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## 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)

### ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED DECEMBER 31, 2022 AND CHANGE IN USE OF PROCEEDS

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 (collectively, the “**Group**”) for the year ended December 31, 2022 (the “**Reporting Period**”), together with the comparative figures for the year ended December 31, 2021. The consolidated financial statements of the Group for the Reporting Period have been reviewed by the audit committee of the Company (the “**Audit Committee**”) and audited by the Company’s auditors, Deloitte Touche Tohmatsu (the “**Auditor**”).

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** increased from RMB50.2 million for the year ended December 31, 2021 to RMB101.9 million for the year ended December 31, 2022, primarily attributable to the increase in CDMO service.
- **Other income** increased by RMB13.5 million from RMB32.9 million for the year ended December 31, 2021 to RMB46.4 million for the year ended December 31, 2022, primarily due to interest income and government grants recognized during the year ended December 31, 2022.
- **Other gains and losses** increased by RMB1,229.7 million from a loss of RMB1,200 million for the year ended December 31, 2021 to a gain of RMB29.7 million for the year ended December 31, 2022, primarily due to the losses of fair value of financial liabilities at fair value through profit or loss from the preferred shares issued by the Company in 2021.

- **Research and development expenses** increased by RMB5.4 million from RMB344.4 million for the year ended December 31, 2021 to RMB349.8 million for the year ended December 31, 2022, primarily attributable to our pipeline advancement and resource prioritization.
- **Administrative and selling expenses** decreased by RMB32.8 million from RMB145.2 million for the year ended December 31, 2021 to RMB112.4 million for the year ended December 31, 2022, primarily attributable to the decrease in personnel cost and professional services.
- As a result of the above factors, **loss and total comprehensive expenses for the year** decreased by RMB1,296.1 million from RMB1,713.8 million for the year ended December 31, 2021 to RMB417.7 million for the year ended December 31, 2022, primarily attributable to the increase of CDMO service revenue in 2022 and the losses of financial liabilities at fair value through profit or loss from the preferred shares in 2021.

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

- **Revenue** increased from RMB50.2 million for the year ended December 31, 2021 to RMB101.9 million for the year ended December 31, 2022, primarily attributable to the increase in CDMO service.
- **Other income** increased by RMB13.5 million from RMB32.9 million for the year ended December 31, 2021 to RMB46.4 million for the year ended December 31, 2022, primarily due to interest income and government grants recognized during the year ended December 31, 2022.
- **Research and development expenses** excluding the share-based payment expenses decreased by RMB2.0 million from RMB342.5 million for the year ended December 31, 2021 to RMB340.5 million for the year ended December 31, 2022, primarily attributable to our pipeline advancement and resource prioritization.
- **Administrative and selling expenses** excluding the share-based payment expenses decreased by RMB11.6 million from RMB116.5 million for the year ended December 31, 2021 to RMB104.9 million for the year ended December 31, 2022, primarily attributable to the decrease in personnel cost and professional services.
- **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 decreased by RMB84.1 million from RMB485.0 million for the year ended December 31, 2021 to RMB400.9 million for the year ended December 31, 2022, primarily due to the increase of CDMO service revenue in 2022 and the losses of financial liabilities at fair value through profit or loss from the preferred shares in 2021.

## BUSINESS HIGHLIGHTS

### Summary

2022 was a productive year for the Company, several significant clinical and regulatory milestones have been achieved that broadened our product portfolio and advanced our pipeline. Our lead asset, the Claudin18.2-targeting antibody osemitamab (TST001), has delivered encouraging clinical efficacy with favorable safety profile in the ongoing Phase Ib chemotherapy combination trial and is now poised for a global Phase III pivotal trial for 1L unresectable locally advanced or metastatic gastric or gastroesophageal junction (G/GEJ) cancer. A proprietary Claudin18.2 companion diagnostic assay has also been developed to support the patient screening for pivotal trial. Pivotal trial material has been manufactured and cleared by regulatory agencies such as U.S. Food and Drug Administration (FDA) and Center for Drug Evaluation (CDE). As a biopharmaceutical company with highly integrated capability and global strategy, we are committed to developing osemitamab (TST001) as the cornerstone of the new treatment paradigm in Claudin18.2 expressing solid tumors including gastric or gastroesophageal junction (G/GEJ) cancer, pancreatic cancer (PDAC) and non-small cell lung cancer (NSCLC). In addition, we have made important progress for other pipeline programs. We completed four dose cohorts evaluation and opened the enrollment at the last and highest dose level cohort for the ongoing global Phase I dose escalation study for TST005. We also completed the enrollment of three dose cohorts, with encouraging bone mineral density (BMD) increasing activity observed for TST002. We received IND clearance for TST003 (anti-gremlin1 antibody) and TST004 (anti-MASP2 antibody). Our research group has also developed multiple novel therapeutic candidates for treating cancer and autoimmune disorders. During 2022, we have established a global clinical collaboration with Bristol Myers Squibb (“BMS”) to test the combination treatment of osemitamab (TST001) with Opdivo® (nivolumab) in Claudin18.2 positive 1L unresectable locally advanced or metastatic G/GEJ cancer. We have also received strong interests from MNC and other industry players for collaboration with our pipeline molecules such as osemitamab (TST001), TST002 and TST003. Among the manufacturing milestones we achieved, we have further advanced our continuous bioprocessing platform technology, completed late-stage process development and pivotal trial material production for both internal and external programs and generated significantly increased CDMO business revenue.

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

### Clinical Programs Achievements

#### ***Osemitamab (TST001) (A Humanized ADCC enhanced anti-Claudin18.2 mAb for Solid Tumors)***

- In June 2022, clinical data from our lead asset osemitamab (TST001) was presented at the ASCO annual meeting in Chicago. The clinical data for the dose-escalation part of the Phase I study of osemitamab (TST001) in combination with CAPOX as 1L treatment of advanced or metastatic G/GEJ cancer were presented, and tolerability and encouraging preliminary anti-tumor activities have been observed.
- In September 2022, we presented the interim efficacy data from osemitamab (TST001) in combination with chemotherapy at ESMO 2022 meeting. Of the 15 1L locally advanced or metastatic G/GEJ cancer evaluable patients with Claudin18.2 expression, 11 achieved partial response and 4 stable disease.

- In September 2022, we initiated the exploration of several combinations of osemitamab (TST001) with nivolumab in G/GEJ cancer in China: in 1L osemitamab (TST001) with nivolumab and CAPOX; in later lines, osemitamab (TST001) and nivolumab.
- In September 2022, we opened the enrollment of the combination of osemitamab (TST001) and nivolumab for 2L and later G/GEJ adenocarcinoma patients in the U.S.. In November, we added a cohort of osemitamab (TST001) combined with mFOLFOX6 plus nivolumab for 1L G/GEJ adenocarcinomas to the same protocol. Such data will lay the foundation for regulatory interactions with CDE, FDA and the European Medicines Agency (EMA) about our pivotal Phase III trial design.
- In November 2022, we presented the prevalence of Claudin18.2 and PD-L1 Expression in Chinese G/GEJ adenocarcinoma as a poster presentation at the 37th Society for Immunotherapy of Cancer's (SITC) Annual Meeting in Boston, MA, on November 8-12, 2022.

#### **CDx Progress for Osemitamab (TST001)**

- In 2022, we completed the optimization of the Claudin18.2 IHC assay and we are moving into the CDx kit production and ready to support the pivotal trial for osemitamab (TST001).

#### ***TST002 (Bloszumab) (A Humanized Sclerostin mAb for Osteoporosis)***

- In April 2022, the first patient was successfully dosed in China in the Phase I Study of TST002 for the treatment of osteoporosis, leveraging the phase II data generated by our partner, Eli Lilly.
- In December 2022, we completed evaluation of the third dose cohort, opened the fourth one and obtained encouraging BMD increasing activities for early dose cohorts.

#### ***TST003 (A First-in-Class Humanized Antibody Candidate)***

- In May 2022, in collaboration with researchers at Renji Hospital, Shanghai Jiao Tong University School of Medicine, we published in Nature Cancer the results of preclinical studies of TST003 for the treatment of androgen receptor low/negative castration resistant prostate cancer resistant/refractory to existing therapy.
- In September 2022, we received IND clearance from FDA for TST003.
- In November 2022, we presented preclinical data of TST003 at the 10th TEMTIA meeting in Paris, France.

***TST005 (A PD-L1/TGF- $\beta$  Bi-functional Antibody Candidate for Solid Tumors)***

- In April 2022, we presented TST005, a bifunctional fusion protein of PD-L1/TGF- $\beta$ , with potent anti-tumor activities and good safety profile as a poster presentation at the AACR annual meeting 2022.
- In November 2022, at SITC, we presented a Trial in Progress (TiP) scientific poster for the phase I, first in human, open-label, TST005 dose escalation and dose expansion study in patients with locally advanced or metastatic solid tumors.
- In December 2022, we completed four dose cohorts evaluation and opened the enrollment at the last and highest dose level cohort for this ongoing global phase I dose escalation study.

***TST004 (A Humanized MASP-2 mAb Candidate for Kidney Diseases including IgA nephropathy)***

- In October 2022, we received IND clearance from U.S. Food and Drug Administration (FDA) for TST004.

**Business Development Achievements**

***Osemitamab (TST001) (A Humanized ADCC enhanced anti-Claudin18.2 mAb for Solid Tumors)***

- On March 22, 2022, we entered a global clinical trial collaboration with BMS to evaluate the safety, tolerability and efficacy of the combination of osemitamab (TST001) with Opdivo<sup>®</sup> (nivolumab) for the treatment of patients with Claudin18.2 expressing unresectable locally advanced or metastatic G/GEJ cancer.

***TST003 (A First-in-Class Humanized Antibody Candidate)***

- In December 2022, we established a collaboration with a prominent research university in the U.S. on further evaluating the potential of Gremlin1 antibody for the treatment of castration-resistant prostate cancer (CRPC).

## **CMC&CDMO Updates**

***We have improved our Integrated Continuous Bioprocessing (“ICB”) platform and expanded our CMC capabilities. Our CMC capabilities has allowed us to support the development of our internal programs and generate income by providing CDMO service to external clients and partners.***

### ***Platform technology advancement***

- Our platform technology enables us to conduct both fed-batch and continuous bioprocess development and manufacturing for all protein therapeutics. We continues to invest in our ICB platform to increase our competitive edge which allows us to accelerate speed to clinic/market, lower manufacturing risks, ensure drug supply, and significantly lower cost of goods.
- We have continued to improve our upstream process and push the boundary of cell culture productivity. In 2022, we demonstrated industry-leading productivity of > 7 g/L per day in our continuous perfusion platform.
- Significant progresses have been made in intensifying downstream processing to support highly productive upstream processing. Specifically, in collaboration with Merck KGaA, we completed fabrication and testing of industry-first automated and single-use flow-through polishing continuous downstream technology, and acquired Mobius Multi-Column Chromatography system, another new technology from Merck KGaA in 2022. With both systems being fully operational, downstream processing shall no longer constrain the facility output in our highly efficient T-BLOC facility.
- Expanded DP fill & finish capability in support of internal and external programs.

### ***CMC deliverables and strong supports to internal program***

- ICB manufacturing has been implemented for both late-stage and early-stage internal programs. In 2022, we completed the development and optimization of osetitamab (TST001) perfusion-based late-stage manufacturing process and received permission to proceed from CDE and FDA for this process change from fed-batch to continuous perfusion. This process change increased productivity by > 8 folds at commercial production scale. In addition, we have applied perfusion-based processes for TST003 and TST005 Phase I clinical material manufacturing.
- In May 2022, we successfully passed audit by the European Union Qualified Person (QP). This demonstrates the robustness and maturity of the Company’s Quality Management System (QMS) to ensure compliance of GMP requirements and the Company is qualified to provide clinical supply materials for clinical studies to be conducted in EU.

### ***CDMO business***

- In 2022, we expanded and grew our CDMO service, including addition of new service categories in analytical testing and DP manufacturing. Over 30 new clients have been added and external contract value increased by more than 80% when compared to 2021.
- The increase of our CDMO business benefited from our advanced ICB technology, improved cell line expression system, proprietary cell culture media and extensive experience in customized media development, diversified analytical testing, and an integrated DP fill & finish line.
- Another important driver for our CDMO business growth is that our perfusion-based bioprocessing can lower cost of goods significantly, which is important for countries having pricing and affordability challenges, and our CMC team has extensive experience in late-stage process development to support pivotal trial and BLA filing.

## MANAGEMENT DISCUSSION AND ANALYSIS

### OVERVIEW

We are a clinical stage biopharmaceutical company with fully integrated capacities in discovery, research, development, and manufacturing. With a more diversified portfolio, promising mid-to-late stage registrational assets and a deep early-stage pipeline in a broad range of indications such as oncology, kidney disease, and osteoporosis, we are confident that the Company is well positioned for multiple waves of innovation that will support long-term growth.

We adopt a multi-regional development strategy to maximize operational efficiency and address requirements of multiple regulatory authorities, which will help forge a global commercial pathway for our products. We have an experienced and fully functional team with extensive global clinical research and development capabilities located both in China and the U.S.. This has also given us a first-mover advantage for several of our development programs. In particular, we are one of the leading global players in the emerging Claudin18.2-targeting therapeutic field, a target that is shown to be overexpressed in various solid tumors, and we are committed to developing osemitamab (TST001) as the cornerstone of the future new treatment paradigm in Claudin18.2 expressing solid tumors.

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. With this platform technology, we have been expanding our application modality from monoclonal antibody to bispecific antibody and antibody drug conjugate to enrich our pipeline, and most recently to diagnostic antibodies to support precision medicine strategy. With a better understanding of biomarker profiles and a global Companion Diagnostic (CDx) developing strategy, we can also maximize potential trial success by enrolling patients with high probability of benefiting from osemitamab (TST001) treatment. Our fully integrated CMC capabilities can support internal and external programs from IND to Biologics License Application (BLA) filing, and commercial production. With our Integrated Continuous Biomanufacturing (ICB) platform, we continued to achieve speed and high-quality development for all protein therapeutics, including difficult to manufactured proteins, while maintaining world-class productivity, providing high quality CDMO services and generating revenue to sustain our operations.

In addition, with the global rights and commercial potential of our pipeline, we continue to execute our global strategy by establishing partnerships with global and local biopharmaceutical companies as well as academic research institutions.



## Our Product Pipeline

We have established a diversified and differentiated pipeline of 13 molecules in oncology, bone disorders and nephrology. Most of antibody candidates were generated in-house by our antibody discovery platform covering validated, partially validated, and novel biological pathways, whereas one pipeline candidate was acquired through in-licensing. The following chart summarizes the drug candidates that are currently under development globally across various therapeutic areas as of the date of this announcement:

	Drug candidate	Target	Indications	Clinical trial region	Preclinical	IND	Phase 1a	Phase 1b/Phase 2a	Pivotal Phase 2b/Phase 3	Rights	Partner				
Oncology	Osemitamab (TST001)	Claudin 18.2	1L	China	Combo with Chemo										
			1L	Global	Combo with Nivolumab/Chemo										
			2/3L	Global	Combo with Nivolumab										
			2L	Global	Combo with Chemo										
			Late-line	Global	Mono							Global	In-house		
			Late-line	Global	Mono										
			1L	Global	Combo with Chemo										
			1L	Global	Combo with Chemo										
	MSB0254	VEGFR2	Solid tumors	Late-line	Global	Mono									
				TST005	PD-L1/TGF-β Bi-functional	Solid tumors (HPV+ and NSCLC, etc)	Global	Mono					Global	In-house	
				TST003	Gremlin1 (FIC)	Solid tumors	Global	Mono						Global	In-house
				TST006	Bi-specific	Solid tumors	Global	Mono						Global	In-house
				TST010	Undisclosed ADCC enhanced mAb	Solid tumors	Global	Mono						Global	In-house
TST012	Undisclosed	Solid tumors	Global	Mono						Global	In-house				
TST013	Undisclosed ADC	Solid tumors	Global	Mono						Global	In-house				
MSB2311	PD-L1	TMB-H solid tumors	Late-line	China	Mono						Global	In-house			
			Solid tumors	China	Combo with VEGFRi										
Non-oncology	TST002	Sclerostin	Osteoporosis	China	Mono					Greater China	Silly				
	TST004	MASP2	IgA nephropathy, TMA	Global	Mono					Global	AEUBING				
	TST008	MSAP2 Bi-Specific (FIC)	SLE	Global	Mono					Global	In-house				
	TST801	Bi-specific	SLE/LN/IgAN	Global	Mono					Global	In-house				

Source: Company

Abbreviations: PD-L1=Programmed death-ligand 1; VEGFR2=Vascular endothelial growth factor receptor 2; TGF-β=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 evidence. 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) and United States.

## **BUSINESS REVIEW**

We are proud to have developed three best-in-class molecules and two first-in-class molecules that address serious unmet medical needs for patients. Our talented clinical development and regulatory teams with proven ability to execute enabled us to continue to progress our pipeline and invest in future sources of innovation.

During the year of 2022, we have made significant progress with our pipeline assets in both oncology and non-oncology therapeutic areas and achieved multiple clinical and preclinical milestones that are listed as follows:

### **Oncology Program**

Our oncology pipeline includes multiple innovative and differentiated biologic molecules targeting major cancer pathways. Several drug candidates, including osemitamab (TST001), MSB0254, TST003, TST005, TST006, TST010, TST012 and TST013, are designed to target tumors with different mechanisms that are potentially synergistic for tumor indications with high unmet medical needs. Our key oncology candidates include:

- Osemitamab (TST001), our lead asset, is a potential best-in-class and differentiated antibody targeting Claudin18.2, a validated tumor associated antigen in several solid tumors indications, including but not limited to gastric and gastroesophageal cancer. A global Phase III registration study in G/GEJ cancer is planned in the third quarter of 2023 as well as further exploratory trials in several other indications.
- MSB0254 is a high affinity humanized antibody against VEGFR2, with an anti-tumor mechanism of action by inhibiting/normalizing tumor angiogenesis. Phase I study of MSB0254 has been completed and RP2D dose has been determined.
- TST003 is a first-in-class antibody targeting GREMLIN-1. It is currently tested in a global First in Human (FIH) trial.
- TST005 is a bifunctional humanized antibody targeting both PD-1/PD-L1 and TGF- $\beta$  pathways, the latter being a key MOA for PD-1 resistance. TST005 is currently being tested in a global Phase I study.
- TST006 is a bispecific Claudin18.2-PD-L1 antibody which is currently in preclinical stage.
- TST010 is a newly nominated preclinical antibody candidate entering IND-enabling stage, targeting regulatory T cells to enhance T cell mediated tumor killing.
- TST012 is an ADCC enhanced mAb candidate targeting biomarker expressing gastric cancer and other solid tumors that is at preclinical stage.
- TST013 is an ADC candidate targeting biomarker expressing breast cancer and other solid tumors that is at preclinical stage.

Our broad portfolio also offers opportunities to cover additional unmet medical needs through combinations: for example, TST005, MSB0254, TST003 and TST010 are highly synergistic with osemitamab (TST001) allowing to enhance our Claudin18.2 franchise through combinations with osemitamab (TST001); TST003 and MSB0254 combinations have the potential to offer new therapeutic alternatives for other indications.

### ***Osemitamab (TST001) (A Humanized ADCC-enhanced anti-Claudin 18.2 mAb for Solid Tumors)***

Osemitamab (TST001), our lead asset, is a potential best-in-class and ADCC enhanced humanized antibody specifically targeting Claudin18.2 with high-affinity. Claudin 18.2 is overexpressed in multiple tumor type cancers, including gastric/gastroesophageal junction cancer, pancreatic cancer, biliary tract cancer and other types of solid tumors. Osemitamab (TST001) is currently ranked among the top two most advanced clinical programs for Claudin18.2 globally, and the first in China.

Osemitamab (TST001) is currently in Phase II development and is expected to enter Phase III global clinical trials in countries including the United States, Europe, China, and other countries of Asia including Japan in 2023, pending health authority consultations.

We have made significant progress in the year of 2022 in advancing the clinical development for osemitamab (TST001), which includes:

#### **Recent Product Developments and Milestones**

- In January 2022, we presented osemitamab (TST001) U.S. Phase I Trial as a Trial-in-Progress poster presentation at the 2022 American Society of Clinical Oncology Gastrointestinal Cancers Symposium from January 20 to January 22, 2022 in San Francisco, CA.
- In February 2022, the first patient successfully dosed in China Phase IIa Study of osemitamab (TST001) combined with Cisplatin and Gemcitabine for the 1L treatment of systemic treatment-naïve locally advanced or metastatic biliary tract cancer patients. Globally we are the first company exploring the potential of Claudin18.2 targeting agent in biliary tract cancer.
- In March 2022, we presented the safety/tolerability and preliminary anti-tumor activity data in gastric and pancreatic cancers of osemitamab (TST001) China phase I clinical trial as a poster presentation at the 2022 International Gastric Cancer Congress (IGCC).
- In March 2022, we also established a global clinical collaboration with BMS to evaluate the combination of osemitamab (TST001) with Opdivo® (nivolumab), BMS's anti-PD-1 therapy, for the treatment of patients with Claudin18.2 expressing unresectable locally advanced or metastatic G/GEJ cancer. Opdivo® is approved globally in the 1L treatment of patients with unresectable locally advanced or metastatic G/GEJ cancer, and is becoming the new standard of care for these patients.
- In April 2022, one of our wholly-owned subsidiaries successfully passed audit of European Union qualified person, and an QP Declaration was issued. The audit is part of the preparation for a global phase III clinical trial application of osemitamab (TST001), which will include EU region, and subsequently for the commercialization of osemitamab (TST001) globally.

- In June 2022, clinical data for the dose-escalation part of the Phase I study of osemitamab (TST001) in combination with CAPOX as the 1L treatment of advanced and metastatic G/GEJ cancer was presented at 2022 ASCO meeting. The data showed that osemitamab (TST001) in combination with CAPOX as 1L treatment of patients with advanced and metastatic G/GEJ cancer is well tolerated and encouraging preliminary anti-tumor activities have been observed.
- In September 2022, we presented the interim efficacy data from osemitamab (TST001) in combination with chemotherapy at ESMO 2022 meeting. Of the 15 1L locally advanced or metastatic G/GEJ cancer evaluable patients with Claudin18.2 expression, 11 achieved partial response and four stable disease.
- In September 2022, we initiated the exploration of several combinations of osemitamab (TST001) with nivolumab in G/GEJ cancer in China: in 1L osemitamab (TST001) with nivolumab and CAPOX; in later line, osemitamab (TST001) and nivolumab.
- In September 2022, we opened the enrollment of the combination of osemitamab (TST001) and nivolumab for 2L and later G/GEJ adenocarcinoma patients in the U.S.. In November, we added a cohort of osemitamab (TST001) combined with mFOLFOX6 plus nivolumab for 1L G/GEJ adenocarcinomas to the same protocol. Such data will lay the foundation for regulatory interactions with CDE, FDA and EMA about our pivotal Phase III trial design.
- In November 2022, we presented a scientific poster related to osemitamab (TST001) at SITC 2022 meeting, regarding the prevalence of Claudin18.2 and PD-L1 Expression in Chinese patients with G/GEJ adenocarcinoma using the Company's proprietary Claudin18.2 specific IHC antibody and a commercial kit for PD-L1 detection. The full text of the poster is available on the Company's website.
- In November 2022, we published the preliminary data from the dose expansion cohort for osemitamab (TST001) in combination with chemotherapy in 1L treatment of locally advanced or metastatic G/GEJ cancer patients with Claudin18.2 expression in Chinese Congress on Oncology (CCO 2022).
- In the year of 2022, we conducted several health authorities consultations with FDA, CDE and other countries for our clinical development programs.

### ***CDx Progress for Osemitamab (TST001)***

### **Recent Product Developments and Milestones**

- In the year of 2022, we continued the development of companion diagnostic immunohistochemistry (IHC) assay for identifying patients with Claudin18.2 expression in tumor samples. We completed the optimization of the assay and are moving into the GMP CDx kit manufacturing to support the pivotal trial for osemitamab (TST001) in 2023.

### ***TST003 (A First-in-Class Humanized Antibody Candidate for Solid Tumors)***

TST003 is a first-in-class and high affinity humanized monoclonal antibody targeting GREMLIN-1, 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.

## Recent Product Developments and Milestones

- In May 2022, in collaboration with researchers at Renji Hospital, Shanghai Jiao Tong University School of Medicine, we published in Nature Cancer (<https://www.nature.com/articles/s43018-022-00380-3>) the results of preclinical studies of TST003 for the treatment of androgen receptor low/negative castration resistant prostate cancer resistant/refractory to existing therapy.
- In June 2022, we completed IND enabling studies for U.S. filing. TST003 has demonstrated significant anti-tumor activities both in vitro and in vivo in preclinical studies, and has the potential to become a first-in-class novel cancer treatment, either as monotherapy or in combination with immune checkpoint inhibitor and/or other anti-tumor agents.
- In August 2022, we submitted U.S. IND application for TST003 and we received clearance from FDA in September.
- In October 2022, we were invited to participate the 10th TEMTIA meeting in Paris, France, from November 7 to 10, 2022. We presented preclinical data of TST003 at the TEMTIA meeting.

### ***TST005 (A PD-L1/TGF- $\beta$ Bi-functional Antibody Candidate for Solid Tumors)***

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

## Recent Product Developments and Milestones

- In April 2022, we presented the preclinical data for TST005, a bifunctional fusion protein of PD-L1/TGF- $\beta$  as a poster presentation at the AACR annual meeting 2022, and demonstrated potent antitumor activities in xenograft models with good safety profiles in GLP toxicology studies.
- In November 2022, at SITC, we have presented a Trial in Progress (TiP) scientific poster for the phase I, first in human, open-label, TST005 dose escalation and dose expansion study in patients with locally advanced or metastatic solid tumors. In December 2022, we completed the 4th dose level evaluation and opened the enrollment at the last and highest dose level cohort for this ongoing global Phase I dose escalation study.

### ***MSB0254 (A Humanized VEGFR-2 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. MSB0254 has been generated using our in-house hybridoma platform. VEGFR-2 is overexpressed in neovascular tumor endothelial cells in many tumors in comparison to normal endothelial cells. VEGFR-2 pathway controls vascular permeability, survival and migration of the vascular endothelial cells. VEGFR-2 inhibitors have been shown to be able to inhibit tumor-induced angiogenesis and effectively block tumor growth, and thus may have a potential therapeutic role in multiple tumor types. VEGFR2 inhibitor could be used in combination with the checkpoint inhibitor and targeted therapies such as osemitamab (TST001), TST003 and TST005 to achieve better anti-tumor activities.

#### **Recent Product Developments and Milestones**

- In June 2022, we completed the Phase I study and determined RP2D dose for MSB0254. The abstract of MSB0254 Phase I trial data were presented as a poster presentation at the 2022 annual meeting of American Society of Clinical Oncology.
- In June 2022, the Phase I dose escalation study of MSB0254 monotherapy in advanced tumor patients has been completed.

### ***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. Please refer to the “Reasons for the Change in Use of Net Proceeds” in this announcement for further details.

#### **Recent Product Developments and Milestones**

- In January 2022, the Phase I dose escalation and expansion study of MSB2311 in advanced tumor patients has been completed.

### ***TST010 (T regulatory cell depleting mAb)***

TST010 is an ADCC enhanced monoclonal antibody designed for depleting Tumor-infiltrating regulatory T cells (Tregs). Tregs’ presence was reported to correlate with tumor progression and a worsening prognosis in many cancers.

#### **Recent Product Developments and Milestones**

- In June 2022, we selected final lead molecule for initiating IND enabling study. We demonstrated 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.

## ***TST006***

TST006 is a bi-specific antibody targeting Claudin18.2 and PD-L1, which has the potential for the treatment of Claudin18.2-expressing cancer patients who are resistant to or refractory from Claudin18.2 mAb or PD-1/PD-L1 mAb therapies, such as late-line gastric cancer patients, pancreatic cancer patients and others. As at the date of this announcement, it remains at preclinical stage.

## **TST012 (ADCC enhanced mAb candidate)**

TST012 is an ADCC enhanced mAb candidate targeting biomarker expressing gastric cancer and other solid tumors. As at the date of this announcement, it remains at preclinical stage.

## **Recent Product Developments and Milestones**

- In the year of 2022, we selected the lead antibody for further development. We demonstrated TST012 showed high binding affinity and potent NK cell mediated antibody dependent cellular cytotoxicity in preclinical target positive tumor cells.

## **TST013 (ADC product candidate)**

TST013 is an ADC candidate targeting biomarker expressing breast cancer and other solid tumors. As at the date of this announcement, it remains at preclinical stage.

## **Recent Product Developments and Milestones**

- In the year of 2022, we selected a shortlist of antibodies for initiating ADC discovery and development. TST013 ADC has demonstrated high affinity binding and potent cytotoxicity in preclinical target positive tumor cells.

## **Non-oncology Program**

Our highly differentiated non-oncology pipelines target bone and kidney diseases (TST002, TST004, and TST008, TST801) that have large patient population and high unmet medical needs.

Within our non-oncology pipeline, we have focused on indications with significant market potentials and forming partnerships to accelerate product development. In addition to developing TST002 and TST004 in fast-to-market indications, we are also expanding these two candidates in additional indications with blockbuster potentials and forming partnerships to accelerate the product development. In addition to our current pipeline in IgA nephropathy, we are also developing preclinical candidates with first-in-class multifunctional antibodies for the treatment of systemic lupus erythematosus (SLE), a disease with a large patient population yet very limited treatment option.

### ***TST002 (Bloszumab) (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 (Bloszumab) 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.

#### **Recent Product Developments and Milestones**

- In April 2022, the first patient was successfully dosed in China Phase I Study of TST002 for the treatment of osteoporosis. This Phase I Study of TST002 is a randomized and double-blind, placebo-controlled, single-ascending-dose, multi-center study that is designed to evaluate the safety, tolerability, and pharmacokinetics profile of TST002 as a treatment in patients with osteoporosis. We plan to leverage Eli Lilly's global phase I and phase II clinical data along with our own clinical data and evolving regulatory landscape to support and accelerate TST002's development in China.
- In December 2022, we completed enrollment for the first three dose level cohorts and got encouraging preliminary BMD data.

### ***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) designed to prevent inflammation and tissue damage mediated by lectin pathway complement activation. It can be potentially applied to multiple MASP2-dependent complement mediated diseases, including IgAN, a highly prevalent chronic kidney disease globally.

#### **Recent Product Developments and Milestones**

- In June 2022, we completed IND enabling studies for IND filing in both the U.S. and China. One key differentiation from first generation molecule is that TST004 can be delivered as a subcutaneous injection which will provide significant competitive advantage.
- In June 2022, our poster, TST004, a Humanized IgG4 Anti-MASP2 Antibody, Demonstrates Potent In Vitro/In Vivo Inhibitory Activities on MASP2 Complement Pathway and Excellent Safety Profiles in Non-Human Primate, and the preclinical data of TST004 were selected for presentation at the 2022 ISN Frontiers Meetings of Complement-Related Kidney Diseases in Bergamo, Italy.
- In October 2022, we received IND clearance from U.S. Food and Drug Administration (FDA).

### ***TST008 (A Bispecific Antibody Combining a MASP2 Antibody)***

TST008 is a first-in-class bispecific antibody combining MASP2 antibody with another molecule blocking B-cell activation and/or differentiation. As at the date of this announcement, it remains at preclinical stage.



## Recent Product Developments and Milestones

- In June 2022, we identified lead molecules for TST008. We demonstrated TST008 simultaneously targets both innate and adaptive immune pathways for a potentially better efficacy for the treatment of Systemic lupus erythematosus (SLE), a complex auto-antibody mediated autoimmune disease with limited treatment option. Current targeted biological therapies for SLE only address the adaptive immune by targeting B-cell pathway.

### ***TST801 (A Bispecific Antibody)***

TST801 is a first-in-class bispecific antibody targeting receptors involved in regulating B cell activation and differentiation and is designed for the treatment of SLE, a disease with high unmet medical needs and high prevalence globally. As at the date of this announcement, it remains at preclinical stage.

## Recent Product Developments and Milestones

- In the year of 2022, we selected the lead molecule for TST801. We demonstrated that TST801 showed excellent developability profile as well as potent and sustainable inhibition against B cell populations and activation in both *in vitro* and *in vivo* preclinical models.

**Cautionary Statement required by Rule 18A.08(3) of the Rules Governing the Listing of Securities on the Stock Exchange of Hong Kong Limited (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 yield candidate antibodies with superior druggability and high commercial potential. We have expanded our discovery pipeline with two new IND-approved programs, which are ready to enter early clinical development by 2023. In addition, we initiated two early-stage programs with intention to develop as ADCC enhanced antibody or antibody drug conjugates (ADC), which provide potential options for GI tract cancer and other tumor types. We have also generated another early-stage program of a bispecific antibody for the treatment of SLE. 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 years. We are expanding two new non-oncology targets to B cell and/or complement pathways for autoimmune diseases in our early discovery pipeline.

## ***Strategic Partnership to Advance Pipeline***

Partnerships and collaborations are essential for maximizing the clinical and commercial potential of our assets, and we attracted interest of global partners with the help of our differentiated or first-in-class molecules. We have established partnerships with BMS for the global clinical trial collaboration of osemitamab (TST001) combination with nivolumab in gastric or gastroesophageal junction cancer (G/GEJ), Eli Lilly & Company for TST002 in Greater China, Alebund Pharmaceuticals for TST004, as well as many research collaborations with prominent academic institutions and industry players around the world, and a technology collaboration with Merck KGaA for downstream processing.

Details of our existing partnerships are shown below.

### ***Osemitamab (TST001)***

We aim to develop osemitamab (TST001) as the cornerstone of the future new treatment paradigm in Claudin18.2 expressing solid tumors including gastric or gastroesophageal junction cancers.

On March 22, 2022, we established a global clinical trial collaboration with BMS to evaluate the combination of osemitamab (TST001) with Opdivo® (nivolumab), BMS' anti-PD-1 therapy, for the treatment of patients with unresectable locally advanced or metastatic Claudin18.2 expressing gastric or gastroesophageal junction cancer (G/GEJ) with or without previous treatment. This collaboration includes two global Phase I/II open-label, multi-center studies, one in the U.S. and the other in China. Under the terms of the agreement, we will be the sponsor of the trials and BMS will supply Opdivo for use in combination with osemitamab (TST001).

We have been approached with multiple MNCs on the potential global collaboration of osemitamab (TST001) for Claudin18.2 positive gastric cancer and other solid tumors. Claudin18.2 targeting antibody in combination with chemotherapy has been further validated by Zolbetuximab as an effective treatment option for Claudin18.2 positive 1L gastric cancer, a tumor type with high prevalence globally, in two Phase III trials.

### ***TST002***

In 2019, we entered into an exclusive and royalty bearing license agreement with Eli Lilly for LY-2541546 (Blosozumab), LY-3108653 and LY-2950913 (each a “**Licensed Compound**”). We gained exclusive rights to develop, use or commercialize and manufacture the Licensed Compound in Greater China regions including the PRC, Hong Kong, Macau and Taiwan.

We completed technology transfer, established manufacturing process for Blosozumab (internal project code TST002), and GMP production for clinical use and all the additional preclinical studies required for TST002 IND application in China. We received IND Clearance from CDE in 2021.

On April 28, 2022, the first patient was successfully dosed in China Phase I Study of TST002 for the treatment of osteoporosis. We will use data from this phase I clinical trial and leverage phase II data from the studies completed by Eli Lilly in ex-China regions to support the pivotal study IND application in China. As of December 2022, we have completed the enrollment of third dose cohorts and observed encouraging BMD increasing activity of TST002.

We have also been approached by multiple domestic pharmaceutical companies for the potential collaboration on the development and commercialization of TST002 in Greater China.

## **TST004**

We collaborate with Shanghai Alebund Pharmaceuticals Limited (“**Alebund Pharmaceuticals**”) after establishing a joint venture in 2020 to carry out pre-clinical research and conduct clinical trials in Greater China region. Currently, we have completed GMP material productions, in vitro/in vivo product characterization studies, non-GLP tox studies, GLP tox studies and pharmacology studies.

We have obtained IND clearance from the U.S. FDA and is currently working with Alebund Pharmaceuticals on China IND.

### **Translational Research Collaborations**

We also entered multiple research collaborations with prominent academic institutions around the world, including the Dana-Farber Cancer Institute of Harvard Medical School, Beijing Cancer Hospital, Shanghai Pulmonary Hospital, Zhongshan Hospital, Zhongshan University, and Shanghai Jiao Tong University. The research collaborations covered osemitamab (TST001), TST003 and TST005. We also established strategic collaborations with multiple technology platform companies to explore different modalities for innovative targets. These research collaborations further enhanced our global leading position in Claudin18.2 targeted combination therapies and strengthened our oncology programs.

### **Technology Partnership & Advancement**

Our technology partnership strategy is to develop and implement novel bioprocessing technology to increase facility output and dramatically lower cost of goods. We are two and a half years into the multi-year technology collaboration with Merck KGaA to develop novel continuous downstream technology to maximize facility output. We completed the design, fabrication, and delivery of the industry’s first automated and single-use flow-through polishing continuous downstream GMP technology in early 2022. We acquired Mobius Multi-Column Chromatography system for integrated product capture, a new technology from Merck KGaA. We continue to work collaboratively and closely with Merck KGaA to evaluate other new technologies we believe has the potential to further upgrade our manufacturing capability and capacity and allow us to establish global leadership position in continuous biomanufacturing platform for protein therapeutics.

### **Upgrade Manufacturing Technology and Expand Capacity**

In the year of 2022, we have made significant progress in developing and implementing novel bioprocessing technologies to enhance our manufacturing capability and capacity.

- **CMC Advancement:**
  - In May 2022, we successfully passed audit by the European Union Qualified Person (QP). This demonstrates the robustness and maturity of the Company’s Quality Management System (QMS) to ensure compliance of GMP requirements and the Company is qualified to provide clinical supply materials for clinical studies of programs such as osemitamab (TST001) to be conducted in EU.
  - In April and October 2022, we received permission to proceed from CDE and FDA, respectively, for osemitamab (TST001) process change from fed-batch to intensified perfusion process which increased productivity by > 8 folds at commercial production scale.

- In June 2022, we completed IND enabling CMC data package and dossier for TST003 and TST004.
- Since the arrival of the automated single-use flow-through polishing technology from Merck KGaA in early 2022, we have completed numerous rigorous testings, the system is now ready for GMP operation, well in advance of osetamab (TST001) pre-PPQ (Process Performance Qualification) run in 2023.
- Lastly, our team continues to improve and optimize our perfusion technology. Most recently, the team achieved another industry best productivity of 7 g/L per day.
- ***Capacity Expansion:***
  - The DP Fill & Finish line was put into operation and has the capacity to fill 100,000 vials of finished product per batch. In addition to 2, 6, 10, and 20mL vial sizes, we added 25 and 30mL vial molds in 2022. All vial sizes were configured and qualified providing precise fill volume from 0.4mL/vial to 35mL/vial. The well-established DP line has supported both internal and external programs.
  - The Suzhou facility project has progressed according to the plan. We have completed the design phase of the project.

- ***CDMO Business:***

In the year of 2022, our external contract value increased more than 80% comparing to the same reporting period in 2021. Our CDMO business unit added a new cell line expression system to provide our clients with lower cost and more robust cell line choices. We started to provide exploratory experimental services for clients seeking Continuous Bioprocessing development in order to attract contract business using our ICB platform. During the Reporting Period, our CDMO business added over 30 new clients in China and the U.S. with expanded service in analytical testing, formulation studies, particle investigation and drug product fills.

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

COVID-19 has not resulted in material negative impacts to our business operations or financial performance for the year ended December 31, 2022. Patient enrollment and follow-up for ongoing clinical trials experienced limited impact in April, May, and December 2022 from COVID-19. To minimize the impact, we have developed and implemented a contingency plan during the pandemic in compliance with Health Authority guidelines and GCP to ensure the study continuity, data completeness and integrity of the Company. This plan includes, among others, referring patients to other hospitals to keep them enrolled and also enrolling new patients to our trials. In addition, we accelerated patient enrolment in our U.S. trials. The management of the Company is striving to keep the impact minimized and committed to execute on our business goals globally despite the continued uncertainty caused by the pandemic.

## **EVENTS AFTER THE REPORTING PERIOD**

### **Clinical Development**

- In January 2023, we presented the design of two cohorts from a Phase I/IIa study of osemitamab (TST001) in combination with Nivolumab plus Capecitabine and Oxaliplatin as first-line or with Nivolumab as late-line treatment in locally advanced and metastatic gastric/gastroesophageal junction (G/GEJ) cancer at ASCO GI 2023.
- In January 2023, we received IND clearance from the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) for TST003.
- In January 2023, we completed the dose escalation of TST002 study and successfully enrolled more than 30 patients in total. As of the date of this announcement, we have observed encouraging BMD increasing activity of TST002 with favorable safety profile. In addition, we plan to use the treatment-related change in bone mineral density (BMD) as a surrogate endpoint for fractures in future trials, pending regulatory consultation.
- In March 2023, in collaboration with leading researchers at Beijing Cancer Hospital and other institutes, we published the study results of CLDN18.2-targeting Immuno-PET probe [89Zr]Zr-DFO-TST001 for non-invasive imaging in gastrointestinal tumors on Journal of Pharmaceutical Analysis.
- In March 2023, we dosed our first patient in the dose escalation of TST003 FIH study.
- In March 2023, we filed the supplementary application to current China IND of TST002 for Phase IIa study.
- In March 2023, we completed the enrollment in the dose escalation part of the Phase I study for TST005.
- In March 2023, we received orphan drug designation from the U.S. FDA for the treatment of patients with pancreatic cancer for osemitamab (TST001).

### **Business Development**

- We have initiated partnership discussions with multiple MNCs on the potential global collaboration of osemitamab (TST001) which is planned to enter into Phase III trial for first-line gastric cancer in the third quarter of 2023.

### **CDMO & CMC**

- We started to offer services with new technologies such as media development and conjugation/purification process development for ADC molecules.
- We have completed osemitamab (TST001) process characterization studies, defining process control strategies, and preparing pre-PPQ run using advanced ICB platform. The productivity and efficiency are continuously being improved.

## **FUTURE OUTLOOK**

We expect to advance multiple key pipeline molecule programs and especially to initiate our first global registration trial for osemitamab (TST001). We also strive to establish global collaboration on our leading assets such as osemitamab (TST001) and TST002. We also plan to further advance our CMC platform and grow our CDMO revenue. A detailed breakdown of expected developments for the rest of 2023 is as follows:

### **Clinical Developments**

#### ***Osemitamab (TST001)***

- We will initiate a global pivotal trial of osemitamab (TST001) for 1L G/GEJ adenocarcinoma patients with Claudin18.2 overexpression. We anticipate submitting pivotal trial declarations with FDA, EMA, CDE and other regions of the world including Japan.
- We will present clinical data at several medical conferences, including AACR, ASCO, ESMO and SITC.
- We will continue and expand explorations in early-stage treatment for G/GEJ cancer as well as several Claudin18.2 expressing solid tumors other than G/GEJ cancer.

#### ***TST002 (Bloszumab)***

- We anticipate releasing interim data in first half of 2023. We plan to initiate a Phase II study in second half of 2023.

#### ***TST003***

- We will expand TST003 FIH trial to open enrollment in China and explore combinations, including with our own portfolio. We will present our preclinical data at AACR 2023.

#### ***TST004***

- We plan to file IND in China.

#### ***TST005***

- We anticipate to submit/present TST005 dose escalation study data in 2023 ASCO.

#### ***TST010***

- We will initiate IND-enabling study for TST010. We will present our preclinical data at AACR.

#### ***TST012***

- We will select the candidate for initiating IND-enabling study for TST012.

### ***TST013***

- We will select the candidate for initiating IND-enabling study for TST013.

### ***TST801***

- We will select the candidate for initiating IND-enabling study for TST801.

### ***MSB2311***

- We proposed to deprioritize MSB2311 due to the overall evolving competitive landscape and substantial price cuts for PD-L1 products resulting from the negotiations and reimbursement from the national medical insurance system, and we will shift the resources to osemitamab (TST001) due to its higher competitive advantage and commercial potentials. MSB2311 will be kept for potential combo studies. Please refer to the “Reasons for the Change in Use of Net Proceeds” in this announcement for further details.

### **Potential Partnerships**

- We expect that further clinical data from our lead asset osemitamab (TST001) will help advance our discussions with MNCs for global partnership of osemitamab (TST001) in Claudin18.2 expressing solid tumors including gastric or gastroesophageal junction (G/GEJ) cancer, pancreatic cancer and NSCLC.
- We will continue partnership discussions for the Greater China rights of clinical asset TST002 to maximize the value of this asset.
- Our first-in-class asset TST003 also attracted interests from MNCs and we are having active conversations with potential partners.
- We are engaging in partnership discussions and seeking global partnership with companies having clinical and commercial expertise in chronic kidney diseases and/or other autoimmune diseases such as systemic lupus erythematosus (SLE) for our pipeline molecules.
- We also continue to work to identify, evaluate and build new technology platforms that can expand our existing antibody discovery capabilities through external collaboration and partnerships.

### **CMC and Technology Developments**

- Complete testing of Merck KGaA’s Mobius Multi-Column Chromatography system and implement it together with novel single-use flow-through polishing continuous downstream technology in the upcoming osemitamab (TST001) pre-PPQ run. Generate comprehensive comparability data package in support of PPQ activities in 2024.
- We will continue to improve cell line expression system and perfusion productivity in support of internal and CDMO projects.
- We will scale up perfusion from 300L to 1,000L while continuing to intensify downstream platform and implement key enabling technologies (media concentrates, buffer in-line conditioning) to maximize facility output and dramatically lower cost of goods.

- We will set up infrastructure and capabilities for developing ADC products and lyophilized DP to support internal and CDMO projects.
- We will install second 2,000L single-use bioreactor to increase capacity.
- We plan to further expand our CDMO service leveraging our CMC capabilities, especially providing cell culture media development service for both fedbatch and perfusion processing.

## **CDMO**

- We will continue to strengthen and expand BD activities globally to increase CDMO contracts from both China and U.S. clients.
- We plan to increase our competitiveness by improving operation efficiency, reducing cost, adding new capabilities such as drug product development for mRNA therapeutics, process development for ADC, and media development.
- We will offer more diversified and tailored service from developability assessment, cell line development, media development, process development and optimization, formulation and DP product development, analytical testing as well as integrated service package for IND and BLA filings.
- We aim to increase CDMO project using perfusion process and further establish ourselves as leader in continuous bioprocessing.

## **Outlook Beyond 2023**

We have instilled a global vision from the very beginning. Looking ahead, we aim to continue the expansion of our pipeline by developing one new drug candidate into clinical trials each year. Meanwhile we will keep exploring partnerships to enhance the global development and maximize the commercial value of our drug candidates. We will continue to develop and implement leading technology to improving productivity with lower cost.

We are driven by our vision of providing patients with differentiated and competitive biologics developed through cutting-edge technologies. Leading with our global strategy and vision, we will be able to unlock the full potential of our portfolio and drive long term value creation.



## FINANCIAL REVIEW

### YEAR ENDED DECEMBER 31, 2022 COMPARED TO YEAR ENDED DECEMBER 31, 2021

	Year ended December 31,	
	2022	2021
	RMB'000	RMB'000
<b>Revenue</b>	<b>101,892</b>	50,242
Cost of sales	<u>(82,003)</u>	<u>(40,874)</u>
<b>Gross profit</b>	<b>19,889</b>	9,368
Other income	<b>46,402</b>	32,906
Other gains and losses, net	<b>29,729</b>	(1,199,972)
Research and development expenses	<b>(349,781)</b>	(344,370)
Administrative and selling expenses	<b>(112,449)</b>	(145,215)
Listing expenses	–	(48,605)
Impairment losses under expected credit loss model	–	(1,641)
Share of results of a joint venture	<b>(23,145)</b>	(2,952)
Finance costs	<u><b>(17,636)</b></u>	<u>(15,167)</u>
<b>Loss before tax</b>	<b>(406,991)</b>	(1,715,648)
Income tax credit	<u>246</u>	<u>105</u>
Loss for the year	<u><b>(406,745)</b></u>	<u>(1,715,543)</u>
Other comprehensive income for the year		
<i>Item that may be reclassified subsequently to profit or loss:</i>		
Exchange differences arising on translation of a foreign operation	<u>(10,947)</u>	<u>1,751</u>
Loss and total comprehensive expenses for the year	<u><b>(417,692)</b></u>	<u>(1,713,792)</u>
<b>Non-IFRS measure<sup>(Note 1)</sup>:</b>		
Add: Adjusted for share-based compensation expenses and fair value (loss)/gain of financial liabilities at FVTPL	<u>16,817</u>	<u>1,228,751</u>
Adjusted loss and total comprehensive expenses for the year	<u><b>(400,875)</b></u>	<u>(485,041)</u>

<sup>1</sup> 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**  
*AS AT DECEMBER 31, 2022*

	<b>At December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>RMB'000</b>	<b>RMB'000</b>
	<b>(Audited)</b>	<b>(Audited)</b>
<b>Non-current assets</b>	<b>1,078,070</b>	1,149,353
<b>Current assets</b>	<b>1,056,475</b>	1,395,602
	<hr/>	<hr/>
<b>Total assets</b>	<b>2,134,545</b>	2,544,955
	<hr/> <hr/>	<hr/> <hr/>
<b>Current liabilities</b>	<b>550,370</b>	425,810
<b>Non-current liabilities</b>	<b>110,275</b>	153,576
	<hr/>	<hr/>
<b>Total liabilities</b>	<b>660,645</b>	579,386
	<hr/> <hr/>	<hr/> <hr/>
<b>Net current assets</b>	<b>506,105</b>	969,792
	<hr/> <hr/>	<hr/> <hr/>

## 1. Revenue

The Group provides contract development and manufacturing (“CDMO”) services and research and development services. CDMO services stands as an integrated platform to support the development of manufacturing processes and the production of advanced intermediates and active pharmaceutical ingredients and formulation development and dosage drug product manufacturing, for preclinical, clinical trials, new drug application, and commercial supply of chemical drugs as well as wide spectrum development from early to late stage. The research and development services are mainly for investigational new drug enabling studies based on customers’ needs.

The Group primarily earns revenues by providing CDMO services and research and development services to its customers through fee-for-service (“FFS”) contracts. Contract duration is generally a few months to two years. 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.

Disaggregated revenue information:

	<b>Year ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b><i>RMB’000</i></b>	<b><i>RMB’000</i></b>
CDMO services	<b>87,949</b>	44,200
Research and development services	<b>13,943</b>	6,042
	<b><u>101,892</u></b>	<b><u>50,242</u></b>

### **Transaction price allocated to the remaining performance obligation for contracts with customers**

The transaction price allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at December 31 2022 and the expected timing of recognising revenue are as follows:

	<b>CDMO services</b>	<b>Research and development services</b>
	<b><i>RMB’000</i></b>	<b><i>RMB’000</i></b>
Within one year	64,030	13,090
More than one year	15,190	—
	<b><u>79,220</u></b>	<b><u>13,090</u></b>

## 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, 2022, other income of our Group increased by RMB13.5 million to RMB46.4 million, from RMB32.9 million for the year ended December 31, 2021. The increase was primarily due to interest income and government grants recognised during the year ended December 31, 2022.

## 3. *Other Gains and Losses, Net*

Our other net gains and losses changed from losses of RMB1,200 million for the year ended December 31, 2021 to gains of RMB29.7 million for the Reporting Period. 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 in 2021.

## 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 1.6% from RMB344.4 million for the year ended December 31, 2021 to RMB349.8 million for the year ended December 31, 2022, primarily due to the pipeline advancement in 2022.

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

	<b>Year ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
Clinical expenses	<b>151,179</b>	134,654
Staff cost	<b>141,560</b>	94,326
Materials consumed	<b>12,596</b>	64,460
Depreciation and amortization expenses	<b>32,201</b>	29,488
Others	<b>12,245</b>	21,442
<b>Total</b>	<b><u>349,781</u></b>	<b><u>344,370</u></b>

## 5. *Administrative and Selling Expenses*

Our administrative expenses decreased 22.6% from RMB145.2 million for the year ended December 31, 2021 to RMB112.4 million for the year ended December 31, 2022, primarily due to the decrease in personnel cost and professional services.

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,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Salaries and related benefits costs	<b>51,786</b>	87,754
Professional fees	<b>21,567</b>	17,902
Depreciation and amortization expenses	<b>11,600</b>	16,290
Office expenses	<b>20,252</b>	13,888
Traveling and transportation expenses	<b>3,213</b>	3,734
Others	<b>4,031</b>	5,647
	<b>112,449</b>	145,215

## 6. Trade and Other Receivables

	At December 31,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Trade receivables	34,012	2,565
Less: Allowance for credit losses	—	—
	<u>34,012</u>	<u>2,565</u>
Other receivables:		
Promissory note receivables	—	8,465
Interest receivables	12,016	—
Prepayments for:		
Research and development services	18,719	24,207
Legal and professional services	2,083	1,063
Purchase of raw materials	2,039	3,356
Refundable rental deposits	1,707	1,316
Others	754	3,724
	<u>71,330</u>	<u>44,696</u>
Analyzed as:		
Non-current	1,707	1,316
Current	69,623	43,380
	<u>71,330</u>	<u>44,696</u>

The Group normally grants a credit period of 30 days or a particular period agreed with customers effective from the date when the services have been completed and accepted by customers.

## 7. Trade and Other Payables

	At December 31,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Trade payables	<b>48,154</b>	31,430
Accrued research and development expenses	<b>51,246</b>	36,100
Other payables:		
Purchase of property, plant and equipment	<b>10,520</b>	2,856
Legal and professional fee	<b>1,125</b>	3,435
Others	<b>7,351</b>	3,440
Interest payables	<b>576</b>	462
Other tax payables	<b>1,238</b>	949
Accrued staff costs and benefits	<b>27,022</b>	22,389
Other accruals	<b>1,149</b>	903
	<b>148,381</b>	<b>101,964</b>

The average credit period on purchases of goods and services of the Group is 30 days.

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

	NOTES	Year ended December 31,	
		2022 RMB'000 (Audited)	2021 RMB'000 (Audited)
Revenue	3	101,892	50,242
Cost of sales		<u>(82,003)</u>	<u>(40,874)</u>
Gross profit		19,889	9,368
Other income		46,402	32,906
Other gains and losses, net	4	29,729	(1,199,972)
Research and development expenses		(349,781)	(344,370)
Administrative and selling expenses		(112,449)	(145,215)
Listing expenses		–	(48,605)
Impairment losses under expected credit loss model		–	(1,641)
Share of results of a joint venture		(23,145)	(2,952)
Finance costs		<u>(17,636)</u>	<u>(15,167)</u>
Loss before tax		(406,991)	(1,715,648)
Income tax credit	5	<u>246</u>	<u>105</u>
Loss for the year		<u><b>(406,745)</b></u>	<u><b>(1,715,543)</b></u>
<b>Other comprehensive (expense) income for the year</b>			
<b><i>Item that may be reclassified subsequently to profit or loss:</i></b>			
Exchange differences arising on translation of a foreign operation		<u>(10,947)</u>	<u>1,751</u>
		<u><b>(417,692)</b></u>	<u><b>(1,713,792)</b></u>
Loss for the year attributable to:			
– Owners of the Company	6	<u><b>(406,745)</b></u>	<u><b>(1,715,543)</b></u>
Total comprehensive expense for the year attributable to:			
– Owners of the Company		<u><b>(417,692)</b></u>	<u><b>(1,713,792)</b></u>
Loss per share			
– Basic and diluted (RMB)		<u><b>(0.94)</b></u>	<u><b>(9.34)</b></u>



## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

		As at December 31,	
		2022	2021
	NOTES	RMB'000	RMB'000
		(Audited)	(Audited)
<b>Non-current assets</b>			
Property, plant and equipment		418,992	435,103
Intangible assets		95,996	96,135
Right-of-use assets		31,302	38,057
Goodwill		471,901	471,901
Interests in a joint venture		1,219	24,364
Value-added-tax (“VAT”) recoverable		–	64,647
Deposits paid for acquisition of property, plant and equipment		6,673	11,719
Other receivables	7	1,707	1,316
Time deposits		50,000	–
Pledged bank deposits		280	6,111
		<u>1,078,070</u>	<u>1,149,353</u>
<b>Current assets</b>			
Inventories		20,566	20,792
Trade and other receivables	7	69,623	43,380
Contract costs		17,636	33,275
Amounts due from related parties		–	76,129
VAT recoverable		5,564	–
Pledged bank deposits		47,636	–
Bank balances and cash		895,450	1,222,026
		<u>1,056,475</u>	<u>1,395,602</u>
<b>Current liabilities</b>			
Trade and other payables	8	148,381	101,964
Amount due to a director		–	268
Contract liabilities		1,146	35,967
Short-term loan		387,600	273,339
Lease liabilities		5,243	6,272
Deferred income		8,000	8,000
		<u>550,370</u>	<u>425,810</u>
<b>Net current assets</b>		<u>506,105</u>	<u>969,792</u>
<b>Total assets less current liabilities</b>		<u>1,584,175</u>	<u>2,119,145</u>

	<b>As at December 31,</b>	
	<b>2022</b>	<b>2021</b>
<i>NOTES</i>	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
	<b>(Audited)</b>	<b>(Audited)</b>
<b>Non-current liabilities</b>		
Long-term loan	<b>16,000</b>	77,390
Lease liabilities	<b>2,617</b>	7,710
Deferred income	<b>66,300</b>	42,868
Deferred tax liabilities	<b>25,358</b>	25,608
	<u><b>110,275</b></u>	<u>153,576</u>
<b>Net assets</b>	<u><b>1,473,900</b></u>	<u>1,965,569</u>
<b>Capital and reserves</b>		
Share capital	<b>272</b>	291
Treasury shares	<b>(9)</b>	(7)
Reserves	<b>1,473,637</b>	1,965,285
	<u><b>1,473,900</b></u>	<u>1,965,569</u>
<b>Total equity</b>	<u><b>1,473,900</b></u>	<u>1,965,569</u>

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

## 1. GENERAL INFORMATION

Transcenta Holding Limited (the “Company”) was incorporated in the British Virgin Islands as an exempted company with limited liability on August 20, 2010, and re-domiciled to the Cayman Islands on March 26, 2021 as an exempted company with limited liability under the laws of Cayman Islands. On September 29, 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 Renminbi (“RMB”), which is the same as the presentation currency of the consolidated financial statements.

## 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 (“IASB”) for the first time, which are mandatorily effective for the Group’s annual period beginning on January 1, 2022 for the preparation of the consolidated financial statements.

Amendments to IFRS 3	Reference to the Conceptual Framework
Amendments to IAS 16	Property, Plant and Equipment – Proceeds before Intended Use
Amendments to IAS 37	Onerous Contracts – Cost of Fulfilling a Contract
Amendments to IFRS Standards	Annual Improvements to IFRSs 2018-2020

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 IFRS Standards that have been issued but are not yet effective:

IFRS 17 (including the June 2020 and December 2021 Amendments to IFRS 17)	Insurance Contracts <sup>1</sup>
Amendments to IFRS 10 and IAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture <sup>2</sup>
Amendments to IFRS 16	Lease Liability in a Sale and Leaseback <sup>3</sup>
Amendments to IAS 1	Classification of Liabilities as Current or Non-current <sup>3</sup>
Amendments to IAS 1	Non-current Liabilities with Covenants <sup>3</sup>
Amendments to IAS 1 and IFRS Practice Statement 2	Disclosure of Accounting Policies <sup>1</sup>
Amendments to IAS 8	Definition of Accounting Estimates <sup>1</sup>
Amendments to IAS 12	Deferred Tax related to Assets and Liabilities arising from a Single Transaction <sup>1</sup>

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

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

3. Effective for annual periods beginning on or after January 1, 2024.

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 January 1, 2023, with early application permitted. As at December 31 2022, the carrying amounts of right-of-use assets and lease liabilities which are subject to the amendments amounted to RMB7,437,000 (2021: RMB13,141,000) and RMB7,860,000 (2021: RMB13,982,000), respectively. Upon the application of the amendments, there is no impact on the opening balance of accumulated losses.

### 3. REVENUE

The Group provides contract development and manufacturing (“CDMO”) services and research and development services. CDMO services stands as an integrated platform to support the development of manufacturing processes and the production of advanced intermediates and active pharmaceutical ingredients and formulation development and dosage drug product manufacturing, for preclinical, clinical trials, new drug application, and commercial supply of chemical drugs as well as wide spectrum development from early to late stage. The research and development services are mainly for investigational new drug enabling studies based on customers’ needs.

The Group primarily earns revenues by providing CDMO services and research and development services to its customers through fee-for-service (“FFS”) contracts. Contract duration is generally a few months to two years. 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.

Disaggregated revenue information:

	Year ended December 31,	
	2022	2021
	RMB'000	RMB'000
CDMO services	87,949	44,200
Research and development services	13,943	6,042
	<u>101,892</u>	<u>50,242</u>

## Transaction Price allocated to the remaining performance obligation for contracts customer

The transaction price allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at December 31, 2022 and the expected timing of recognising revenue are as follows:

	<b>CDMO services</b> <i>RMB'000</i>	<b>Research and development services</b> <i>RMB'000</i>
Within one year	64,030	13,090
More than one year	15,190	–
	<u>79,220</u>	<u>13,090</u>

## 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 accounting policies and no further analysis of the single segment is presented.

## Geographical information

The Group's operations are located in the People's Republic of China (the "PRC") and the USA.

All the Group's revenue from continuing operations from external customers is derived from the PRC. As at December 31, 2022, non-current assets of RMB339,000 (2021: RMB746,000) are located in the USA. The remaining non-current assets are all located in the PRC.

## Information about major customers

Revenue from customers contributing over 10% of the total revenue of the Group during the corresponding years are as follows:

	<b>Year ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
Customer A	<b>41,809</b>	6,042
Customer B	<b>20,651</b>	–
Customer C	N/A	12,774
Customer D	N/A	17,346

N/A: not disclosed as amounts less than 10% of total revenue

#### 4. OTHER GAINS AND LOSSES, NET

	Year ended December 31,	
	2022	2021
	RMB'000	RMB'000
Gain on deemed disposal of interests in a joint venture	–	26,816
Net foreign exchange gain (loss)	33,073	(28,516)
Fair value change of financial liabilities at FVTPL	–	(1,198,173)
Loss on disposal of property, plant and equipment	(51)	(37)
Loss arising on revision of interest rate of promissory note receivables	(3,299)	–
Gain on disposal of right-of-use assets	6	–
Others	–	(62)
	<u>29,729</u>	<u>(1,199,972)</u>

#### 5. INCOME TAX CREDIT

	Year ended December 31,	
	2022	2021
	RMB'000	RMB'000
Current tax:		
PRC Enterprise Income Tax	<u>(4)</u>	<u>(5)</u>
Deferred tax	<u>250</u>	<u>110</u>
	<u>246</u>	<u>105</u>

The Company was incorporated in the BVI and re-domiciled to the Cayman Islands and is exempted from income tax.

Under the two-tiered profits tax rates regime which was effective on March 21, 2018, the first Hong Kong dollar (“HK\$”) 2 million of profits of the qualifying group entity will be taxed at 8.25%, and profits above HK\$2 million will be taxed at 16.5%. The profits of group entities not qualifying for the two-tiered profits tax rates regime will continue to be taxed at a flat rate of 16.5%. The directors of the Company considered the amount involved upon implementation of the two-tiered profits tax rates regime is insignificant to the Group, since the group entities did not have tax assessable profit subject to Hong Kong Profits Tax for both years.

Under the Law of the People’s Republic of China on Enterprise Income Tax (the “EIT Law”) and Implementation Regulation of the EIT Law, the tax rate of the PRC subsidiaries is 25% for both years.

On December 1, 2020, HJB Hangzhou is qualified as a High and New Tech Enterprise recognised by Ministry of Science and Technology and enjoys a preferential tax rate of 15% for a period of three years starting from 2020.

Taxation arising in other jurisdictions is calculated at the rates prevailing in the relevant jurisdictions.

## 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 December 31,	
	2022	2021
	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	<u>(406,745)</u>	<u>(1,715,543)</u>

### Number of shares

	Year ended December 31,	
	2022	2021
Weighted average number of ordinary shares for the purpose of calculating basic and diluted loss per share	<u>432,827,091</u>	<u>183,599,740</u>

The weighted average number of shares for the year shown above has been arrived after deducting 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 since their assumed exercise would result in a decrease in loss per share.

## 7. TRADE AND OTHER RECEIVABLES

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

	At December 31,	
	2022	2021
	RMB'000	RMB'000
Within 30 days	31,965	2,565
31 – 60 days	1,936	–
61 – 90 days	96	–
91 – 120 days	–	–
121 – 365 days	15	–
	<u>34,012</u>	<u>2,565</u>

Analysis of trade and other receivables of the Group denominated in currencies other than the functional currency of the relevant group entities is set out below:

	At December 31,	
	2022	2021
	RMB'000	RMB'000
US\$	<u>1,461</u>	<u>8,840</u>

*Note:* The promissory note receivable balance arises from the exercise of share options by certain employees of the Group. The promissory notes carry interest rate of 0.3% per annum (2021: 3.6%). The promissory notes were settled in 2022.

## 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 December 31,	
	2022	2021
	RMB'000	RMB'000
0 – 30 days	32,579	20,531
31 – 60 days	1,669	2,262
61 – 90 days	4,271	8,460
91 – 120 days	287	–
121 – 365 days	9,240	131
Over 365 days	108	46
	<u>48,154</u>	<u>31,430</u>

Analysis of trade and other payables of the Group denominated in currencies other than the functional currency of relevant group entities is set out below:

	At December 31,	
	2022	2021
	RMB'000	RMB'000
US\$	<u>2,900</u>	<u>5,406</u>

## 9. DIVIDENDS

No dividend was paid or declared by the Company for ordinary shareholders of the Company during 2022, nor has any dividend been proposed since the end of the reporting period (2021: nil).

## Listing Expenses

Our listing expenses was nil for the year ended December 31, 2022 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 was RMB1.8 million for year ended December 31, 2021 and other comprehensive expense as of December 31, 2022 is RMB10.9 million.

## 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.



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.

	<b>Year ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>RMB'000</b>	<b>RMB'000</b>
Total comprehensive expenses for the year:	<b>(417,692)</b>	(1,713,792)
Add:		
Share-based compensation expenses	<b>16,817</b>	30,578
Fair value (loss)/gain of financial liabilities at FVTPL	—	1,198,173
	<u>16,817</u>	<u>1,228,751</u>
Sub-total	<b>16,817</b>	1,228,751
Adjusted loss and total comprehensive expenses for the year	<b><u>(400,875)</u></b>	<b><u>(485,041)</u></b>

### **Employees and Remuneration Policies**

The following table sets forth a breakdown of our employees as at December 31, 2022 by function:

	<b>Number of employees</b>	<b>% of total number of employees</b>
Research and Development	172	53.75
General and Administrative	59	18.44
Manufacturing	89	27.81
	<u>320</u>	<u>100.00</u>
<b>Total</b>	<b><u>320</u></b>	<b><u>100.00</u></b>

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 employee 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 of the Company dated September 14, 2021 (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, 2022, bank balances and cash, pledged bank deposits and time deposits were RMB993.4 million, as compared to RMB1,222.0 million as of December 31, 2021. The decrease was mainly due to the operating cashflow out.

### **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, 2022 and December 31, 2021, 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 five percent or more of the Group’s total assets as at December 31, 2022) during the Reporting Period. The Group did not have any material acquisitions or disposals of subsidiaries, associated companies or joint ventures for the year ended December 31, 2022.

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

The functional currency of the Company is Renminbi. During the Reporting Period, certain bank balances and cash, trade and other receivables, amounts due from related parties, trade and other payables, financial instrument at financial liabilities at fair value through profit or loss 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, 2022, bank borrowings amounting to RMB49,100,100 (2021: RMB105,769,000) and RMB33,000,000 (2021: nil), are secured by property, plant and equipment with carrying amount of RMB106,027,000 (2021: RMB124,841,000). All bank borrowings were denominated in RMB. We had an aggregate of RMB333,600,000 overdrafts with fixed interest rates as at December 31, 2022.

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,	
	2022	2021
	RMB'000	RMB'000
US\$	—	—

### ***Contingent Liabilities***

As at December 31, 2022, the Group did not have any material contingent liabilities.

### **ANNUAL GENERAL MEETING**

The annual general meeting is scheduled to be held on Friday, June 9, 2023 (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 6, 2023 to Friday, June 9, 2023, 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 17/F, Far East Finance Centre, 16 Harcourt Road, Hong Kong for registration not later than 4:30 p.m. on Monday, June 5, 2023.

## **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.

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

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.

During the Reporting Period, the Company has applied the principles of and complied with all the applicable code provisions set out from time to time in the CG Code.

To comply with the CG code, the Company has adopted the Board independence mechanism, Anti-corruption policy and Whistleblowing policy during the Reporting Period. Further information of the corporate governance practice of the Company will be disclosed in the annual report of the Company for the year ended December 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.

### **Compliance with the Model Code for Securities Transactions by Directors**

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 the Directors have confirmed that they have complied with the Model Code during the Reporting Period.

No incident of non-compliance of the Model Code was noted by the Company during the Reporting Period.

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

During the Reporting Period and up to the date of the announcement, the Company repurchased a total of 1,899,500 ordinary shares (the “**Shares Repurchased**”) of the Company on The Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”) at an aggregate consideration of approximately HK\$7,255,189. Particulars of the Shares Repurchased are as follows:

Month of Repurchase	No. of Shares Repurchased	Price paid per share		Aggregate Consideration (HK\$)
		Highest (HK\$)	Lowest (HK\$)	
September	129,500	3.71	2.68	463,915
October	632,500	4.02	3.70	2,459,088
November	967,000	4.05	3.64	3,791,269
December	<u>170,500</u>	3.22	3.00	<u>540,918</u>
<b>Total</b>	<u><u>1,899,500</u></u>			<u><u>7,255,189</u></u>

The Shares Repurchased from September 2022 to November 2022 were subsequently cancelled on November 28, 2022. The Shares Repurchased during the period from November 17, 2022 to December 20, 2022 were cancelled on December 30, 2022.

Save as disclosed above, neither the Company nor any of its subsidiaries purchased, sold or redeemed any of the Company's securities listed on the Stock Exchange during the Reporting Period and up to the date of this announcement.

## Material Litigation

The Company was not involved in any material litigation or arbitration during the year ended December 31, 2022. 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, 2022.

## 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 (the “**Net Proceeds**”). As disclosed in the “Future Plans and Use of Proceeds” section in the Prospectus, we intended to use 30% of the Net Proceeds, or approximately HK\$171.2 million, to fund ongoing and planned clinical trials, preparation for registration filings and potential commercial launches (including sales and marketing) of our core product, MSB2311. On the same date as this announcement, the Board has resolved to change the intended use of Net Proceeds and remove the investment from MSB2311 and put them into TST001 (the “**Change in Use of Net Proceeds**”) based on the reasons disclosed in the section “Reasons for the Change in Use of Net Proceeds” below. The table below sets out the utilization of Net Proceeds as at December 31, 2022 and the latest change in the applications of the Net Proceeds:

Use of Net Proceeds	Intended allocation of Net Proceeds as disclosed in the Prospectus		Unutilized net proceeds as at December 31, 2021		Unutilized net proceeds as at December 31, 2022		Intended allocation of the remaining Net Proceeds after the Change in Use of Net Proceeds		Expected timeline of full utilization of the unutilized Net Proceeds
	% of net proceeds (approximately)	HK\$ million	HK\$ million	HK\$ million	HK\$ million	HK\$ million	% of net proceeds (approximately)	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	-	453.8	82%	453.8	On or before December 31, 2025
(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	-	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, osemitamab (TST001)	20%	110.7	-	110.7	-	110.7	50%	276.7	On or before December 31, 2025
(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	-	55.3	10%	55.3	On or before December 31, 2025

Use of Net Proceeds	Intended allocation of Net Proceeds as disclosed in the Prospectus		Amount utilized as at December 31, 2021		Unutilized net proceeds as at December 31, 2021		Amount utilized as at December 31, 2022		Unutilized net proceeds as at December 31, 2022		Intended allocation of the remaining Net Proceeds after the Change in Use of Net Proceeds		Expected timeline of full utilization of the unutilized Net Proceeds
	% of net proceeds	HK\$ million	HK\$ million	HK\$ million	HK\$ million	HK\$ million	HK\$ million	HK\$ million	HK\$ million	HK\$ million	HK\$ million		
	(approximately)												
(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	-	55.3	-	55.3	-	55.3	10%	55.3	On or before December 31, 2025
(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	-	66.5	-	66.5	-	66.5	12%	66.5	On or before December 31, 2025
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	-	44.3	-	44.3	-	44.3	8%	44.3	On or before December 31, 2025
3. For general working capital purposes and general operation expenses	10%	55.3	-	55.3	-	55.3	-	55.3	-	55.3	10%	55.3	On or before December 31, 2025
<b>Total</b>	<b>100%</b>	<b>553.4</b>	<b>-</b>	<b>553.4</b>	<b>-</b>	<b>553.4</b>	<b>-</b>	<b>553.4</b>	<b>-</b>	<b>553.4</b>	<b>-</b>	<b>553.4</b>	

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 and “Reasons for the Change in Use of Net Proceeds” in this announcement.

As the Company has several fund sources including previous rounds of fund raising, CDMO business income, government subsidies, and tax refund, as at the date of this announcement, the Net Proceeds had not been utilized since the Listing Date. 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. The aforesaid expected timeline of full utilization of the Net Proceeds is based on the Directors’ best estimation barring unforeseen circumstances, and is subject to change in light of future development or any unforeseen circumstances.

## **Reasons for the Change in Use of Net Proceeds**

The Change in Use of Net Proceeds reflects the change in the Company's business focus and the development of clinical programs. Considering the overall competitive landscape and substantial price cuts for PD-L1 products resulting from the negotiations and reimbursement from the national medical insurance system, as well as our advantage in osemitamab (TST001), one of the globally most advanced investigational humanized monoclonal antibody targeting Claudin18.2 with its huge potential in multiple indications and significant commercial value foresaw, the Company is de-prioritizing MSB2311 and shifting the resources to more valuable business, our leading asset osemitamab (TST001). We proposed to deprioritize MSB2311 for the strategic reasons based on the evolving landscape and pricing situation and focus on osemitambab (TST001) due to its higher competitive advantage and commercial potentials. MSB2311 will not be removed from the portfolio and it will be kept for potential combo studies. In order to improve the return on investments and for the best benefits of the shareholders and the long term growth and value creation of the Company, we are allocating more resources to programs with much higher potential and business value. The Board will closely monitor the utilization of the Net Proceeds. The Board further confirms that there is no material change in the business of the Group as set out in the Prospectus. The Board considers that the Change in Use of Net Proceeds will not have any material adverse impact on the operations of the Group and is in line with our vision and in the best interests of the Company and its shareholders as a whole.

We will gradually utilize the Net Proceeds, in accordance with the Change in Use of Net Proceeds detailed above, by the end of 2025. Save for the Change in Use of Net Proceeds, there is no other change in use of the Net Proceeds.

## **Audit Committee**

The Company has established the 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, 2022 and has met with the Auditor. 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 Messers. 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, 2022 as set out in this announcement have been agreed by Group's Auditor, Messers. Deloitte Touche Tohmatsu to the amounts set out in the audited consolidated financial statements for the year as approved by the Board of Directors on March 30, 2023. The work performed by the Messers. Deloitte Touche Tohmatsu in this respect did not constitute an assurance engagement and consequently no opinion or assurance conclusion has been expressed by the Messers. 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, 2022.

## **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, 2022 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 30, 2023

*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, Mr. Xiaolu Weng as executive Director, Dr. Yining (Jonathan) Zhao as chairman and non-executive Director, and Mr. Jiasong Tang, Dr. Jun Bao, Mr. Zhihua Zhang and Dr. Kumar Srinivasan as independent non-executive Directors.*