ENKTL met the primary endpoint. We plan to submit an NDA to the NMPA for R/R ENKTL in the near term and will present the topline results in an oral abstract session at 2022 ASCO Annual Meeting.

  – Results showed that sugemalimab significantly enhanced the objective response rate ("**ORR**"), as assessed by the Independent Radiology Review Committee ("**IRRC**"), compared with historical control. The investigator-assessed ORR was consistent with the evaluation by IRRC. Sugemalimab also demonstrated a well-tolerated safety profile in patients with R/R ENKTL, and no new safety signals were observed.

  – We completed the enrolment for the phase II registrational trial of sugemalimab as monotherapy for the treatment of ENKTL in May 2021. We received the BTD from the NMPA in February 2021 for treating patients with R/R ENKTL.

- In January 2022, we completed the enrolment for the phase III trial of sugemalimab in combination with standard-of-care chemotherapies for first-line treatment of patients with unresectable or metastatic gastric cancer.

- In January 2022, we completed the enrolment for the phase III trial of sugemalimab in combination with standard-of-care chemotherapies for first-line treatment of patients with unresectable or metastatic esophageal squamous cell cancer.

CAUTIONARY STATEMENT REQUIRED BY RULE 18A.05 OF THE LISTING RULES: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET SUGEMALIMAB, OR ANY OF OUR PIPELINE PRODUCTS, SUCCESSFULLY.

Nofazinlimab (CS1003, PD-1 antibody)

- In March 2022, we completed the enrolment for the global phase III trial of nofazinlimab in combination with LENVIMA® (lenvatinib) in patients with advanced HCC. The phase Ib study of nofazinlimab combined with lenvatinib as first-line treatment in Chinese patients will be presented for online publication in 2022 ASCO Annual Meeting.

Lorlatinib (ROS-1 inhibitor)

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

Fisogatinib (CS3008, FGFR4 inhibitor)

- We have received positive feedback from the Center for Drug Evaluation ("**CDE**") regarding the single-arm registration strategy in China for the third-line and later-line treatment of hepatocellular carcinoma(HCC) with fisogatinib monotherapy, based on the phase I trial data.

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

- The first-in-human study of CS2006 is ongoing and includes sites in the U.S. and Taiwan, China. We anticipate completion of monotherapy dose-escalation in the first half of 2022. We received an IND approval from the NMPA in September 2021 and expect a much-abbreviated phase I study to start in China in the second half of 2022.

- In April 2022, the preclinical data was presented at the 2022 Annual Meeting of the American Association for Cancer Research ("**AACR**"). The results from pharmacokinetic/pharmacodynamic modelling demonstrated that binding affinity optimization of CS2006 allowed optimal PD-L1 blockade and 4-1BB stimulation concomitantly, at a broad dose range thereby and facilitating dose-finding in the clinic. In addition, the results showed that CS2006 was efficacious as monotherapy in both hot and cold tumor models. These data provide translational support for the ongoing clinical development of CS2006 as a potential best-in-class, next-generation immune-oncology agent.

CS1002 (CTLA-4 antibody)

- In July 2021, we presented the preliminary data of the phase I study of CS1002 in combination with CS1003 at ESMO 2021, followed by an update of the study at ESMO-IO 2021. Our results showed that the combination of CS1002 and CS1003, when given at different dosing schedules, had a very manageable safety profile and demonstrated encouraging anti-tumor responses in patients with anti-PD-(L)1-naïve, pretreated MSI-H/dMMR tumors, anti-PD-(L)1-refractory melanoma, and anti-PD-(L)1-refractory HCC.

- In view of proof-of-concept data shown in the above-mentioned phase I trial of CS1002, we have established a strategic partnership with Hengrui to develop, manufacture and commercialize CS1002 in Greater China. CStone maintains the development and commercialization rights of CS1002 in regions outside of Greater China. In May 2022, Hengrui received the IND approval from the NMPA.

CS5001 (LCB71, ROR1 ADC)

- In December 2021, we received the IND approval from the U.S. FDA. The Australia EC submission has also been achieved.

- In March 2022, the first patient was enrolled in the U.S. for the international multi-center phase I clinical trial of CS5001, representing a remarkable milestone for CStone's Pipeline 2.0 strategy.

- Additionally, we submitted IND application to the NMPA in March 2022 and received the approval in May 2022.

Trademarks

Blueprint Medicines, AYVAKIT, 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 in 2020 and continuing into 2022, 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 results of our efforts are evident in the progress of our pre-clinical drug candidates, CS5001 in particular. CS5001 is an ADC composed of a human monoclonal antibody targeting the tyrosine kinase-like orphan receptor 1 ("**ROR1**"), which 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. We presented the pre-clinical data of CS5001 as a Late-Breaking Abstract at the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics in October 2021. Importantly, we received the STP letter from the U.S. FDA for the IND of CS5001 in December 2021. The Australia EC submission has also been achieved in December 2021. In March 2022, the first patient was enrolled in the U.S. for the international multi-center phase I clinical trial. Additionally, we submitted IND application to the NMPA in March 2022 and received the approval in May 2022.

In addition, our global discovery collaboration with DotBio is intended to expand our emerging portfolio of next-generation innovative therapeutics. Together, we will jointly develop up to three preclinical first-in-class or best-in-class next-generation antibody therapies using DotBio's proprietary technology. This partnership bolsters CStone's Pipeline 2.0 strategy by adding a powerful new source of organic and transformative innovation to our R&D engine.

To further strengthen our in-house discovery research capability, we are establishing the CStone Global R&D Center, a brand-new research facility located adjacent to the manufacturing plant in Suzhou. The Center will be a cutting-edge discovery and translational research institute where state-of-the-art technical and functional platforms such as antibody discovery and development, systems pharmacology, and bioinformatics drive CStone's Pipeline 2.0 forward. It will also house a business incubator to foster the growth of biotech startups developing promising molecules and technological platforms to which we can have early access. We will broadly select candidates for the incubator based on their potential to contribute molecules for discovery platforms that would be highly complementary to our Pipeline 2.0 efforts. DotBio is slated to be the first with additional candidates to be announced soon.

Finally, we have systemically revised our research strategy to harness the modular nature of biologics that allows "plug-and-play" of various modules into an antibody backbone to provide different specificity and functionality. Such research strategy offers an efficient and streamlined approach for CStone to create a suite of FIC/BIC/FW molecules via collective efforts of in-house research and platform partner collaborations. Following this modular research framework, we have initiated and have in progress a total of over 10 discovery projects in 2021 including multi-specifics, ADCs, antibody-cytokine fusion molecules, as well as a proprietary platform for targeting otherwise undruggable intracellular proteins.

Business Development and Strategic Partnerships

Our business development team plays a vital strategic role in the growth of our business. They will pursue partnerships to expand commercialization of our in-market and late-stage drugs, bolster our early-stage pipeline of potential FIC/BIC molecules, and access technologies that complement our research and development efforts. In addition, they are supporting the development of our existing strategic partnerships including Pfizer and EQRx.

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

- ***DotBio***

  – CStone and DotBio signed a global discovery collaboration to develop up to three pre-clinical first-in-class or best-in-class next-generation antibody therapies for which CStone would lead the design of the target combination based on the intended mechanism of action and DotBio will lead the design and engineering of the molecules. As part of this collaboration, CStone will take an equity position in DotBio, a biotech company specializing in next generation antibody therapies. This partnership bolsters CStone's Pipeline 2.0 strategy by adding a powerful new source of organic and transformative innovation to its R&D engine.

- ***Hengrui***

  – We established a new strategic partnership with Hengrui. We signed an exclusive licensing agreement on the Greater China right of anti-CTLA-4 mAb (CS1002) in November 2021. Under the terms of the agreement, CStone will be eligible for an upfront payment and potential milestone payments up to US$200 million in addition to double-digit royalties. Hengrui will obtain the exclusive rights for research, development, registration, manufacturing, and commercialization of CS1002 in Greater China. CStone will retain the rights to develop and commercialize CS1002 outside of Greater China. This strategic partnership could help us to fully unlock the commercial potential of this asset.

- ***Pfizer***

  – In December 2021, we received the first approval of sugemalimab for stage IV NSCLC including both squamous and non-squamous patients. CStone and Pfizer have been working closely to prepare for a successful launch 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 is working closely with EQRx to advance regulatory discussions in multiple countries and jurisdictions outside of Greater China to discuss regulatory pathways for sugemalimab in multiple indications.

  – For the global study of nofazinlimab in HCC, CStone and EQRx enrolled patients in the U.S. and major EU markets.

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

The Impact of the Novel Coronavirus ("COVID-19")

During the Reporting Period, the impact of COVID-19 on our business operations was immaterial. The Company followed government mandates and took various mitigation measures to ensure employees' safety and minimize disruptions to business operations.

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

However, lockdowns in some parts of East and North China since March 2022 have led to disruptions to physician-patient interactions and posed challenges to supply chain management. These will likely have an impact on our operating performance in the second quarter of this year, though it is difficult to quantify at present. The extent of the impact will depend on the development of the pandemic and public health responses, which are beyond our control. We will continue to monitor the situation closely and will provide an update with our interim results announcement.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE YEAR ENDED DECEMBER 31, 2021

	NOTES	For the year ended December 31, 2021 RMB'000 (Audited)	2020 RMB'000 (Audited)
Revenue	3	**243,718**	1,038,832
Cost of revenue		**(106,832)**	(241,421)
Gross profit		**136,886**	797,411
Other income	5	**45,773**	51,671
Other gains and losses	5	**(134,188)**	(179,419)
Research and development expenses		**(1,304,945)**	(1,404,684)
Selling and marketing expenses		**(363,788)**	(142,150)
Administrative expenses		**(297,596)**	(342,508)
Finance costs	6	**(2,242)**	(1,320)
Loss for the year	7	**(1,920,100)**	(1,220,999)
Other comprehensive income (expense):			
Items that may be reclassified subsequently to profit or loss:			
Exchange differences arising on translation of foreign operations		**399**	(1,274)
Fair value gain on debt instruments at fair value through other comprehensive income ("**FVTOCI**")		**–**	31
Reclassified to profit or loss upon redemption of debt instruments at FVTOCI		**–**	(31)
Other comprehensive income (expense) for the year		**399**	(1,274)
Total comprehensive expense for the year		**(1,919,701)**	(1,222,273)
		RMB	*RMB*
Loss per share	9		
– Basic		**(1.65)**	(1.17)
– Diluted		**(1.65)**	(1.17)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

AT DECEMBER 31, 2021

	NOTES	**December 31, 2021** ***RMB'000*** **(Audited)**	December 31, 2020 *RMB'000* (Audited)
Non-current assets			
Property, plant and equipment		**154,166**	39,367
Right-of-use assets		**28,631**	27,175
Prepayments for acquisition of property, plant and equipment and intangible assets		**5,126**	35,411
Intangible assets		**70,539**	6,509
Financial assets measured at fair value through profit or loss ("**FVTPL**")		**3,188**	–
Other receivables		**52,158**	81,987
		313,808	190,449
Current assets			
Trade receivables	*11*	**117,598**	–
Deposits, prepayments and other receivables		**52,345**	178,040
Financial assets measured at FVTPL		**122,895**	10,125
Inventories		**61,363**	–
Restricted bank deposits		**–**	720
Time deposits with original maturity over three months		**860,720**	358,870
Cash and cash equivalents		**742,724**	3,024,548
		1,957,645	3,572,303
Current liabilities			
Trade and other payables and accrued expenses	*12*	**881,549**	708,525
Bank borrowings	*13*	**30,700**	2,662
Deferred income		**7,451**	7,210
Lease liabilities		**13,248**	8,652
		932,948	727,049
Net current assets		**1,024,697**	2,845,254
Total assets less current liabilities		**1,338,505**	3,035,703

	NOTE	**December 31, 2021** ***RMB'000*** **(Audited)**	December 31, 2020 *RMB'000* (Audited)
Non-current liabilities			
Bank borrowings	*13*	**115,811**	54,340
Deferred income		**1,247**	8,698
Lease liabilities		**14,439**	18,205
		131,497	81,243
Net assets		**1,207,008**	2,954,460
Capital and reserves			
Share capital		**796**	787
Treasury shares held in the trusts		**(11)**	(19)
Reserves		**1,206,223**	2,953,692
Total equity		**1,207,008**	2,954,460

NOTES

1. GENERAL

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 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 and sale of pharmaceutical products.

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

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

Amendments to IFRSs that are mandatorily effective for the current year

In the current year, the Group has applied the following amendments to IFRSs issued by the International Accounting Standards Board (the "**IASB**") for the first time, which are mandatory effective for the annual periods beginning on or after January 1, 2021 for the preparation of the 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

In addition, the Group applied the agenda decision of the IFRS Interpretations Committee of the IASB issued in June 2021 which clarified the costs an entity should include as "estimated costs necessary to make the sale" when determining the net realisable value of inventories.

The application of the amendments to IFRSs in the current year has had no material impact on the Group's financial positions and performance for the current and prior years and/or on the disclosures set out in these consolidated financial statements.

New and amendments to IFRSs in issue but not yet effective

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

IFRS 17	Insurance Contracts and the related Amendments[3]
Amendments to IFRS 3	Reference to the Conceptual Framework[2]
Amendments to IFRS 10 and IAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture[4]
Amendment to IFRS 16	Covid-19-Related Rent Concessions beyond June 30, 2021[1]
Amendments to IAS 1	Classification of Liabilities as Current or Non-current[3]
Amendments to IAS 1 and IFRS Practice Statement 2	Disclosure of Accounting Policies[3]
Amendments to IAS 8	Definition of Accounting Estimate[3]
Amendments to IAS 12	Deferred Tax related to Assets and Liabilities arising from a Single Transaction[3]
Amendments to IAS 16	Property, Plant and Equipment: Proceeds before Intended Use[2]
Amendments to IAS 37	Onerous Contracts – Cost of Fulfilling a Contract[2]
Amendments to IFRS Standards	Annual Improvements to IFRS Standards 2018-2020[2]

1 Effective for annual periods beginning on or after April 1, 2021

2 Effective for annual periods beginning on or after January 1, 2022

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

4 Effective for annual periods beginning on or after a date to be determined.

3. REVENUE

Disaggregation of revenue from contracts with customers

	For the year ended December 31,	
	2021	2020
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Type of goods or service		
Sales of pharmaceutical products	**162,764**	–
License fee income	**80,954**	1,038,832
	243,718	1,038,832
Timing of revenue recognition		
A point in time	**243,718**	1,038,832

4. SEGMENT INFORMATION

The Group has been operating in one reportable segment, being the research and development of highly complex biopharmaceutical products, sale of pharmaceutical products and provide license of its IP or commercialisation license to customers. The Group's chief operating decision maker ("**CODM**") has been identified as the chief executive of the Group.

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

Geographical information

Substantially, all of the Group's operation and non-current assets are located in the People's Republic of China (the "**PRC**"). The geographical information of the Group's revenue, determined based on geographical location of the registered office of the customers, during the year is as follows:

Geographical markets

	For the year ended December 31,	
	2021	2020
	RMB'000	*RMB'000*
The PRC	**243,718**	4,717
United States of America	**–**	1,034,115
	243,718	1,038,832

Information about major customers

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

	For the year ended December 31,	
	2021	2020
	RMB'000	*RMB'000*
Customer A	**158,941**	–
Customer B	**49,057**	–
Customer C	**31,897**	–
Customer D	**–**	1,034,115

5. OTHER INCOME AND OTHER GAINS AND LOSSES

Other income

	For the year ended December 31,	
	2021	2020
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Bank and other interest income	**9,803**	24,161
Government grants income	**35,970**	23,891
Income from pharmaceutical products	**–**	3,619
	45,773	51,671

Other gains and losses

	For the year ended December 31,	
	2021	2020
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Net (loss) gain on fair value changes of financial assets measured at FVTPL	**(64,214)**	396
Net gain on fair value changes of money market funds	**10**	1,990
Net gain on disposal of debt instruments at FVTOCI	**–**	31
Net foreign exchange losses	**(69,130)**	(181,836)
Loss on disposal of property, plant and equipment	**(901)**	–
Others	**47**	–
	(134,188)	(179,419)

6. FINANCE COSTS

	For the year ended December 31,	
	2021	2020
	RMB'000	*RMB'000*
Interest on lease liabilities	**1,254**	241
Interest on bank borrowings	**3,871**	1,079
Total borrowing costs	**5,125**	1,320
Less: amounts capitalised in the cost of qualifying assets	**(2,883)**	–
	2,242	1,320

7. LOSS FOR THE YEAR

	For the year ended December 31,	
	2021	2020
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Loss for the year has been arrived at after charging:		
Depreciation of property, plant and equipment	**5,611**	6,446
Depreciation of right-of-use assets	**11,300**	5,580
Amortisation of intangible assets	**5,750**	2,775
	22,661	14,801
Directors' emoluments	**120,952**	164,101
Other staff costs:		
Salaries and other allowances	**262,297**	194,880
Performance related bonus	**75,904**	62,934
Retirement benefit scheme contributions	**49,745**	16,534
Share-based payment expenses	**109,393**	199,219
	497,339	473,567
	618,291	637,668
Auditor's remuneration	**1,620**	1,900
Write-down of inventories (included in cost of revenue)	**24,816**	–

8. INCOME TAX EXPENSE

No income tax expense has been incurred by the Group for the years ended December 31, 2020 and 2021.

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,	
	2021	2020
	(Audited)	(Audited)
Loss (RMB'000)		
Loss for the year attributable to owners of the Company for the purpose of basic and diluted loss per share	**(1,920,100)**	(1,220,999)
Number of shares ('000)		
Weighted average number of ordinary shares for the purpose of basic and diluted loss per share	**1,165,209**	1,046,032

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

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

10. DIVIDENDS

No dividend was paid or declared by the Company during the year ended December 31, 2020 and 2021 nor has any dividend been proposed since the end of the reporting period.

11. TRADE RECEIVABLES

	2021	2020
	RMB'000	*RMB'000*
Trade receivables	**117,598**	–

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

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

	2021	2020
	RMB'000	*RMB'000*
0 – 60 days	**117,598**	–

12. TRADE AND OTHER PAYABLES AND ACCRUED EXPENSES

	December 31, 2021	December 31, 2020
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Trade payables	**33,024**	28,030
Other payables and accruals	**848,525**	680,495
	881,549	708,525

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:

	December 31, 2021	December 31, 2020
	RMB'000	*RMB'000*
	(Audited)	(Audited)
0 – 30 days	**32,514**	28,030
31 – 60 days	**510**	–
	33,024	28,030

13. BANK BORROWINGS

	December 31, 2021	December 31, 2020
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Unsecured and unguaranteed	**22,933**	17,680
Secured and unguaranteed	**123,578**	39,322
	146,511	57,002

The carrying amounts of the above borrowings are repayable*:

Within 1 year	**30,700**	2,662
Within a period of more than 1 year but not exceeding 2 years	**7,767**	1,877
Within a period of more than 2 years but not exceeding 5 years	**108,044**	52,463
	146,511	57,002
Less: amount due within 12 months shown under current liabilities	**(30,700)**	(2,662)
Amount show under non-current liabilities	**115,811**	54,340

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

Financial Review

Year Ended December 31, 2021 Compared to Year Ended December 31, 2020

	For the year ended December 31,	
	2021	2020
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Revenue	**243,718**	1,038,832
Cost of revenue	**(106,832)**	(241,421)
Gross profit	**136,886**	797,411
Other income	**45,773**	51,671
Other gains and losses	**(134,188)**	(179,419)
Research and development expenses	**(1,304,945)**	(1,404,684)
Selling and marketing expenses	**(363,788)**	(142,150)
Administrative expenses	**(297,596)**	(342,508)
Finance costs	**(2,242)**	(1,320)
Loss for the year	**(1,920,100)**	(1,220,999)
Other comprehensive income (expense):		
Items that may be reclassified subsequently to profit or loss:		
Exchange differences arising on translation of foreign operations	**399**	(1,274)
Fair value gain on debt instruments at FVTOCI	**–**	31
Reclassified to profit or loss upon redemption of debt instruments at FVTOCI	**–**	(31)
Other comprehensive income (expense) for the year	**399**	(1,274)
Total comprehensive expense for the year	**(1,919,701)**	(1,222,273)
Non-IFRS measures:		
Adjusted loss for the year	**(1,697,429)**	(864,976)

Revenue. Our revenue was RMB243.7 million for the year ended December 31, 2021, composed of RMB162.8 million in sales of pharmaceutical products, representing sales of the Company's newly launched pharmaceutical products (avapritinib and pralsetinib), and RMB80.9 million in license fee income, representing a decrease of RMB957.9 million from RMB1,038.8 million in the previous year as a result of decrease in the one-off license fee income.

Other Income. Our other income decreased by RMB5.9 million from RMB51.7 million for the year ended December 31, 2020 to RMB45.8 million for the year ended December 31, 2021. This was primarily due to reduced interest income.

Other Gains and Losses. Our other gains and losses decreased by RMB45.2 million from losses of RMB179.4 million for the year ended December 31, 2020 to losses of RMB134.2 million for the year ended December 31, 2021. This decrease was primarily due to decreased foreign exchange losses for the year ended December 31, 2021, which was offset by losses on fair value changes of other investments classified as financial assets at FVTPL.

Research and Development Expenses. Our research and development expenses decreased by RMB99.8 million from RMB1,404.7 million for the year ended December 31, 2020 to RMB1,304.9 million for the year ended December 31, 2021. This decrease was primarily attributable to (i) a decrease of RMB56.6 million in milestone fee and third party contracting cost from RMB1,088.7 million for the year ended December 31, 2020 to RMB1,032.1 million for the year ended December 31, 2021 for different phases of our clinical trials; and (ii) share-based payment expenses decreased by RMB36.1 million and other employee cost decreased by RMB9.8 million.

	For the year ended December 31,	
	2021	2020
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Employee cost	**267,470**	313,402
Milestone fee and third party contracting cost	**1,032,138**	1,088,706
Others	**5,337**	2,576
Total	**1,304,945**	1,404,684

Administrative Expenses. Our administrative expenses decreased by RMB44.9 million from RMB342.5 million for the year ended December 31, 2020 to RMB297.6 million for the year ended December 31, 2021. This was primarily due to the decrease of RMB69.4 million in employee cost from RMB238.0 million for the year ended December 31, 2020 to RMB168.6 million for the year ended December 31, 2021.

	For the year ended December 31,	
	2021	2020
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Employee cost	**168,570**	238,022
Professional fees	**65,256**	57,927
Rental expenses	**2,475**	3,160
Depreciation and amortization	**17,347**	14,594
Others	**43,948**	28,805
Total	**297,596**	342,508

Selling and Marketing Expenses. Our selling and marketing expenses increased by RMB221.6 million from RMB142.2 million for the year ended December 31, 2020 to RMB363.8 million for the year ended December 31, 2021. The increase was primarily attributable to sales force build-up and marketing activities for product launches.

	For the year ended December 31,	
	2021	2020
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Employee cost	**182,251**	86,244
Professional fees	**62,775**	24,486
Others	**118,762**	31,420
Total	**363,788**	142,150

Finance Costs. The finance costs increased by RMB0.9 million from RMB1.3 million for the year ended December 31, 2020 to RMB2.2 million for the year ended December 31, 2021, primarily due to the increase in bank borrowings during the Reporting Period.

Other Comprehensive Income. Our other comprehensive income increased by RMB1.7 million from other comprehensive expenses of RMB1.3 million for the year ended December 31, 2020 to other comprehensive income of RMB0.4 million for the year ended December 31, 2021.

Non-IFRS Measures

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

Adjusted loss for the year represents the loss for the year excluding the effect of certain non-cash items and onetime events, namely the share-based 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 years indicated:

	For the year ended December 31,	
	2021	2020
	RMB'000	*RMB' 000*
	(Audited)	(Audited)
Loss for the year	**(1,920,100)**	(1,220,999)
Added:		
Share-based payment expenses	**222,671**	356,023
Adjusted loss for the year	**(1,697,429)**	(864,976)

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

	For the year ended December 31,	
	2021	2020
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Research and development expenses for the year	**(1,304,945)**	(1,404,684)
Added:		
Share-based payment expenses	**122,835**	158,972
Adjusted research and development expenses for the year	**(1,182,110)**	(1,245,712)

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

	For the year ended December 31,	
	2021	2020
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Administrative and selling and marketing expenses for the year	**(661,384)**	(484,658)
Added:		
Share-based payment expenses	**99,836**	197,051
Adjusted administrative and selling and marketing expenses for the year	**(561,548)**	(287,607)

Employees and Remuneration Policies

The following table sets forth a breakdown of our employees as at December 31, 2021 by function:

Function	Number of employees	% of total number of employees
Research and Development	**204**	33.39
Sales, General and Administrative	**407**	66.61
Total	**611**	100.0

As of December 31, 2021, we had 263 employees in Shanghai, 64 employees in Beijing, 90 employees in Suzhou and 194 employees in other regions of the PRC and overseas. Our employees' remuneration comprises salaries, bonuses, employee provident fund and social security contributions and other welfare payments. In accordance with applicable Chinese laws, we have made contributions to social security insurance funds (including pension plans, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance) and housing funds for our employees.

Liquidity and Financial Resources

The Group has always adopted a prudent treasury management policy. The Group has taken a multi-source approach to fund our operations and meet development demands for capital, including service and milestone and upfront payments from our collaboration partners, bank borrowings, investments from other third parties and proceeds from our listing on the Stock Exchange.

On February 26, 2019, 186,396,000 Shares of US$0.0001 each were issued at a price of HK$12.00 per Share in connection with the Company's IPO on the Stock Exchange. The proceeds of HK$146,294.76 representing the par value, were credited to the Company's share capital. The remaining proceeds of HK$2,236,605,705.24, (before deduction of the expenses relating to the Company's IPO) were credited to the share premium account. The translation from US$ to HK$ is made at the exchange rate set forth in the H.10 weekly statistical release of the Federal Reserve System of the United States as of February 26, 2019.

On September 30, 2020 (before trading hours), the Company entered into the share subscription agreement with Pfizer, pursuant to which Pfizer has conditionally agreed to subscribe for an aggregate of 115,928,803 subscription shares at the subscription price of approximately HK$13.37 per Share. The gross proceeds from the allotment and issue of the subscription shares were approximately US$200.0 million (equivalent to approximately RMB1,355.9 million).

As of December 31, 2021, our cash and cash equivalents and time deposits were RMB1,603.4 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 and marketing expenses.

Gearing Ratio

Gearing ratio is calculated using total liabilities divided by total assets and multiplied by 100%. As at December 31, 2021, our gearing ratio was 46.9% (as at December 31, 2020: 21.5%).

Charge on Assets

As of December 31, 2021, the Group did not pledge any group assets.

Other Financial Information

Significant Investments, Material Acquisitions and Disposals

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

The aggregate amount committed to the Investment was approximately HKD227.7 million (equivalent to approximately RMB189.2 million). Based on the Investment's underlying securities valuation, the fair value of the Investment as at December 31, 2021 was RMB122,895,000, representing approximately 5.4% of the total assets of the Group as at December 31, 2021. As such, the unrealized loss of the Investment for the year ended December 31, 2021 amounted to RMB64,214,000. The Investment was made without the Board's knowledge or approval, and the Company aims to redeem the Investment as soon as practicable. For details, please refer to the announcement of the Company dated May 31, 2022.

Save as disclosed above, as at December 31, 2021, we did not hold any significant investments. As at the date of this announcement, we have no specific future plan for material investments or capital assets, as well as material acquisitions or disposals of subsidiaries, associates and joint ventures. We will make further announcement in accordance with the Listing Rules, where applicable, if any material investments and acquisition opportunities materialize.

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 of the Group monitors foreign exchange exposure and will consider hedging significant foreign currency exposure should the need arise.

Bank Loans and Other Borrowings

On January 7, 2020, the Group obtained two new bank loan facilities amounting to RMB175 million and RMB25 million, respectively, for the purpose of the construction of the facilities. During the year ended December 31, 2021, the Group has drawn down RMB96,215,000 and repaid RMB10,577,000 of principal and interest in accordance with the payment schedules.

Contingent Liabilities

As of December 31, 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 Rules Governing the Listing of Securities on the Stock Exchange ("**Listing Rules**"), except for the deviation explained below.

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

Subsequent to and as from the cessation of Dr. Frank Ningjun Jiang's acting as the Chairman of the Board and Dr. Wei Li's taking up the role of the Chairman of the Board on May 31, 2022, the Company has fully complied with the requirements under code provision C.2.1 of the CG Code. For further details, please refer to the announcement of the Company dated May 31, 2022.

The Company will continue to regularly review and monitor its corporate governance practices to ensure compliance with the CG Code, and maintain a high standard of corporate governance practices of the Company.

Model Code for Securities Transactions by Directors of Listed Issuers

We have adopted our own code of conduct regarding Directors' securities transactions, namely the policy on management of securities transactions by directors (the "**Securities Transactions Code**"), which applies to all Directors on terms not less exacting than the required standard indicated by the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix 10 to the Listing Rules (the "**Model Code**").

Specific enquiries have been made to all the Directors and they have confirmed that they have complied with the Securities Transactions Code during the Reporting Period. The Company's employees, who are likely to be in possession of our unpublished inside information, are subject to the Model Code. No incident of non-compliance of the Model Code by the employees was noted by the Company as of the date of this announcement.

Purchase, Sale or Redemption of Listed Securities

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

Material Litigation

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

Material Events after the Reporting Period

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

Use of Net Proceeds

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

	% of use of proceeds *(Approximately)*	**Net proceeds from the HK IPO** *(RMB million)*	**Actual usage up to December 31, 2021** *(RMB million)*	**Unutilized net proceeds as of December 31, 2021** *(RMB million)*
Fund ongoing and planned clinical trials, preparation for registration filings and commercial launches of sugemalimab	30.0%	627.04	627.04	–
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**	**2,090.16**	–

Notes: Net IPO proceeds were received in Hong Kong dollars and translated to Renminbi for application planning, and have been completely used up 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, 2021:

	% of use of proceeds *(Approximately)*	Proceeds from the subscription *(RMB million)*	Actual usage up to December 31, 2021 *(RMB million)*	Unutilized net proceeds as of December 31, 2021 *(RMB million)*
Fund the development activities under the collaboration agreement	100.0%	1,355.9	405.7	950.2

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 reviewed and discussed the audited annual results of the Company for the year ended December 31, 2021 together with the Group's consolidated financial statements for the year ended December 31, 2021 which the independent auditor has issued an unmodified opinion.

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 31,2021 as set out in this preliminary announcement have been agreed by the Group's auditor, Messrs. Deloitte Touche Tohmatsu, to the amounts set out in the 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 this announcement.

FINAL DIVIDEND

The Board does not recommend the payment of a dividend for the year ended December 31, 2021 (2020: Nil).

ANNUAL GENERAL MEETING

The date of the annual general meeting of the Company (the "**AGM**") will be announced in due course. Shareholders of the Company should refer to details regarding the AGM in the circular of the Company, the notice of AGM and form of proxy accompanying thereto to be dispatched by the Company.

PUBLICATION OF ANNUAL RESULTS ANNOUNCEMENT AND ANNUAL REPORT

This announcement will be published on the websites of the Stock Exchange (***www.hkexnews.hk***) and the Company (***http://www.cstonepharma.com***).

As more time is required to prepare the annual report for the year ended December 31, 2021 containing all the information required by Appendix 16 to the Listing Rules, it will be despatched to shareholders of the Company and published on the respective websites of the Stock Exchange and the Company in due course.

RESUMPTION OF TRADING

At the request of the Company, trading in the shares of the Company on The Stock Exchange was suspended from 9:00 a.m. on Friday, April 1, 2022, pending the release of this annual results announcement for the year ended December 31, 2021. Application has been made by the Company to the Stock Exchange for the resumption of trading in the Shares on the Stock Exchange with effect from 9:00 a.m. on June 1, 2022.

APPRECIATION

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

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

Suzhou, PRC, May 31, 2022

As at the date of this announcement, the Board comprises Dr. Frank Ningjun Jiang as executive Director, Dr. Wei Li as Chairman and non-executive Director, Mr. Kenneth Walton Hitchner III, Mr. Yanling Cao, Mr. Xianghong Lin and Mr. Edward Hu as non-executive Directors, and Dr. Paul Herbert Chew, Mr. Ting Yuk Anthony Wu and Mr. Hongbin Sun as independent non-executive Directors.