Transcenta Holding Limited
創勝集團醫藥有限公司

(registered by way of continuation in the Cayman Islands with limited liability)

(Stock Code: 6628)

ANNOUNCEMENT OF ANNUAL RESULTS FOR THE YEAR ENDED DECEMBER 31, 2021

The board (the "**Board**") of directors (the "**Directors**") of Transcenta Holding Limited (the "**Company**") is pleased to announce the audited consolidated results of the Company and its subsidiaries (the "**Group**") for the year ended December 31, 2021 (the "**Reporting Period**"), together with comparative figures for the year ended December 31, 2020. The consolidated financial statements of the Group for the Reporting Period have been reviewed by the audit committee of the Company and audited by the Company's auditors, Deloitte Touche Tohmatsu. Unless otherwise defined herein, capitalised terms used in this announcement shall have the same meaning ascribed thereto in the prospectus of the Company dated September 14, 2021 (the "**Prospectus**").

In this announcement, "we", "us" and "our" refer to the Company (as defined above) and where the context otherwise requires, the Group (as defined above). Certain amount and percentage figure included in this announcement have been subject to rounding adjustments, or have been rounded to one or two decimal places. Any discrepancies in any table, chart or elsewhere between totals and sums of amounts listed therein are due to rounding.

FINANCIAL HIGHLIGHTS

International Financial Reporting Standards ("IFRS") Measures:

- **Revenue** decreased from RMB81.0 million for the year ended December 31, 2020 to RMB50.2 million for the year ended December 31, 2021, primarily attributable to the decrease in provision of Contract Development and Manufacturing Organization (CDMO) service to external customers in order to support the increasing needs for in-house Chemistry, Manufacturing and Controls (CMC) for clinical trials. This is in line with the development of the business and reflects the significant progress we have made in advancing our pipeline.

- **Other income** increased by RMB21.0 million from RMB11.9 million for the year ended December 31, 2020 to RMB32.9 million for the year ended December 31, 2021, primarily attributable to an increase of government grants we recognized during the year ended December 31, 2021.

- **Other gains and losses** decreased by RMB1,226.7 million from a gain of RMB26.7 million for the year ended December 31, 2020 to a loss of RMB1,200 million for the year ended December 31, 2021, primarily attributable to losses in fair value of financial liabilities at fair value through profit or loss from the preferred shares issued by the Company.

- **Research and development expenses** increased by RMB144.1 million from RMB200.3 million for the year ended December 31, 2020 to RMB344.4 million for the year ended December 31, 2021, primarily attributable to our pipeline advancement. Such increase is in line with where we want to be as our pipeline assets progress through various clinical milestones.

- **Selling and administrative expenses** decreased by RMB12.7 million from RMB157.9 million for the year ended December 31, 2020 to RMB145.2 million for the year ended December 31, 2021, primarily attributable to the decrease of share-based payment expenses.

- As a result of the above factors, **loss and total comprehensive expenses for the year** increased by RMB1,394.3 million from RMB319.5 million for the year ended December 31, 2020 to RMB1,713.8 million for the year ended December 31, 2021, primarily attributable to losses in fair value of financial liabilities at fair value through profit or loss from the preferred shares and R&D expenditures to advance our key pipelines.

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

- **Revenue** decreased from RMB81.0 million for the year ended December 31, 2020 to RMB50.2 million for the year ended December 31, 2021, primarily attributable to decrease in provision of external CDMO service to support the in-house CMC needs for increasing supply to our clinical trials.

- **Research and development expenses** excluding the share-based payment expenses increased by RMB175.0 million from RMB167.5 million for the year ended December 31, 2020 to RMB342.5 million for the year ended December 31, 2021, primarily attributable to our pipeline advancement.

- **Selling and administrative expenses** excluding the share-based payment expenses increased by RMB37.7 million from RMB78.8 million for the year ended December 31, 2020 to RMB116.5 million for the year ended December 31, 2021, primarily attributable to increase in personnel cost and professional fees.

- **Adjusted loss and total comprehensive expenses for the year** excluding the effect of the fair value changes of financial liabilities at fair value through profit or loss from the preferred shares and share-based payment expenses increased by RMB239.4 million from RMB245.6 million for the year ended December 31, 2020 to RMB485.0 million for the year ended December 31, 2021, primarily due to R&D expenditures to advance our key pipelines.

BUSINESS HIGHLIGHTS

Summary

2021 was a record year for the Company as we became a listed company and made significant progress in demonstrating our fully integrated capabilities in discovery, research, development and manufacturing of differentiated antibody therapies. Several of our development programs made rapid progress, giving us a risk-balanced pipeline with multiple assets well into clinical development. We began paving the way for our first global registration study of our lead asset. Our multi-regional clinical development strategy maximized efficiency and accelerated various development processes. We continued to shape our next wave of innovation through advancing IND-enabling programs for candidates discovered through our proprietary antibody discovery platform that have first-in-class or best-in-class potential. We expanded manufacturing capacity and further reduced cost of goods through upgrading and optimizing our manufacturing technology platform.

As of the date of this announcement, a shortlist of our achievements includes the following:

Advanced our lead asset, Claudin 18.2 targeting antibody TST001, in multiple indications and paving the way for first global registration study

- Advanced TST001 in multiple indications simultaneously, both globally and in China.
- Initiated a phase IIa trial for late-line gastric cancer in August 2021.
- Initiated a phase IIa trial for late-line pancreatic cancer in September 2021.
- Initiated a phase IIa trial of TST001 in combination with chemotherapy as a first-line treatment of gastric cancer with Claudin 18.2 over-expression in December 2021.
- Received orphan drug designation from the U.S. FDA for the treatment of gastric cancer including esophagogastric junction cancer in July 2021.
- Generated the package for Investigational New Drug (IND) submission for a global registration trial of TST001 in gastric cancer which is expected to start in the second half of 2022 pending IND approval.
- Produced CMC data package in support of regulatory submission in China and the U.S.
- Developed an immunohistochemistry detection assay to enable patient screen for the clinical trial.

Maximised efficiency and accelerated speed to address requirements of multiple regulatory authorities with multi-regional development strategy

- Advanced TST001 global trials to enable the submission of IND for global registration trial which is to start in later 2022 – expedited the process by one year compared to our original timeline.

- Initiated global trial for TST005 (PD-L1/TGF-β bispecific) in both the U.S. and China.

- Obtained IND approval from the NMPA for TST002 in China in September 2021 and leveraged Eli Lilly's global phase I and phase II clinical data to accelerate the development in China by directly conducting phase I trial in osteoporosis patients instead of starting in healthy volunteers.

Generated candidates with superior profile and high commercial potential using proprietary antibody discovery platform

- Advanced IND-enabling programs for three candidates discovered with our proprietary antibody discovery platform, including TST003, a potentially first-in-class therapeutic antibody candidate targeting a novel immune regulatory protein produced by tumor-associated fibroblasts.

- Two of those programs are expected to file IND in 2022.

Established pivotal trial CMC process and upgraded manufacturing facility for commercial production of our lead assets

- Achieved breakthrough progress on integrated continuous bioprocessing technology, achieving >10-fold increase in productivity when compared to conventional fed-batch process.

- Established and scaled up TST001's intensified perfusion process to GMP commercial scale.

- Completed upgrades to our Hangzhou facility, adopting a fully automated approach and expanding our manufacturing capability to enable commercial launch of our drugs.

Raised approximately HK$553.4 million in a Listing on the Main Board of the Hong Kong Stock Exchange

- Completed listing on the Main Board of the Hong Kong Stock Exchange on September 29, 2021 with the stock code 6628, raising approximately HK$553.4 million in net proceeds.

These achievements advance our Company further into the clinical stage of its development and give us the potential to deliver material growth in 2022.

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:

Significant Progress Achieved in Clinical Development

Wholly-owned global programs

TST001 (A Humanized Claudin 18.2 mAb for Solid Tumors) – the first Claudin 18.2 drug candidate developed by a Chinese company has been in Phase II development and to enter Phase III clinical trials and to be developed concurrently in multiple global markets, including in China, the United States, Europe, and other countries of Asia.

- Initiated a phase IIa trial for late-line gastric cancer in August 2021.
- Initiated a phase IIa trial for late-line pancreatic cancer in September 2021.
- Initiated a Phase IIa trial of TST001 in combination with chemotherapy as a first-line treatment of gastric cancer with Claudin 18.2 over-expression in December 2021.
- Initiated a Phase I trial of TST001 in combination with chemotherapy as a second-line treatment of gastric cancer and dosed multiple patients in May 2021.
- Received orphan drug designation from the U.S. FDA for the treatment of gastric cancer including esophagogastric junction cancer in July 2021.
- Completed the single agent Phase Ia dose-escalation trial in solid tumors for TST001 in China in August 2021.
- Funded an investigator-initiated study in advanced biliary tract cancer, which was approved by the Institutional Review Board (IRB) of the study site in November 2021.

TST005 (A PD-L1/TGF-β Bi-functional Antibody Candidate for Solid Tumors)

- Initiated a global Phase I trial in the United States for solid tumors in July 2021.
- Obtained IND approval in China in December 2021.
- Presented and highlighted the differentiated compound profile of TST005 at the 2021 AACR annual meeting.

TST003 (A First in Class Humanized Antibody Candidate for PD1 Resistant Tumors)

- Initiated IND-enabling studies and completed GLP tox in-life studies.

TST010 (T regulatory cell depleting mAb to target immune checkpoint inhibitor resistance)

- Initiated IND-enabling studies in December 2021.

Collaboration Programs

TST002 (Blosozumab) (A Humanized Sclerostin mAb for Osteoporosis) – in collaboration with Eli Lilly and Company ("Eli Lilly")

- Obtained IND approval from the NMPA in China in September 2021 and the phase I study was approved by the IRB of the leading study site.

TST004 (A Humanized MASP-2 mAb Candidate for Kidney Diseases including IgA nephropathy) – in partnership with Alebund Pharmaceuticals

- Completed process development and GMP material productions.
- Initiated GLP tox studies which is currently ongoing.

Elevated Manufacturing Capabilities

- Achieved industry best productivity of over 6 g/L-day through our Integrated Continuous Bioprocessing (ICB) platform, which corresponds to >15-fold increase in productivity when compared to conventional fed-batch process.
- Scaled up lead asset TST001's intensified perfusion process to GMP commercial scale.
- In collaboration with Merck, completed design and fabrication of industry's first automated and single use flow-through polishing continuous downstream GMP equipment, which will significantly intensify downstream operations and debottleneck manufacturing output.
- Upgraded Hangzhou facility for commercial launch.

Other Corporate Milestones

- Completed listing on the Main Board of the Hong Kong Stock Exchange and raised approximately HK$553.4 million in net proceeds.
- Received RMB6.0 million milestone payment from Alebund Pharmaceuticals for co-development agreement on TST004.

MANAGEMENT DISCUSSION & ANALYSIS

OVERVIEW

We are a clinical stage biopharmaceutical company with fully integrated capacities in discovery, research, development, and manufacturing of differentiated antibody therapies for cancer, bone disorders and nephrology.

We adopt a multi-regional development strategy to maximize operational efficiency and address requirements of multiple regulatory authorities. This has also given us a first-mover advantage for several of our development programs, in particular we are global leader in the emerging Claudin 18.2 targeting therapeutic field. Our proprietary antibody discovery platform, the Immune Tolerance Breaking ("**IMTB**") technology platform, enables us to generate antibodies that are challenging to discover by using conventional platforms, and also allows us to select candidate molecules with enhanced druggability attributes for which we hold global intellectual property rights.

We have built a diversified and risk-balanced pipeline of antibodies with best-in-class or first-in-class potential in therapeutic areas with high unmet medical needs, including oncology, nephrology and bone diseases. As of December 31, 2021, we have discovered and developed nine of ten antibody candidates in-house. We are also developing a number of early-stage biotherapeutic candidates with high therapeutic potential.

All our molecules currently in development have a comprehensive translational research strategy to realize their full clinical and commercial potential. By elevating the role of translational science, we have better understanding of disease biology and better selection of the right patient population to increase the probability of trial success. We have established fully integrated CMC capabilities to support both IND and Biologics License Application (BLA) filing. In addition, we have made significant progress in partnerships for our products, and will continue to expand our strategic partnerships with global and local biopharmaceutical companies as well as academic research institutions.

Product Pipeline

We have established a pipeline of ten innovative molecules in oncology, bone disorders and nephrology. Most of these molecules are discovered and developed in house with one pipeline candidate acquired through in-licensing. The following chart summarizes drug candidates that are currently under development in China and worldwide across various therapeutic areas as of the date of this announcement:

Source: Company

Abbreviations: PD-L1=Programmed death-ligand 1; VEGFR2=Vascular endothelial growth factor receptor 2; TGFβ=Transforming growth factor beta; MASP2=Mannan-binding lectin serine protease 2; IND=Investigational new drug; FIC=First in class; HPV=Epstein-Barr Virus; BMP Antagonist=Bone morphogenetic protein Antagonist; TACI=transmembrane activator and CAML interactor; CAML=calcium-modulator and cyclophilin ligand; NSCLC=Non-small cell lung cancer; SLE=Systemic lupus erythematosus; TMA=Thrombotic microangiopathy; IgA nephropathy=Immunoglobulin A nephropathy; Combo=Combination; Chemo=Chemotherapy; VEGFRi=Vascular endothelial growth factor receptor 2 inhibitor

(1) Solid tumors in the "Indications" column include all the tumor types other than hematologic malignancies. The particular tumor types as indications for each product depends on the mechanism of action of the corresponding drug candidate and emerging or established pre-clinical/clinical evidences. See the subsections headed "Clinical Development Plan" for each of our drug candidates in "Business" section of the Prospectus for the specific tumor types targeted for clinical development.

(2) Global in the "Clinical trial region" column represents Asia (including China), United States, European Union and Oceania.

BUSINESS REVIEW

We adopted a global Multi-Regional Development Strategy to maximize opportunities for operational efficiency. We simultaneously leverage the efficient regulatory approval pathway in the United States so as to accelerate IND applications and early-phase clinical trials while also taking advantage of the large patient population in China to expedite clinical trials in indications with significant unmet medical needs. We design the trials that allow clinical data from each trial to be used for pooled analysis and for the use of supporting registration, including in China, the United States and other countries in Asia and Europe. In addition, clinical data from multi-regional clinical trials will enable future indication expansion for the drug(s) investigated. We keep the core clinical development functions in-house, including clinical trial design, planning and management, while utilizing contract research organizations (CROs) for trial execution. Our global clinical development and regulatory teams, based in Beijing, Shanghai and Princeton, New Jersey, have extensive knowledge and experience in designing and executing global clinical trials at all stages in indications with high unmet medical needs.

During 2021, we have made significant progress with our pipeline assets in both oncology and non-oncology therapeutic areas at multiple clinical stages and IND stages, including the following milestones and achievements:

Oncology Program

Our oncology pipeline includes multiple innovative and differentiated biologic molecules targeting major cancer pathways which have potential synergistic mechanisms of actions (MOA) for tumor indications with high unmet medical needs. This includes:

- TST001, currently at Phase II development in multiple solid tumor indications including but not limited to gastric and pancreatic cancers, is a humanized antibody targeting Claudin 18.2, a well validated tumor associated antigen both clinically and commercially.

- TST005 is a bifunctional humanized antibody targeting PD1/PD-L1-TGF-β pathway, a key MOA for PD1 resistance.

- TST003 is a global first-in-class humanized antibody currently in IND-enabling stage, targeting cancer associated stromal cells, which are key source of immunosuppressive factors.

- TST010, a newly nominated preclinical antibody candidate entering IND-enabling stage, targeting regulatory T cells to enhance T cell mediated tumor killing.

Our programs (TST005, TST003 and TST010) are highly synergistic with TST001 for gastrointestinal cancers and are designed to enhance Claudin 18.2 franchise through combination with TST001.

TST001 (A Humanized Claudin 18.2 mAb for Solid Tumors)

TST001, one of the key products in our oncology pipeline, is a high-affinity humanized antibody specifically targeting Claudin 18.2, which is over-expressed in multiple tumor type cancers, including gastric/gastroesophageal junction cancer, pancreatic cancer, and other types of solid tumors.

TST001 is in development concurrently in global markets, including in China, the United States, Europe, and other countries of Asia. It is currently in Phase II of the development and is expected to enter Phase III clinical trials in later 2022.

We have made significant progress in 2021 in advancing the clinical development for TST001, ranked among the top two most advanced clinical programs for Claudin 18.2 globally, and the first in China.

- In April 2021, we initiated a Phase I trial of TST001 in combination with chemotherapy as a first-line treatment of gastric cancer to establish the safety and tolerability of this combination. Later in December 2021, we initiated the expansion of cohort (Phase IIa).

- In May 2021, we also started a Phase I trial of TST001 in combination with chemotherapy as a second-line treatment of gastric cancer.

- In August 2021, we initiated phase IIa study of TST001 monotherapy in late-line gastric cancer.

- In September 2021, we initiated phase IIa study of TST001 monotherapy in late-line pancreatic cancer.

- In November 2021, we funded an investigator-initiated study of TST001 in advanced biliary tract cancer, which was approved by ethical committee of the study site.

- We also established multiple academic collaborations for TST001:

    - We collaborated with Beijing Cancer Hospital to explore real time TST001 drug distribution and target engagement in cancer patients by using both ^{124}I radio-labeled drug tracer and ^{18}F FDG tumor tracer to non-invasively image the drug distribution in patients by PET/CT/MRI.

    - We also worked with Beijing Cancer Hospital to study the prevalence of Claudin 18.2 and co-expression pattern with other therapeutic targets in gastrointestinal cancer.

    - Our collaboration with Shanghai Zhongshan Hospital led to promising results validating Claudin 18.2 as an important target in biliary tract cancer (BTC) and the initiation of an investigator-initiated trial of TST001 in BTC.

    - We also initiated collaboration with the Dana-Farber Cancer Institute of Harvard Medical School for TST001 efficacy in patient derived tumor xenograft (PDX) mouse models.

    - We conducted the combination treatment studies with standard chemotherapies and TST001 in multiple PDX mouse models. The result demonstrated the synergistic effects of the combination treatment, providing the preclinical evidence for potential combination treatment benefits in patients.

- We have developed a specific detection antibody for Claudin 18.2 immunohistochemistry detection to enable patient screening for TST001 clinical trials. We evaluated various testing platforms for validating the assay for patient screening. This antibody is being further co-developed with a global company experienced in companion diagnostics (CDx) development.

- We have developed an optimized intensified continuous perfusion and downstream process in support of future clinical studies and commercial launch. This process maintained product comparability while increased process output by approximately 10 folds when compared to Phase I fed-batch process for early clinical trial material supply. We have scaled up this process in T-BLOC, our GMP manufacturing facility. The registration trial material has been produced using this process to support the start of Phase III trial in gastric cancer in second half of 2022. We have produced required data package in support of regulatory submission to NMPA and FDA for the process change.

TST005 (A PD-L1/TGF-β Bi-functional Antibody Candidate for Solid Tumors)

- One of our key oncology products TST005, a bi-functional antibody designed to simultaneously target two immunosuppressive pathways, transforming growth factor-β (TGF-β) and programmed cell death ligand-1 (PD-L1), that are commonly used by cancer cells to evade the immune system, entered the clinical development in 2021.

- We filed an IND application for TST005 with the FDA in March 2021 and obtained IND clearance from the FDA in April 2021 for initiating Phase I clinical trial of TST005 in the United States.

- In July 2021, the first patient of the global Phase I trial of TST005 in the United States was enrolled.

- We also filed an IND application for TST005 with the NMPA of China in September 2021 and obtained Phase I study approval in China in December 2021.

- We presented at 2021 AACR annual meeting and highlighted our differentiated profile.

- We collaborated with Shanghai Pulmonary Hospital affiliated with Tongji University to study the mechanism of primary/acquired resistance to immune-therapy in non-small cell lung cancer (NSCLC) using single cell sequencing platform.

- We have established a perfusion-based process for the production of TST005 for clinical supply. The CMC package was accepted by both FDA and NMPA.

TST003 (A First in Class Humanized Antibody Candidate for PD1 Resistant Tumors)

- TST003 is a high affinity humanized monoclonal antibody targeting a regulatory protein that is highly expressed by stromal cells in diverse human carcinomas, especially in esophageal cancer, pancreatic cancer, gastric cancer, colon cancer, lung cancer, breast cancer and prostate cancer, among others. TST003 has demonstrated significant anti-tumor activities both in vitro and in vivo in preclinical studies. TST003 has the potential to become a novel cancer treatment, either as monotherapy or in combination with immune checkpoint inhibitor and/or other anti-tumor agents.

- TST003 is currently in IND-enabling stage with ongoing preclinical studies.

- We implemented a perfusion process and have produced GMP drug substance (DS) and drug product (DP) for clinical trial supply.

MSB0254 (A Humanized VEGFR2 mAb Candidate for Solid Tumors)

- MSB0254 is a high affinity humanized antibody against VEGFR2, with an anti-tumor mechanism of action by inhibiting tumor angiogenesis.

- As of March 2021, Ramucirumab of Eli Lilly is the only VEGFR2 antibody drug approved by the FDA in the United States with indications including monotherapy or combination treatment with chemotherapy for gastric cancer, second line treatment of metastatic colorectal cancer, hepatocellular carcinoma and first-line treatment for metastatic EGFR-mutated NSCLC. In March 2022, China NMPA has approved Ramucirumab in combination with Taxol for the treatment of patients with gastric/gastroesophageal junction cancer progressed during or after first line chemotherapy.

- We completed phase Ia dose escalation study and determined the recommended phase II dose in October 2021. In November 2021, expansion cohorts were initiated in selected tumor types.

- Results of phase Ia trial of MSB0254 was reported at the Chinese Society of Clinical Oncology (CSCO) 2021.

MSB2311 (A Humanized PD-L1 mAb Candidate for Solid Tumors)

- MSB2311, is a second-generation PD-L1 inhibitor with unique pH dependent PD-L1 binding property, an important differentiation from other PD-(L)1 antibodies.

- Encouraging clinical activities has been obtained for Phase I trial results of MSB2311 and the data were reported at the American Society of Clinical Oncology (ASCO) and the CSCO 2021.

- The IND of MSB2311 and MSB0254 combination therapy was formally accepted by the NMPA in November 2021.

TST006

- TST006 is a bi-specific antibody targeting Claudin 18.2 and PD-L1, which has the potential for the treatment of Claudin 18.2-expressing cancer patients who are resistant to or refractory from Claudin 18.2 mAb or PD-1/PD-L1 mAb therapies, such as late-line gastric cancer patients, pancreatic cancer patients and others.

- We nominated the final pre-clinical candidate (PCC) in 2021, which demonstrated a good in vivo antitumor activity and CMC developability.

TST010 (T regulatory cell depleting mAb)

- Tumor-infiltrating regulatory T cells (Tregs) function to suppress T effectors, and its presence was reported to correlate with tumor progression and a worsening prognosis in many cancers.

- In December 2021, we advanced a new pre-clinical candidate TST010 in our oncology pipeline, with a MOA of Treg cell depletion to target checkpoint inhibitor resistance.

- TST010 displayed potent and selective Treg depleting activity and can liberate T effectors in tumor microenvironment to induce immune mediated killing of cancer cells in preclinical tumor models.

Non-oncology Program

Our highly differentiated non-oncology pipelines focus on novel indications with high unmet medical needs in bone and kidney diseases (TST002, TST004, and TST008). This strategy allows us to be an important player in a field facing less competition and reach high market potentials. We have developed partnerships to leverage our core expertise and knowledge in these disease areas. We have leveraged Eli Lilly's global phase I and phase II clinical data to accelerate TST002's development in China by directly conducting phase I trial in osteoporosis patients instead of starting in healthy volunteers. In addition to developing TST002 and TST004 in fast-to-market indications, we are also expanding TST002 and TST004 in additional indications with blockbuster potentials and to form partnerships to accelerate the product development. To further expand our current pipeline in IgA nephropathy, we are also developing preclinical candidate with first-in-class tri-functional antibody targeting systemic lupus erythematosus (SLE), a disease with a large patient population yet very limited treatment options.

TST002 (Blosozumab) (A Humanized Sclerostin mAb for Osteoporosis)

- TST002, one of our key products, is a humanized monoclonal antibody with neutralizing activity against sclerostin for which we in-licensed the Great China rights from Eli Lilly. TST002 (Blosozumab) has completed phase II trials by Eli Lilly in postmenopausal women in the United States and Japan, and has shown an ability to induce statistically significant dose-dependent increases in spine, femoral neck, and total hip bone mineral density (BMD) as compared with placebo. In the highest dose group, TST002 treatment increased BMD by 17.7% at the spine, and 6.2% at the total hip from baseline within 12 months.

- In June 2021, we submitted an IND application for TST002 for postmenopausal osteoporosis in China to NMPA.

- In September 2021, we received IND approval from the NMPA.

- In November 2021, the TST002 phase I study was approved by the IRB of the leading study site.

TST004 (A Humanized MASP-2 mAb Candidate for Kidney Diseases)

- TST004, one of our key products, is a humanized mAb targeting mannan-binding lectin serine protease 2 (MASP2) and designed to prevent the inflammation and tissue damage mediated by lectin pathway complement activation.

- TST004 is currently at IND-enabling stage with GLP toxicology studies and CMC studies ongoing.

- We developed a SubQ formulation for enhancing IgA nephropathy patient compliance.

TST008 (A Tri-functional Antibody Combining a MASP2 Antibody)

- Lupus is a complex autoimmune disease involving both innate and adaptive immune systems. Current targeted biological therapies for SLE only address the adaptive immune by targeting B-cell. In addition to B-cell, the complement system also plays a major role in SLE disease progression.

- TST008 is a first-in-class tri-functional antibody combining a MASP2 antibody fused with a transmembrane activator and CAML interactor (TACI) protein, which simultaneously targets both innate and adaptive immune pathways for a potentially better efficacy for the treatment of SLE.

- TST008 is currently at preclinical stage.

Cautionary Statement required by Rule 18A.08(3) of the Listing Rules: The Company cannot guarantee that it will be able to develop, or ultimately market, any of the above drug candidates successfully. Shareholders and potential investors of the Company are advised to exercise due care when dealing in the shares of the Company.

Research and Early Development Efforts

We are dedicated to the discovery and development of differentiated and competitive biologics. Our proprietary antibody discovery platform, Immune Tolerance Breaking (IMTB) technology platform, enables us to generate antibodies with diverse epitopes. With the platform, we have a greater probability of producing mAbs, including those that cannot be generated by other platforms. Our Research and CMC teams have also established and optimized several bispecific antibody platforms with plug-and-play potentials to provide solutions to target disease biology complexity and address unmet patient needs.

We take a risk-balanced approach in our R&D efforts, aiming to shape an innovative and risk-balanced drug pipeline covering both oncology and non-oncology disease areas, and such efforts bore fruits in the past year. In 2021, we initiated two IND-enabling programs (TST003 in oncology and TST004 in kidney diseases); advanced a new pre-clinical candidate TST010 to IND-enabling studies in our oncology pipeline, with a MOA of Treg cell depletion to target CPI resistance; and launched several new targets in our early research and discovery pipeline. These targeted programs could provide additional treatment options for gastrointestinal cancer and lung cancer with either monoclonal antibody modality and/or antibody-drug conjugate modality.

Strategic Partnership to Advance Pipeline

Partnerships and collaborations play an important role in maximizing the clinical and commercial potential of our assets.

Our existing partnerships include a co-development and commercialization agreement with Eli Lilly for TST002 in Greater China, a joint-venture with Alebund Pharmaceuticals for TST004, and multiple research collaborations with prominent academic institutions around the world. In addition, we have a technology collaboration with Merck KGaA to increase operational efficiency and productivity of our downstream process.

By leveraging our advantage in owning the global rights of our assets and generating clinical data from studies inside and outside of China, we made significant progress in advancing partnership discussions for some of our key products. These include clinical and/or commercial partnership opportunities with multinational pharmaceutical companies.

Details of our existing partnerships are shown below.

TST002

We entered into a license agreement with Eli Lilly to in-license LY-2541546 (Blosozumab), LY-3108653 and LY-2950913 (each a "**Licensed Compound**") for an exclusive, royalty bearing license for the development, use or commercialization and manufacturing Licensed Compound in Greater China regions including the PRC, Hong Kong, Macau and Taiwan in March 2019.

We successfully completed technology transfer, established manufacturing process for Blosozumab (internal project code TST002) in our own manufacturing facility, and completed GMP production for clinical use and all the additional preclinical studies as required by the CDE for TST002 IND application in China. We received IND Clearance from NMPA on September 22, 2021. Currently, the TST002 phase I study was approved by the IRB of the leading study site.

TST004

We entered into a collaboration and licensing agreement with Shanghai Alebund Pharmaceuticals Limited ("**Alebund Pharmaceuticals**"), pursuant to which we and Alebund Pharmaceuticals will establish a joint venture to carry out pre-clinical research and conduct clinical trials regarding TST004 in Greater China region in December 2020.

Currently, we have completed GMP material productions and in vitro/in vivo product characterization studies, as well as non-GLP tox studies. GLP tox studies and pharmacology studies are currently ongoing.

Translational Research Collaborations

We also entered multiple research collaborations with prominent academic institutions around world, including the Dana-Farber Cancer Institute of Harvard Medical School, Beijing Cancer Hospital, Shanghai Pulmonary Hospital and Jiaotong University.

Technology Partnership

To significantly increase operational efficiency and productivity of our downstream process, we entered into a multi-year technology collaborative agreement with Merck (June 29, 2020), one of the leading technology providers in the biotech industry, to co-develop an automated single-use continuous downstream technology in June 2020. Upon integration of our highly productive continuous perfusion platform with this novel downstream technology, it will debottleneck GMP manufacturing, maximize facility output and further reduce cost of goods, and allow us to establish global leadership position in biomanufacturing platform for protein therapeutics.

Upgrade Manufacturing Technology and Expand Capacity

Our modular GMP facility offers high flexibility and scalability, and our proprietary integrated continuous bioprocessing platform allows us to maximize facility output while lowering the cost of goods by up to 50%. It does not only help us to better address the pricing pressure but also accelerates drug development and future commercialization of complex biologics.

We have scaled up manufacturing capacity to address near-term increase in production demand, and achieved breakthrough progress on integrated continuous bioprocessing technology to increase productivity by >10-fold when compared to conventional fed-batch process. We have further improved cost efficiency through locally sourcing critical materials and key equipment in manufacturing.

- ***Capacity Expansion***

  In anticipation of near-term increase in production demand, we have expanded GMP fill and finish (F/F) line to increase output. Our Hangzhou facility now has the capacity to support the potential commercial launch of our lead assets such as TST001.

- ***Upgrading Technology Platform***

  Our novel biomanufacturing platform called Integrated Continuous Bioprocessing (ICB) maximizes facility output and significantly lowers cost of goods. ICB leverages the power of ultra-high cell density continuous perfusion process and our proprietary cell culture media to integrate with automated and intensified continuous downstream technology that we are co-developing with Merck. In addition, the smaller scale operations of ICB eliminates the need for risky large commercial process scale up.

In 2021, we achieved significant progress in ICB platform development and implementation:

- Demonstrated industry-leading volumetric productivity of over 6 g/L-day, corresponding to over 15-fold increase in productivity when compared to same cell line in conventional fed-batch process.

- Implemented a continuous upstream perfusion process into GMP manufacturing for TST005, TST001 and TST003.

- Completed design and fabrication of industry's first automated flow-through polishing continuous downstream equipment and single-use flexware that we are co-developing with Merck.

- ***Cost Saving Through Localization***

  We are further evaluating options for raw materials sourcing in order to reduce our cost of goods. In 2021, we initiated efforts in localization of critical materials and key equipment in manufacturing and made significant progress in cost savings.

- ***CDMO Services***

  Leveraging our state-of-the-art manufacturing platform, we provided CDMO services to our customers and generated revenue to support R&D expenditures. We had 17 independent third-party customers during the year ended December 31, 2021. The services we provide mainly include process development, GMP/cGMP production, cell line development, sample detection, formulation optimization, and drug developability evaluation. Our services have led to four IND approvals in 2021 for our customers, including two in China and two in the United States.

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

COVID-19 has not resulted in material negative impacts on our business operations or financial performance during the year ended December 31, 2021. The Company, following government mandates, has encountered some difficulty in the supply of raw materials and clinical samples and managed to complete all the work with no impact to the clinical and regulatory timeline. This is partly made possible by ongoing efforts to localize high-risk materials, consumables and equipment used in product manufacturing early on. The management of the Company currently does not foresee significant disruption in the ongoing trials or delays in the initiation of new clinical trials due to COVID-19 going forward. We are committed to minimizing the impact and continue to execute on our business goals globally despite the uncertainty of the pandemic.

EVENTS AFTER THE REPORTING PERIOD

Pipeline Programs:

- IND application for a registration enabling global trial of TST001 for gastric cancer was filed and accepted by NMPA in Q1, 2022.

- First patient was enrolled and dosed in January 2022 in an Investigator Initiated TST001 Phase II trial in biliary tract cancer at the Fudan Zhongshan Hospital.

- TST001 U.S. Phase I trial abstract was presented as a Trial in Progress poster at the 2022 American Society of Clinical Oncology Gastrointestinal Cancers Symposium from January 20 to January 22, 2022 in San Francisco, CA. In the dose escalation phase, patients without preselection of tumor Claudin 18.2 expression were given increasing doses of TST001 intravenously every two weeks (Q2W) or three weeks (Q3W) using a 3+3 design. TST001 single agent will be further evaluated for the safety and efficacy in the expansion cohorts of patients with gastric cancer or pancreatic cancer/biliary tract cancer with Claudin 18.2 over-expression. TST001 in combination with nivolumab will also be further investigated in gastric cancer patient.

- First patient was enrolled and dosed in February 2022 in a Phase Ib/IIa trial of TST001 in combination with chemotherapy in first-line biliary tract cancer.

- We presented a poster of the TST001 China Phase I trial dose-escalation part data at the International Gastric Cancer Congress 2022 from March 6 to March 9, 2022 in Houston, TX. In the dose escalation phase, patients without preselection of tumor Claudin 18.2 expression were given increasing doses of TST001 intravenously every three weeks (Q3W) using a 3+3 design. As of November 23, 2021, 11 patients had been treated at the dose levels of 3, 6, and 10 mg/kg Q3W, respectively. Nine patients were dose limiting toxicities (DLT) evaluable with no DLT reported and maximum tolerated dose (MTD) has not been reached. TST001 demonstrated a manageable and tolerable safety profile in patients with advanced solid tumors and preliminary anti-tumor activity in heavily pretreated gastric and pancreatic cancer patients expressing Claudin 18.2.

- Completed TST001 data package and regulatory documentation in support of late phase manufacturing process change; amendment was filed to CDE in January 2022.

- TST002 Phase I study was approved by the Human Genetic Resources Administration of China (HGRAC) in January 2022.

- Initiated TST010 IND-enabling studies and CMC process development in January 2022.

Technology Advancement:

- Completed site acceptance test and IQ/OQ of industry's first automated flow-through polishing continuous downstream equipment at T-BLOC.

Save as disclosed above, the Group has had no material event since the end of the Reporting Period and up to the date of this announcement.

FUTURE OUTLOOK

2022 is set to be a transformational year for us. We expect to begin our first global registration trial for TST001 and achieve strong progress across our pipeline and business operations. A detailed breakdown of expected developments for the rest of 2022 is as follows:

Clinical Developments

TST001 (Claudin 18.2):

- Plan to initiate a global registration trial in Claudin 18.2 over-expressing gastric cancers in the second half of 2022, pending IND approval.

- Further advance multiple Phase Ib/IIa trials as monotherapy and combination therapy in multiple tumor types including gastric cancer, pancreatic and biliary tract cancer, and expect to obtain interim results from these trial in 2022.

- Initiate phase Ib/IIa trials of TST001 in combination with PD1 inhibitor in both first-line and late-line gastric cancer.

- Anticipate positive responses from the NMPA and FDA for TST001 process change and start BLA filing enabling CMC work.

TST005 (PD-L1/TGF-β bispecific): Complete TST005 Phase Ia dose escalation in the United States and China by year end.

TST002: Initiate Phase I study in osteoporosis patients.

TST004: File IND for TST004 with subcutaneous formulation, a potential novel treatment option for Thrombotic microangiopathy (TMA) and IgA nephropathy.

TST003: File IND in the United States and China and plan to initiate clinical study.

TST010: Initiate IND-enabling study for TST010, a novel agent for enhancing immune checkpoint therapy by depleting Tregs.

Potential Partnerships

- We are having continuing discussions with potential partners to maximize the value of our assets and generate additional cash flow. In the near-term, we will focus on establishing partnerships for TST001, TST002, and TST004.

- We will continue to identify, evaluate and build new technology platforms that can expand our existing antibody discovery capabilities through external collaboration and partnership.

Manufacturing Developments

- The industry's first automated flow-through polishing continuous downstream technology co-developed with Merck will be fully qualified and put into GMP operation.

- We will continue to develop our CDMO business to fully utilize our manufacturing capacities and to generate income to offset our R&D expenditures.

Outlook beyond 2022

The next three to five years will be an inflection point for us. We aim to launch our first product within this timeframe and rapidly advance our pipeline molecules. In addition, we aim to expand our pipeline by having one new drug candidate entering clinical trials each year.

We will continue to develop and implement cutting-edge technology to maximize productivity and lower cost of goods to ensure we maintain a healthy margin.

We will continue to explore partnerships to expedite the global development and commercialization of our drug candidates.

We believe that focusing on these aspects of our business will allow us to unlock the full potential of our portfolio and drive long-term value creation as we strive towards our vision of employing cutting-edge technology to help patients with differentiated and competitive biologics.

FINANCIAL REVIEW

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

	Year ended December 31,	
	2021	2020
	RMB'000	*RMB'000*
Revenue	**50,242**	80,980
Cost of sales	**(40,874)**	(62,778)
Gross profit	**9,368**	18,202
Other income	**32,906**	11,944
Other gains and losses, net	**(1,199,972)**	26,745
Research and development expenses	**(344,370)**	(200,312)
Selling and Administrative expenses	**(145,215)**	(157,949)
Listing expenses	**(48,605)**	(5,570)
Impairment losses under expected credit loss model	**(1,641)**	–
Share of loss of a joint venture	**(2,952)**	–
Finance costs	**(15,167)**	(16,070)
Loss before tax	**(1,715,648)**	(323,010)
Income tax credit	**105**	110
Loss for the year	**(1,715,543)**	(322,900)
Other comprehensive income for the year		
Item that may be reclassified subsequently to profit or loss:		
Exchange differences arising on translation of a foreign operation	**1,751**	3,359
Loss and total comprehensive expenses for the year	**(1,713,792)**	(319,541)
Non-IFRS measure[*(Note)*]**:**		
Add: Adjusted for share-based compensation expenses and fair value (loss)/gain of financial liabilities at FVTPL	**1,228,751**	73,943
Adjusted loss and total comprehensive expenses for the year	**(485,041)**	(245,598)

Note: See section below headed "FINANCIAL INFORMATION - Non-IFRS Measure" for the details of the non-IFRS measure adjustments.

Selected Data from Statement of Financial Position

	At December 31,	
	2021	2020
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Non-current assets	**1,149,353**	1,199,467
Current assets	**1,395,602**	891,457
Total assets	**2,544,955**	2,090,924
Current liabilities	**425,810**	194,537
Non-current liabilities	**153,576**	2,712,632
Total liabilities	**579,386**	2,907,169
Net current assets	**969,792**	696,920

1. Revenue

For the year ended December 31, 2021, the Group generated revenue from (i) provision of CDMO services; and (ii) research and development services. The following table sets forth the components of the revenue from contracts with customers for the year indicated.

	Year ended December 31,	
	2021	2020
	RMB'000	*RMB'000*
CDMO services	**44,200**	80,980
Research and development services	**6,042**	–
	50,242	80,980

2. Other Income

Other income consists of bank interest income, promissory note interest income and government grants. Government grants represent 1) various subsidies granted by the PRC local government authorities to our subsidiaries as incentives for our research and development activities, which are recognized when payments were received; and 2) amortisation of subsidies received from the PRC local government authorities to subsidize the purchase of the Group's property, plant and equipment.

For the year ended December 31, 2021, other income of our Group increased by RMB21.0 million, from RMB11.9 million for the year ended December 31, 2020. The increase was primarily due to an increase of government grants we recognized during the year ended December 31, 2021.

3. Other Gains and Losses, Net

Other net gains and losses changed from a gain of RMB26.7 million for the year ended December 31, 2020 to losses of RMB1,200 million for the year ended December 31, 2021. The changes were primarily due to losses in fair value of financial liabilities at fair value through profit or loss from the preferred shares issued by the Company.

4. Research and Development Expenses

Research and development expenses primarily consist of pre-clinical expenses including testing fee and pre-clinical trial expenses, staff cost for our research and development personnel, clinical expenses including testing fee and clinical trial expenses, materials consumed for research and development of our drug candidates, depreciation and amortization expenses and others.

The research and development expenses increased by RMB144.1 million from RMB200.3 million for the year ended December 31, 2020 to RMB344.4 million for the year ended December 31, 2021, primarily due to 1) the increase in pre-clinical expenses and clinical expenses with the progress of research and development activities of our pipelines; and 2) the increase in staff costs accompanied with the expansion of our research and development department.

The following table sets forth the components of the Group's research and development expenses for the year indicated.

	Year ended December 31,	
	2021	2020
	RMB'000	*RMB'000*
Clinical expenses	**134,654**	78,701
Staff cost	**94,326**	87,892
Materials consumed	**64,460**	13,982
Depreciation and amortization expenses	**29,488**	14,977
Others	**21,442**	4,760
Total	**344,370**	200,312

5. Selling and Administrative Expenses

The selling and administrative expenses decreased by RMB12.7 million from RMB157.9 million for the year ended December 31, 2020 to RMB145.2 million for the year ended December 31, 2021, primarily attributable to the decrease of share-based payment expenses.

Our selling expenses primarily consist of personnel cost, travel, depreciation and amortization and others. Our administrative expenses consist primarily of salaries and related benefits costs for our administrative personnel, professional fees for services provided by professional institutions, depreciation and amortization expenses, office expenses for our daily operation, traveling and transportation expenses, and others.

The following table sets forth the components of the Group's selling and administrative expenses for the year indicated.

	Year ended December 31,	
	2021	2020
	RMB'000	*RMB'000*
Salaries and related benefits costs	**87,754**	116,492
Professional fees	**17,902**	13,926
Depreciation and amortization expenses	**16,290**	15,234
Office expenses	**13,888**	5,799
Traveling and transportation expenses	**3,734**	1,887
Others	**5,647**	4,611
	145,215	157,949

6. Trade and Other Receivables

	At December 31,	
	2021	2020
	RMB'000	*RMB'000*
Trade receivables	**2,565**	16,351
Less: Allowance for credit losses	**–**	–
	2,565	16,351
Other receivables:		
Promissory note receivables *(note)*	**8,465**	10,085
Interest receivable	**–**	231
Prepayments for:		
Research and development services	**24,207**	6,106
Legal and professional services	**1,063**	1,034
Purchase of raw materials	**3,356**	5,021
Deferred issue costs	**–**	1,764
Refundable rental deposits	**1,316**	587
Others	**3,724**	541
	44,696	41,720

The trade and other receivables increased by RMB3.0 million from RMB41.7 million as of December 31, 2020 to RMB44.7 million as of December 31, 2021, primarily due to the increase of payments in research and development services with the progress of our pipeline development.

7. Trade and Other Payables

	At December 31,	
	2021	2020
	RMB'000	*RMB'000*
Trade payables	**31,430**	34,448
Other payables:		
Purchase of property, plant and equipment	**2,856**	10,892
Transaction cost for issuance of Preferred Shares	**–**	7,019
Legal and professional fee	**3,435**	6,551
Listing expenses and issue costs	**–**	4,946
Others	**3,440**	1,635
Interest payables	**462**	–
Other tax payables	**949**	5,165
Accrued research and development expenses	**36,100**	–
Accrued staff costs and benefits	**22,389**	15,853
Other accruals	**903**	2,181
	101,964	88,690

The trade and other payable increased by RMB13.3 million from RMB88.7 million as of December 31, 2020 to RMB102.0 million as of December 31, 2021, primarily due to the increase of payable for research and development services with the progress of our pipeline development.

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE YEAR ENDED DECEMBER 31, 2021

	NOTES	Year ended December 31, 2021 RMB'000 (Audited)	2020 RMB'000 (Audited)
Revenue	3	**50,242**	80,980
Cost of sales		**(40,874)**	(62,778)
Gross profit		**9,368**	18,202
Other income		**32,906**	11,944
Other gains and losses, net	4	**(1,199,972)**	26,745
Research and development expenses		**(344,370)**	(200,312)
Selling and administrative expenses		**(145,215)**	(157,949)
Listing expenses		**(48,605)**	(5,570)
Impairment losses under expected credit loss model		**(1,641)**	–
Share of loss of a joint venture		**(2,952)**	–
Finance costs		**(15,167)**	(16,070)
Loss before tax		**(1,715,648)**	(323,010)
Income tax credit	5	**105**	110
Loss for the year		**(1,715,543)**	(322,900)
Other comprehensive income for the year			
Item that may be reclassified subsequently to profit or loss:			
Exchange differences arising on translation of a foreign operation		**1,751**	3,359
		(1,713,792)	(319,541)
Loss for the year attributable to:			
– Owners of the Company		**(1,715,543)**	(316,626)
– Non-controlling interests		**–**	(6,274)
		(1,715,543)	(322,900)
Total comprehensive expenses for the year attributable to:			
– Owners of the Company		**(1,713,792)**	(313,267)
– Non-controlling interests		**–**	(6,274)
		(1,713,792)	(319,541)
Loss per share			
– Basic and diluted (RMB)	6	**(9.34)**	(4.53)

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

AS AT DECEMBER 31, 2021

	NOTES	As at December 31, **2021**	2020
		RMB'000	*RMB'000*
		(Audited)	(Audited)
Non-current assets			
Property, plant and equipment		**435,103**	449,176
Intangible assets		**96,135**	95,781
Right-of-use assets		**38,057**	24,057
Goodwill		**471,901**	471,901
Interests in a joint venture		**24,364**	–
Value-added-tax ("VAT") recoverable		**64,647**	62,954
Deposits paid for acquisition of property, plant and equipment		**11,719**	2,169
Other receivables	*7*	**1,316**	10,085
Amounts due from related parties		**–**	77,250
Restricted bank deposits		**6,111**	6,094
		1,149,353	1,199,467
Current assets			
Inventories		**20,792**	7,901
Trade and other receivables	*7*	**43,380**	31,635
Contract costs		**33,275**	38,329
Amounts due from related parties		**76,129**	–
Bank balances and cash		**1,222,026**	813,592
		1,395,602	891,457
Current liabilities			
Trade and other payables	*8*	**101,964**	88,690
Amount due to a director		**268**	–
Contract liabilities		**35,967**	7,029
Bank borrowings		**273,339**	91,312
Lease liabilities		**6,272**	7,506
Deferred income		**8,000**	–
		425,810	194,537
Net current assets		**969,792**	696,920
Total assets less current liabilities		**2,119,145**	1,896,387

	As at December 31,	
	2021	2020
	RMB'000	*RMB'000*
	(Audited)	(Audited)
Non-current liabilities		
Bank borrowings	**77,390**	145,938
Lease liabilities	**7,710**	9,543
Deferred income	**42,868**	57,200
Financial liabilities at fair value through profit or loss ("FVTPL")	**–**	2,474,233
Deferred tax liabilities	**25,608**	25,718
	153,576	2,712,632
Net assets (liabilities)	**1,965,569**	(816,245)
Capital and reserves		
Share capital	**291**	66
Treasury shares	**(7)**	–
Reserves	**1,965,285**	(816,311)
Total equity (deficits)	**1,965,569**	(816,245)

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1. GENERAL INFORMATION

The Company was incorporated in the British Virgin Islands as an exempted company with limited liability on 20 August 2010, and re-domiciled to the Cayman Islands on 26 March 2021 as an exempted company with limited liability under the laws of Cayman Islands. On 29 September 2021, the Company's shares became listed on the Main Board of the Stock Exchange of Hong Kong Limited. The respective address of the registered office and the principal place of business of the Company are set out in the section headed "Corporate Information" section to the annual report.

The Company is an investment holding company. The Company and its subsidiaries (collectively referred to as the "Group") is an integrated biopharma platform that brings drug candidates from the discovery stage to the commercial stage, spanning discovery, research, development, manufacturing and commercialization.

The functional currency of the Company is RMB, which is the same as the presentation currency of the consolidated financial statements.

2. APPLICATION OF AMENDMENTS TO IFRSs

The Group has applied the following amendments to International Financial Reporting Standards ("IFRSs") issued by the International Accounting Standards Board ("IASB"), which are mandatorily effective for the annual periods beginning on or after 1 January 2021 for the preparation of the consolidated financial statements:

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

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

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 30 June 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 Estimates[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 HKFRSs 2018-2020[2]

[1] Effective for annual periods beginning on or after 1 April 2021.
[2] Effective for annual periods beginning on or after 1 January 2022.
[3] Effective for annual periods beginning on or after 1 January 2023.
[4] Effective for annual periods beginning on or after a date to be determined.

Except disclosed below, the directors of the Company anticipate that the application of these new and amendments to IFRSs will have no material impact on the Group's consolidated financial statements in the foreseeable future.

Amendments to IAS 12 Deferred Tax related to Assets and Liabilities arising from a Single Transaction

The amendments narrow the scope of the recognition exemption of deferred tax liabilities and deferred tax assets in paragraphs 15 and 24 of IAS 12 Income Taxes so that it no longer applies to transactions that, on initial recognition, give rise to equal taxable and deductible temporary differences.

As disclosed in the consolidated financial statements, for leasing transactions in which the tax deductions are attributable to the lease liabilities, the Group applies IAS 12 requirements to the relevant assets and liabilities as a whole. Temporary differences relating to relevant assets and liabilities are assessed on a net basis.

Upon the application of the amendments, the Group will recognise a deferred tax asset (to the extent that it is probable that taxable profit will be available against which the deductible temporary difference can be utilised) and a deferred tax liability for all deductible and taxable temporary differences associated with the right-of-use assets and the lease liabilities.

The amendments are effective for annual reporting periods beginning on or after 1 January 2023, with early application permitted. As at 31 December 2021, the carrying amounts of right-of-use assets and lease liabilities which are subject to the amendments amounted to RMB13,141,000 and RMB13,982,000, respectively. The Group is still in the process of assessing the full impact of the application of the amendments. The cumulative effect of initially applying the amendments will be recognised as an adjustment to the opening balance of accumulated losses (or other component of equity, as appropriate) at the beginning of the earliest comparative period presented.

3. REVENUE

The Group has two revenue streams. It provides contract development and manufacturing ("CDMO") services to its customers. It also provides contract research services to one customer.

The Group primarily earns revenues by providing CDMO and research services to its customer through fee-for-service ("FFS") contracts. Contract duration is generally a few months. Under FFS method, the contracts usually have multiple deliverable units, which are generally in the form of technical laboratory reports and/or samples, each with individual selling price specified within the contract. The Group identifies each deliverable unit as a separate performance obligation, and recognizes FFS revenue of contractual elements at the point in time upon finalization, delivery and acceptance of the deliverable units.

	Year ended 31 December	
	2021	2020
	RMB'000	*RMB'000*
CDMO services	**44,200**	80,980
R&D service	**6,042**	–
	50,242	80,980

Segment Information

Operating segments are identified on the basis of internal reports about components' of the Group that are regularly reviewed by the chief operating decision maker ("CODM"), which is also identified as the chief executive officer of the Group, in order to allocate resources to segments and to assess their performance. During the year, the CODM assesses the operating performance and allocated the resources of the Group as a whole as the Group is primarily engaged in the discovering, developing, manufacturing and commercializing novel drugs. Therefore, the CODM considers the Group only has one operating segment.

The CODM reviews the overall results and financial position of the Group as a whole prepared based on the same accounting policies and no further analysis of the single segment is presented.

Geographical information

The Group's operations are located in the PRC and the USA.

All the Group's revenue from external customers is derived from the PRC. As at 31 December 2021, non-current assets of RMB746,000 (2020: RMB8,089,000) are located in the USA. The remaining non-current assets are all located in the PRC.

4. OTHER GAINS AND LOSSES, NET

	Year ended 31 December	
	2021	2020
	RMB'000	*RMB'000*
Gain on deemed disposal of interests in a joint venture	**26,816**	–
Net foreign exchange loss	**(28,516)**	(1,623)
Fair value change of financial liabilities at FVTPL	**(1,198,173)**	37,926
Transaction costs for issuance of Preferred Shares	**–**	(9,560)
Loss on disposal of property, plant and equipment	**(37)**	(9)
Others	**(62)**	11
	(1,199,972)	26,745

5. INCOME TAX CREDIT

	Year ended 31 December	
	2021	2020
	RMB'000	*RMB'000*
Current tax:		
PRC Enterprise Income Tax	**(5)**	–
Deferred tax	**110**	110
	105	110

6. LOSS PER SHARE

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

	Year ended 31 December	
	2021	2020
	RMB'000	*RMB'000*
Loss for the year attributable to the owners of the Company for the purpose of calculating basic and diluted loss per share	**(1,715,543)**	(316,626)

Number of shares

	Year ended 31 December	
	2021	2020
Weighted average number of ordinary shares for the purpose of calculating basic and diluted loss per share	**183,599,740**	69,892,264

The weighted average number of shares for the year shown above has been arrived after deducting shares held on trust and treasury shares.

Diluted loss per share is calculated by adjusting weighted average number of ordinary shares outstanding assuming conversion of all dilutive ordinary shares. The computation of diluted loss per share did not assume the exercise of share options and over-allotment option before expiration (2020: exercise of share options and conversion of the Preferred Shares) since their assumed exercise (2020: exercise or conversion) would result in a decrease in loss per share.

7. TRADE AND OTHER RECEIVABLES

The following is an aged analysis of trade receivable presented based on the date of completion of service at the end of each reporting period:

	At 31 December	
	2021	2020
	RMB'000	*RMB'000*
Within 30 days	**2,565**	13,501
31 – 60 days	**–**	10
61 – 90 days	**–**	901
91 – 120 days	**–**	9
121 – 365 days	**–**	1,930
	2,565	16,351

8. TRADE AND OTHER PAYABLES

The following is an aged analysis of trade payables, presented based on earlier of the date of goods and services received and the invoice dates at the end of each reporting period:

	At 31 December	
	2021	2020
	RMB'000	*RMB'000*
0 – 30 days	**20,531**	23,458
31 – 60 days	**2,262**	–
61 – 90 days	**8,460**	24
91 – 120 days	**–**	2
121 – 365 days	**131**	10,552
Over 365 days	**46**	412
	31,430	34,448

9. DIVIDEND

No dividend was paid or declared by the Company for ordinary shareholders of the Company during 2021 or 2020, nor has any dividend been proposed since the end of the reporting period.

Listing Expenses

Our listing expenses was RMB5.6 million for the year ended December 31, 2020 and RMB48.6 million for the year ended December 31, 2021 with the progress of our initial public offering.

Other Comprehensive Income

Our other comprehensive income decreased from RMB3.4 million for year ended December 31, 2020 to RMB1.8 million for year ended December 31, 2021.

Non-IFRS Measure

To supplement the Group's consolidated financial statements, which are presented in accordance with the IFRS, the Company also uses adjusted loss and total comprehensive expenses for the year and other adjusted figures as additional financial measures, which are not required by, or presented in accordance with, 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 year to year and company to company to the extent applicable.

Adjusted loss and total comprehensive expenses for the year represents the loss and total comprehensive expenses for the year excluding the effect of certain non-cash item, namely fair value change on financial liabilities at FVTPL and share-based compensation expenses. The table below sets forth a reconciliation of the loss and total comprehensive expenses for the year to adjusted loss and total comprehensive expenses for the year during the years indicated:

	Year ended December 31,	
	2021	2020
	RMB'000	*RMB'000*
Total comprehensive expenses for the year:	**(1,713,792)**	(319,541)
Add:		
Share-based compensation expenses	**30,578**	111,869
Fair value (loss)/gain of financial liabilities at FVTPL	**1,198,173**	(37,926)
Sub-total	**1,228,751**	73,943
Adjusted loss and total comprehensive expenses for the year	**(485,041)**	(245,598)

Employees and Remuneration

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

	Number of employees	% of total number of employees
Research and Development	186	51
General and Administrative	62	17
Manufacturing	115	32
	363	100.0

The Group believes in the importance of attraction, recruitment and retention of quality employees in achieving the Group's success. Our success depends on our ability to attract, retain and motivate qualified personnel. The number of employees employed by the Group varies from time to time depending on our needs. Employees' remuneration is determined in accordance with prevailing industry practice and employees' educational background, experience and performance. The remuneration policy and package of the Group's employees are periodically reviewed.

Our employees' remuneration comprises salaries, bonuses, 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.

The Company also has adopted the "Post-IPO Share Award Scheme" and "Pre-IPO Equity Incentive Plan". Please refer to the section headed "Appendix IV Statutory and General Information – D. Share Schemes" in the Prospectus for further details.

During the Reporting Period, the Group did not experience any significant labour disputes or any difficulty in recruiting employees.

Liquidity and Financial Resources

On September 29, 2021, 40,330,000 ordinary shares of US$0.0001 par value each were issued at HK$16.00 per share for a total gross cash consideration of HK$645,280,000 (equivalent to RMB536,034,000).

As of December 31, 2021, bank balances and cash were RMB1,222.0 million, as compared to RMB813.6 million as of December 31, 2020. The increase was mainly due to issuance of ordinary shares.

Gearing Ratio

The gearing ratio of the Group was calculated using interest-bearing borrowings less cash and cash equivalents divided by (deficiency of) total equity and multiplied by 100%. Since the Group maintained a net cash position as at December 31, 2021 and December 31, 2020, the gearing ratio is not applicable.

Other Financial Information

Significant Investments, Material Acquisitions and Disposals

The Group did not make any significant investments (including any investment in an investee company with a value of 5 percent or more of the Group's total assets as at December 31, 2021) during the year ended December 31, 2021. The Group did not have any material acquisitions or disposals of subsidiaries, associated companies or joint ventures for the year ended December 31, 2021.

Foreign Exchange Risk

The functional currency of the Company is Renminbi. During the year ended December 31, 2021, certain bank balances and cash, trade and other receivables, amounts due from related parties and trade and other payables are denominated in U.S. dollars, which are exposed to foreign currency risk. The Group currently does not have a foreign currency hedging policy. However, the management monitors foreign exchange exposure and will consider hedging significant foreign currency exposure should the need arise.

Bank Loans and Other Borrowings

As at December 31, 2021, bank borrowings amounting to RMB105,769,000 (2020: RMB142,250,000), are secured by property, plant and equipment with carrying amount of RMB124,841,000 (2020: RMB140,287,000).

The Group's borrowings that are denominated in currencies other the functional currencies of the relevant group entities are set out below:

	Year ended December 31,	
	2021	2020
	RMB'000	*RMB'000*
US$	**–**	26,099

Contingent Liabilities

As at December 31, 2021, we did not have any material contingent liabilities.

ANNUAL GENERAL MEETING

The annual general meeting is scheduled to be held on Friday, June 10, 2022 (the **"AGM**"). A notice convening the AGM will be published and dispatched to the shareholders of the Company (the "**Shareholders**") in the manner required by the Listing Rules in due course.

CLOSURE OF THE REGISTER OF MEMBERS

The register of members of the Company will be closed from Tuesday, June 7, 2022 to Friday, June 10, 2022, both days inclusive, in order to determine the identity of the Shareholders who are entitled to attend and vote at the AGM, during which period no share transfers will be registered. To be eligible to attend and vote at the AGM, unregistered holders of shares must lodge all properly completed transfer forms accompanied by the relevant share certificates with the Company's branch share registrar in Hong Kong, Tricor Investor Services Limited, at Level 54, Hopewell Centre, 183 Queen's Road East, Hong Kong for registration not later than 4:30 p.m. on Monday, June 6, 2022.

CORPORATE GOVERNANCE AND OTHER INFORMATION

The Company was incorporated under the laws of the British Virgin Islands on August 20, 2010 and continued in the Cayman Islands on March 26, 2021 as an exempted company with limited liability, and the Shares of the Company were listed on the Main Board of the Stock Exchange on September 29, 2021 (the "**Listing Date**").

The Company is committed to maintaining and promoting stringent corporate governance. The principle of the Company's corporate governance is to promote effective internal control measures and to enhance the transparency and accountability of the Board to all Shareholders.

The Company has adopted the principles and code provisions set out in the Corporate Governance Code contained in Appendix 14 to the Listing Rules (the "**CG Code**") as the basis of the Company's corporate governance practices, and the CG Code has been applicable to the Company with effect from the Listing Date.

Compliance with the Corporate Governance Code

The Board is committed to achieving high corporate governance standards. The Board believes that high corporate governance standards are essential in providing a framework for the Group to safeguard the interests of Shareholders and to enhance corporate value and accountability.

During the year ended December 31, 2021, the Company has complied with all applicable code provisions set out in the CG Code except for the following deviation.

Code provision E.1.5 of the CG Code provides that an issuer should have a policy on the payment of dividends and should disclose such policy in the annual report. As the Company was in a loss-making position as at December 31, 2021, it had not implemented such policy for the year ended December 31, 2021. The Company has adopted a dividend policy effective as of March 22, 2021.

Further information concerning the corporate governance practices of the Company will be set out in the corporate governance report in the annual report of the Company for the year ended December 31, 2021.

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.

Compliance with the Model Code for Securities Transactions by Directors of Listed Issuers

The Company has adopted the Model Code for Securities Transactions by Directors of Listed Issuers (the "**Model Code**") as set out in Appendix 10 to the Listing Rules as its own securities dealing code to regulate all dealings by Directors and relevant employees in securities of the Company and other matters covered by the Model Code.

The provisions under the Listing Rules in relation to compliance with the Model Code by the Directors regarding securities transactions have been applicable to the Company since the Listing Date. Having made specific enquiry, all Directors have confirmed that they have complied with the Model Code since the Listing Date and up to the date of this announcement.

No incident of non-compliance of the Model Code was noted by the Company since the Listing Date and up to the date of this announcement.

Purchase, Sale or Redemption of the Company's Listed Securities

Neither the Company nor any of its subsidiaries purchased, sold or redeemed any of the Company's securities listed on the Stock Exchange since the Listing Date and up to December 31, 2021.

Material Litigation

The Company was not involved in any material litigation or arbitration during the year ended December 31, 2021. The Directors are also not aware of any material litigation or claims that were pending or threatened against the Group during the year ended December 31, 2021.

Use of Net Proceeds

With the Shares of the Company listed on the Stock Exchange on September 29, 2021 and based on the Offer Price of HK$16.00 per Offer Share, the net proceeds from the Global Offering were approximately HK$553.4 million. There was no change in the intended use of net proceeds as previously disclosed in the Prospectus and the table below sets out the planned applications of the net proceeds and amount utilized as at December 31, 2021:

Use of Net Proceeds	**% of net proceeds (Approximately)**	**Net proceeds from the Global Offering**	**Amount utilized as at December 31, 2021**	**Unutilized net proceeds as at December 31, 2021**
		HK$ million	*HK$ million*	*HK$ million*
1. Research and development of our pipeline product candidates, funding of ongoing and planned clinical and pre-clinical trials, preparation for registration filings and other steps or activities related to the commercialization of our four anchor products as follows:	82%	453.8	–	453.8

Use of Net Proceeds	% of net proceeds (Approximately)	Net proceeds from the Global Offering	Amount utilized as at December 31, 2021	Unutilized net proceeds as at December 31, 2021
		HK$ million	*HK$ million*	*HK$ million*
(i) fund ongoing and planned clinical trials, preparation for registration filings and potential commercial launches (including sales and marketing) of our core product, MSB2311	30%	166.0	–	166.0
(ii) fund ongoing and planned clinical trials, preparation for registration filings and potential commercial launch (including sales and marketing) of our key product, TST001	20%	110.7	–	110.7
(iii) fund ongoing and planned clinical trials, preparation for registration filings and potential commercial launch (including sales and marketing) of our key product, TST005	10%	55.3	–	55.3
(iv) fund ongoing and planned clinical trials, preparation for registration filings and potential commercial launch (including sales and marketing) of our key product, TST002	10%	55.3	–	55.3
(v) fund ongoing and planned pre-clinical trials and preparation for registration filings of our key product and other pipeline products, including TST004, MSB0254, TST003, TST006 and TST008	12%	66.5	–	66.5
2. Fund the business development for pipeline expansion and technology development, with a focus in oncology assets that have synergy with our current pipeline and promising clinical evidences, and/or technology platforms that can complement our current discovery and development platforms, such as ADC, small molecule targeted therapies, and other advanced new technologies	8%	44.3	–	44.3
3. For general working capital purposes and general operation expenses	10%	55.3	–	55.3
Total	**100%**	**553.4**	**–**	**553.4**

For detailed description of the intended use of proceeds and the expected timeline, please refer to the section headed "Future plans and use of proceeds" in the Prospectus.

To the extent that the net proceeds of the Global Offering are not immediately required for the above purposes or if we are unable to put into effect any part of our development plan as intended, we will hold such funds in short-term deposits in authorized banks or financial institutions so long as it is deemed to be in the best interests of the Company. In such event, we will comply with the appropriate disclosure requirements under the Listing Rules.

As at the date of this announcement, the net proceeds from the Global Offering had not been utilized since the Listing Date.

Audit Committee

The Company has established an audit committee with written terms of reference in compliance with Rule 3.21 of the Listing Rules and the CG Code. The primary duties of the Audit Committee are to review and supervise the financial reporting process and internal controls system of our Group, review and approve connected transaction (if any) and provide advice and comments to the Board. The Audit Committee comprises three members, namely Mr. Jiasong Tang (唐稼松), Mr. Zhihua Zhang (張志華) and Dr. Yining (Jonathan) Zhao (趙奕寧), with Mr. Jiasong Tang (唐稼松) (being our independent non-executive Director with the appropriate professional qualifications) as chairperson of the Audit Committee.

The Audit Committee has reviewed the audited consolidated financial statements of the Group for the year ended December 31, 2021 and has met with the independent auditor, Deloitte Touche Tohmatsu. The Audit Committee has also discussed matters with respect to the accounting policies and practices adopted by the Company, internal control and financial reporting matters with senior management members of the Group. The Audit Committee considers that this announcement is in compliance with the relevant accounting standards, rules and regulations and appropriate disclosures have been duly made.

Other Board Committees

In addition to the audit committee, the Company has also established a nomination committee and a remuneration committee.

Scope of Work of 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 announcement have been agreed by the Group's auditor, Deloitte Touche Tohmatsu, to the amounts set out in the Group's audited consolidated financial statements for the year ended December 31, 2021. The work performed by 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 Deloitte Touche Tohmatsu on this announcement.

FINAL DIVIDEND

The Board does not recommend the distribution of a final dividend for the year ended December 31, 2021.

PUBLICATION OF THE ANNUAL RESULTS ANNOUNCEMENT AND ANNUAL REPORT

This annual results announcement is published on the websites of the Stock Exchange (**http://www.hkexnews.hk**) and the Company (**http://www.transcenta.com/**).

The annual report of the Group for the year ended December 31, 2021 will be dispatched to the Company's shareholders and published on the aforesaid websites of the Stock Exchange and the Company in due course.

APPRECIATION

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

By Order of the Board
Transcenta Holding Limited
Xueming Qian
Executive Director and
Chief Executive Officer

Hong Kong, March 21, 2022

As at the date of this announcement, the board of directors of the Company comprises Dr. Xueming Qian as executive Director and chief executive officer, Dr. Michael Ming Shi and Mr. Albert Da Zhu as executive Directors, Dr. Yining (Jonathan) Zhao as chairman and non-executive Director, and Mr. Jiasong Tang, Dr. Jun Bao and Mr. Zhihua Zhang as independent non-executive Directors.