Shanghai Henlius Biotech, Inc.
上海復宏漢霖生物技術股份有限公司
(A joint stock company incorporated in the People's Republic of China with limited liability)
(Stock Code: 2696)

(i) ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED 31 DECEMBER 2022; AND (ii) DISCLOSEABLE TRANSACTION

A. ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED 31 DECEMBER 2022

The board of directors (the "**Board**") of Shanghai Henlius Biotech, Inc. (the "**Company**" or "**Henlius**") is pleased to announce the audited consolidated financial results of the Company and its subsidiaries (collectively referred to as the "**Group**" or "**we**") for the year ended 31 December 2022 (the "**Reporting Period**"), prepared under International Financial Reporting Standards ("**IFRSs**").

FINANCIAL SUMMARY:

1. The Group's total revenue increased by approximately RMB1,532.2 million or approximately 91.1% to approximately RMB3,214.7 million for the year ended 31 December 2022, compared to approximately RMB1,682.5 million for the year ended 31 December 2021. Such revenue was mainly from drug sales, research and development ("**R&D**") services provided to customers, and license income.

2. For the year ended 31 December 2022, the Group recognized R&D clinical expenditure of approximately RMB2,183.2 million, representing an increase of approximately RMB419.5 million as compared with approximately RMB1,763.7 million for the year ended 31 December 2021, which was mainly for continuous increase in the investment into innovative R&D projects to accelerate the Company's innovation and transformation.

3. The Group's total loss was approximately RMB695.3 million for the year ended 31 December 2022, representing a decrease of approximately RMB288.8 million compared to approximately RMB984.1 million for the year ended 31 December 2021.

4. The Board does not recommend a final dividend for the Reporting Period.

BUSINESS HIGHLIGHTS:

1. HANQUYOU (trastuzumab for injection, European brand name: Zercepac®):

- HANQUYOU (150mg): completed the tendering process on the procurement platform and was included into the medical insurance procurement platform for all provinces in Mainland China in the first half of 2021.

- HANQUYOU (60mg): completed the tendering process on the procurement platform in 29 provinces and was included into the medical insurance procurement platform in all provinces in Mainland China as at the end of the Reporting Period.

- During the Reporting Period, HANQUYOU was approved for marketing in Australia, Cambodia, Singapore, Argentina and other countries, respectively.

2. HANSIZHUANG (serplulimab injection): as at the end of the Reporting Period, HANSIZHUANG completed the tendering process on the procurement platform in 27 provinces in Mainland China.

- In March 2022, HANSIZHUANG for the treatment of adult patients with advanced unresectable or metastatic Microsatellite Instability-High (MSI-H) solid tumours that have failed to respond to the standard therapy was conditionally approved by the NMPA.

- In October 2022, the new drug application (NDA) for indication of HANSIZHUANG in combination with carboplatin and albumin-bound paclitaxel for the first-line treatment of unresectable locally advanced or metastatic squamous non-small cell lung cancer (sqNSCLC) was approved by the NMPA.

- In January 2023, the new drug application (NDA) for new indication of HANSIZHUANG in combination with carboplatin and etoposide for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC) was approved by the NMPA.

- In August 2022, the new drug application (NDA) for HANSIZHUANG in combination with chemotherapy (Cisplatin + 5-FU) for the first-line treatment of locally advanced/ metastatic esophageal squamous cell carcinoma (ESCC) was accepted by the Center for Drug Evaluation of the NMPA.

3. HANLIKANG (rituximab injection):

- HANLIKANG (100mg/10ml): completed the tendering process on the procurement platform in all provinces and was included into the medical insurance procurement platform in 30 provinces in Mainland China and was procured by more than 70% of major hospitals as at the end of the Reporting Period.

- HANLIKANG (500mg/50ml): completed the tendering process on the procurement platform in 28 provinces and was included into the medical insurance procurement platform in 14 provinces in Mainland China as at the end of the Reporting Period.

4. **HANDAYUAN (adalimumab injection):** completed the tendering process on the procurement platform and was included into the medical insurance procurement platform in all provinces in Mainland China as at the Latest Practicable Date.

5. **HANBEITAI (bevacizumab injection):** completed the tendering process on the procurement platform in 24 provinces and was included into the medical insurance procurement platform in 30 provinces in Mainland China as at the end of the Reporting Period.

6. **Business Expansion:**

   - In February 2022, the Group entered into an agreement with Getz Pharma, pursuant to which, the Group agreed to grant a license to Getz Pharma to commercialise HANDAYUAN in Pakistan, Philippines, Vietnam and other regions.

   - In May 2022, the Company entered into an agreement with Eurofarma, pursuant to which, the Company agreed to grant a license to Eurofarma to commercialise HANLIKANG, HANQUYOU and HANBEITAI in Brazil and surrounding regions.

   - In May 2022, the Company entered into an agreement with Abbott, pursuant to which, the Company agreed to grant a license to Abbott to commercialise HANLIKANG and HANQUYOU in Brazil.

   - In June 2022, the Company entered into an agreement with Organon LLC, pursuant to which, the Company agreed to grant a license to Organon LLC and its affiliates to commercialise HLX11 (recombinant anti-HER2 domain II humanised monoclonal antibody injection) and HLX14 (recombinant anti-RANKL human monoclonal antibody injection) globally except for Mainland China, Hong Kong, Macau and Taiwan regions.

   - In June 2022, the Company entered into a collaboration and license agreement with Palleon to reach a consensus for the global joint development and commercialisation of a Bifunctional HER2-Sialidase Fusion Protein and another Tumour-Related Target-Sialidase Bifunctional Fusion Protein.

   - In December 2022, the Company and Fosun Pharma Industrial Development reached a business cooperation, pursuant to which, the Company agreed to grant a license to Fosun Pharma Industrial Development to commercialise HANSIZHUANG in the United States.

7. **Efficient Advancement on Clinical Study Projects both Domestically and Internationally:**

   – Progress of international clinical study projects: HANSIZHUANG (serplulimab injection)

      - In March 2022, the phase 3 investigational new drug application (IND) of HANSIZHUANG in combination with chemotherapy (carboplatin/cisplatin-etoposide) and concurrent radiotherapy for the treatment of limited-stage small cell lung cancer (LS-SCLC) was approved by the NMPA. The first patient has been dosed in May 2022 in an international multi-centre phase 3 clinical study in Mainland China and the first patient in the United States has been dosed in January 2023. As at the Latest Practicable Date, such study was approved successively to commence in Australia, Spain, Germany and other countries.

- In April and December 2022, HANSIZHUANG was granted the Orphan-drug Designation for the treatment of small cell lung cancer (SCLC) by the United States Food and Drug Administration (FDA) and the European Commission (EC), respectively.

- In August 2022, the phase 1 clinical trial of HLX60 (recombinant humanised anti-GARP monoclonal antibody injection) in combination with HANSIZHUANG for the treatment of advanced or metastatic solid tumours was approved to commence in Australia, and the first patient has been dosed in December 2022.

- In November 2022, the first patient has been dosed in a bridging study in the United States for HANSIZHUANG in combination with chemotherapy (carboplatin-etoposide) for first-line treatment of extensive-stage small cell lung cancer (ES-SCLC).

– Progress of international clinical study projects: other products

- In February 2022, the first patient has been dosed in a phase 1 clinical trial of HLX301 (recombinant anti-PD-L1 and anti-TIGIT bispecific antibody injection) for the treatment of locally advanced or metastatic solid tumours in Australia.

- In April 2022, the first patient has been dosed in an international multi-centre phase 3 clinical study of HLX11 (recombinant anti-HER2 domain II humanised monoclonal antibody injection) for the neoadjuvant therapy of HER2-positive and HR-negative early-stage or locally advanced breast cancer in Mainland China. As at the Latest Practicable Date, such study was approved to commence in Spain, Bulgaria, Poland and other countries.

- In April 2022, the first patient has been dosed in an international multi-centre phase 3 clinical trial of HLX04-O (recombinant anti-VEGF humanised monoclonal antibody injection) for the treatment of wet age-related macular degeneration (wAMD) in Latvia, Australia and other countries. In February 2023, the first patient in the United States has been dosed in such study.

- In April 2022, the phase 1 clinical trial of HLX20 (recombinant fully human anti-PD-L1 monoclonal antibody injection) conducted in patients with advanced solid tumours was completed in Australia, and HLX20 has demonstrated its good safety and tolerability in this trial.

- In June 2022, the first patient has been dosed in an international multi-centre phase 3 clinical trial of HLX14 (recombinant anti-RANKL human monoclonal antibody injection) for the treatment of postmenopausal osteoporosis in women with high fracture risks in Mainland China. In July 2022, this international multi-centre phase 3 clinical trial was approved to commence in Australia, and the first patient in Australia has been dosed in November 2022.

- In August 2022, the phase 2 investigational new drug application (IND) of HLX07 (recombinant anti-EGFR humanised monoclonal antibody injection) for the treatment of locally advanced or metastatic cutaneous squamous cell carcinoma (CSCC) was accepted by the United States Food and Drug Administration (FDA) and approved in September 2022.

– Progress of domestic clinical study projects: HANSIZHUANG (serplulimab injection)

- In February 2022, the phase 2 investigational new drug application (IND) of HANSIZHUANG in combination with HLX07 (recombinant anti-EGFR humanised monoclonal antibody injection) and HANBEITAI for the first-line treatment of unresectable or metastatic hepatocellular carcinoma (HCC) was accepted by the NMPA and approved in April 2022.

- In April 2022, the phase 1 investigational new drug application (IND) of HLX26 (recombinant anti-LAG-3 humanised monoclonal antibody injection) in combination with HANSIZHUANG for the treatment of advanced/metastatic solid tumours or lymphomas was approved by the NMPA. In August 2022, the first patient has been dosed in a phase 1 clinical trial of HLX26 in combination with HANSIZHUANG for the treatment of advanced/metastatic solid tumours in Mainland China. In February 2023, the phase 2 investigational new drug application (IND) of HLX26 in combination with HANSIZHUANG and chemotherapy for the first-line treatment of advanced non-small cell lung cancer (NSCLC) was accepted by the NMPA.

- In May 2022, the phase 3 clinical study of HANSIZHUANG in combination with chemotherapy (Cisplatin + 5-FU) for the first-line treatment of patients with locally advanced/metastatic esophageal squamous cell carcinoma (ESCC), met the co-primary endpoints of progression-free survival (PFS) and overall survival (OS) in a planned interim analysis, evaluated by the Independent Data Monitoring Committee.

- In June 2022, the enrollment of subjects was completed in the phase 3 clinical trial of HANSIZHUANG in combination with HANBEITAI and in combination with chemotherapy (carboplatin-pemetrexed) for the first-line treatment of advanced non-squamous, non-small cell lung cancer (nsNSCLC) in Mainland China.

- In August 2022, the phase 2 investigational new drug application (IND) of HLX22 (anti-human epidermal growth factor receptor-2 (HER2) humanised monoclonal antibody injection) in combination with HANSIZHUANG and in combination with the standard therapy (Trastuzumab in combination with chemotherapy) for the first-line treatment of locally advanced/metastatic gastric cancer (GC) was accepted by the NMPA and approved in October 2022.

- In November 2022, the phase 1b/2 investigational new drug application (IND) of HLX208 (BRAF V600E inhibitor) in combination with HANSIZHUANG and its combination therapy for the treatment of BRAF V600E or BRAF V600 mutation-positive advanced solid tumours was approved by the NMPA. In February 2023, the first patient has been dosed in a phase 1b/2 clinical trial of HLX208 (BRAF V600E inhibitor) in combination with HANSIZHUANG for the treatment of non-small cell lung cancer (NSCLC) in Mainland China.

– Progress of domestic clinical study projects: Other products

  - In January 2022, the phase 1b/2 investigational new drug application (IND) of HLX208 (BRAF V600E inhibitor) monotherapy or in combination therapy for the treatment of BRAF V600E or BRAF V600 mutation-positive advanced solid tumours was approved by the NMPA. In the same month, the first patient has been dosed in the phase 2 clinical trial of HLX208 (BRAF V600E inhibitor) for the treatment of adult Langerhans Cell Histiocytosis (LCH) and Erdheim-Chester disease (ECD) with BRAF V600E mutation in Mainland China.

  - In January 2022, the investigational new drug application (IND) of HLX35 (recombinant humanised anti-EGFR and anti-4-1BB bispecific antibody injection) for the treatment of advanced malignant solid tumours was approved by the NMPA. In June 2022, the first patient has been dosed in the phase 1 clinical trial of HLX35 for the treatment of advanced or metastatic solid tumours in Mainland China.

  - In March 2022, the investigational new drug application (IND) of HLX301 (recombinant anti-PD-L1 and anti-TIGIT bispecific antibody injection) for the treatment of advanced tumours has been approved by the NMPA. In July 2022, the first patient has been dosed in the phase 1/2 clinical trial of HLX301 for the treatment of locally advanced/metastatic solid tumours or lymphomas in Mainland China.

  - In June 2022, the phase 1 investigational new drug application (IND) of HLX53 (anti-TIGIT Fc fusion protein) for the treatment of advanced solid tumours or lymphomas was approved by the NMPA, and the first patient has been dosed in such trial in December 2022.

  - In September 2022, the phase 1 clinical study of HLX22 (anti-human epidermal growth factor receptor-2 (HER2) humanised monoclonal antibody injection) was completed in Mainland China, which has demonstrated the good safety and tolerability of HLX22 in the phase 1 clinical trial conducted in patients with HER2 overexpressing advanced solid tumours.

  - In October 2022, the phase 1 investigational new drug application (IND) of HLX60 (recombinant humanised anti-GARP monoclonal antibody injection) for the treatment of solid tumours and lymphomas was approved by the NMPA, and the first patient has been dosed in such trial in December 2022.

  - In February 2023, the first subject has been dosed in the phase 1 clinical trial of HLX15 (recombinant anti-CD38 human monoclonal antibody injection) in healthy Chinese male subjects.

  - In February 2023, the phase 1b/2 clinical study of HLX07 (recombinant anti-EGFR humanised monoclonal antibody injection) in combination with chemotherapy was completed in Mainland China, which has demonstrated the good safety and tolerability of HLX07 in the phase 1b/2 clinical study in patients with advanced solid tumours.

8. Efficient Advancement for Pre-Clinical Development Projects:

The Group attached great importance to the pre-clinical project pipeline, multiple global clinical trial approvals for 9 products and 5 combination therapies were granted during the Reporting Period, projects covering targets including EGFR×4-1BB, PD-L1×TIGIT, GARP, LAG-3, TIGIT etc., of which the investigational new drug applications (IND) were successfully approved and have entered into clinical study stage. In addition, in January 2023, the investigational new drug application (IND) of HLX51 (recombinant anti – OX40 humanised monoclonal antibody for injection) for the treatment of advanced/metastatic solid tumours and lymphomas was accepted by NMPA and was approved in March 2023.

9. Orientation toward Clinical Value and Injecting Impetus toward the Pipeline:

With clinical-value-oriented early study, coordinated with early R&D teams from China and the U.S., based on new discovery driven by deep data and accelerated bio-computing of molecular design technology, the Group has been assiduously cultivating the field of solid tumours, and further expanding into non-oncology disease areas including metabolic, cardiovascular, renal and nervous system disease, and rare diseases where clinical needs are barely met, so that impetus toward the pipeline can be injected. Being independently innovated, the Group has carried out cooperation with external cutting-edge, leading scientific research institutions, and introduced Tumour-Related Target-Sialidase Bifunctional Fusion Protein, ADC platform technology during the Reporting Period, in order to early incubate the cutting-edging ground-breaking science and technologies, bolstering the strength of independent innovation efficiently. As at the Latest Practicable Date, the Group has 57 molecules (including 10 biosimilar drugs and 47 innovative drugs) in its pipeline, with the form of drug covering monoclonal antibody, bispecific antibody, polyclonal antibody, antibody-drug conjugates(ADC), small molecule-drug conjugates and recombinant protein, etc.

10. Biopharmaceutical Industrialisation Base Layout with International Standards and High Cost-Efficiency:

The Group has been with a total commercial production capacity of 48,000L (including the commercial production capacity of 24,000L of Xuhui Facility, the commercial production capacity of 24,000L of Songjiang First Plant). During the Reporting Period, Songjiang First Plant has been approved to adopt the optimized new production process to carry out domestic commercial production of HANQUYOU, and it has also passed certification by Qualified Person (QP) from the EU. Songjiang First Plant and its supporting quality management system met the requirements of the EU's GMP regulations, and products manufactured by it such as HLX04-O, HLX11 and HLX14 and others were able to carry out clinical trials in Europe. During the Reporting Period, the construction, installation of process equipment, the adjustment of public system and primary liquid production line of the two main production buildings of first and second stage for the Phase I project of Songjiang Second Plant were completed in the second half of 2022, and the QC lab was put into use. For the third stage of Phase I project of the Songjiang Second Plant, piling works, the construction of building envelope and the slab foundation were completed, and purchase procedures for large equipments was kicked off.

For details of the above, please refer to this announcement and (if applicable) the Company's previous announcements published on the websites of the Stock Exchange of Hong Kong Limited (the "**Stock Exchange**") and the Company.

OUR PRODUCT PIPELINE

Marketed

HANSIZHUANG (serplulimab)[1]
PD-1
MSI-H solid tumours, squamous non-small cell lung cancer and extensive-stage small cell lung cancer

HANLIKANG (rituximab)[2]
CD20
Non-Hodgkin lymphoma, chronic lymphocytic leukemia and rheumatoid arthritis[3]

HANQUYOU (trastuzumab)[4]
HER2
Breast cancer and metastatic gastric cancer

HANDAYUAN (adalimumab)[5]
TNF-α
Rheumatoid arthritis, ankylosing spondylitis, psoriasis and uveitis

HANBEITAI(bevacizumab)[6]
VEGF
Metastatic colorectal cancer, advanced, metastatic or recurrent non-small cell lung cancer, Glioblastoma, etc.

MAA

HLX10[1](serplulimab)+**Chemo**
PD-1
Esophageal squamous-cell carcinoma 1L

HLX10[1] (serplulimab)+ **Chemo**
PD-1
Extensive-stage small cell lung cancer 1L

HLX02 (trastuzumab)[4]
HER2
Breast cancer and metastatic gastric cancer

Phase III

HLX10[1] (serplulimab)+**Chemo**
PD-1
Extensive-stage small cell lung cancer 1L

HLX10[1] (serplulimab)+**Chemo**
PD-1
Neo-/adjuvant treatment of gastric cancer

HLX10[1] (serplulimab)+**Chemo**+**Radio**
PD-1
Limited-stage small cell lung cancer 1L

HLX10[1] (serplulimab)+**HANBEITAI**
PD-1+VEGF
Non-squamous non-small cell lung cancer 1L

HLX04-O[7]
VEGF
Wet age-related macular degeneration

HLX11 (pertuzumab)[8]
HER2
Neoadjuvant treatment of breast cancer

HLX14 (denosumab)[9]
RANKL
Osteoporosis

Phase II

HLX10[1] (serplulimab)+**HANBEITAI**
PD-1+VEGF
Metastatic colorectal cancer 1L

HLX10[1] (serplulimab)+**HLX07**
PD-1+EGFR
HNSCC, NPC, GC, ESCC and sqNSCLC

HLX07[10]
EGFR
Solid tumours (CSCC)

HLX22 + **HANQUYOU**
HER2+HER2
Gastric cancer

HLX208[11]
BRAF V600E
LCH/ECD and solid tumours (melanoma, ATC, mCRC, NSCLC, etc.)

HLX208[11] + **HLX10**[1] (serplulimab)
BRAF V600E + PD-1
Non-small cell lung cancer

Phase I

HLX10[1] (serplulimab)+**HLX26**
PD-1+LAG-3
Solid tumours

HLX10[1] (serplulimab)+**HLX60**[12]
PD-1+GARP
Solid tumours

HLX26
LAG-3
Solid tumours and lymphomas

HLX60
GARP
Solid tumours and lymphomas

HLX35[13]
EGFR x 4-1BB
Solid tumours

HLX301[14]
PD-L1 x TIGIT
Solid tumours and lymphomas

HLX53
TIGIT
Solid tumours and lymphomas

HLX05 (cetuximab)[15]
EGFR
Metastatic colorectal cancer and squamous-cell carcinoma of the head and neck

HLX15 (daratumumab)
CD38
Multiple myeloma

IND

HLX51
OX40
Solid tumours and lymphomas

HLX13 (ipilimumab)
CTLA-4
Melanoma, hepatocellular carcinoma, renal cell carcinoma and metastatic colorectal cancer

Pre-clinical

HLX61
Unpublished (I/O)
Solid tumours

HLX6018
GARP/TGFβ1
Chronic inflammation

HLX41
LIV1 ADC
Solid tumours

HLX42
EGFR ADC
Solid tumours

HLX43
PD-L1 ADC
Solid tumours

HLX44
Nectin4 ADC
Solid tumours

HLX80
STEAP1 ADC
Castration-resistant prostate cancer

HLX309
Nectin4 x 4-1BB
Solid tumours

HLX314
HER2 x Sialidase
Solid tumours

HLX17(pembrolizumab)
PD-1
Solid tumours

Innovative mAb
Biosimilar mAb
Innovative BsAb
ADC drugs
Innovative fusion protein
Innovative small molecules
US bridging study
BLA accepted by FDA
Global multi-centre clinical trial
MAA validated by the EMA
The first Chinese mAb approved in both China and the EU

The core products of the Company including HANSIZHUANG, HANLIKANG, HANQUYOU, HANDAYUAN and HANBEITAI are all approved for marketing.

(1) IND approved in China, the United States, the EU, Australia and other countries and regions; approved for marketing by NMPA in March 2022; Business partners: KGBio and Fosun Pharma;
(2) The first domestic biosimilar; Business partners: Fosun Pharma, Farma De Colombia, Eurofarma and Abbott;
(3) The first rituximab approved for the treatment of the indication in China;
(4) Approved for marketing in over 30 countries, including China, the United Kingdom, Germany, France and Australia, with trade name registered in Europe: Zercepac®, trade name registered in Australia: Tuzucip® and Trastucip®; business partners: Accord, Cipla, Jacobson, Elea, Eurofarma and Abbott;
(5) Business partners: Wanbang Biopharma and Getz Pharma;
(6) Business partner: Eurofarma;
(7) IND approved in China, Australia, the United States, Singapore, the EU and other countries and regions; Business partner: Essex;
(8) IND approved in China and the EU; Business partner: Organon;
(9) IND approved in China, the EU and Australia; Business partner: Organon;
(10) IND approved in China and the United States;
(11) Commercialisation rights obtained in China including Hong Kong, Macao and Taiwan region;
(12) IND approvals obtained in Australia;
(13) Business partner: Binacea;
(14) IND approved in China and Australia;
(15) Business partner: Shanghai Jingze

MANAGEMENT DISCUSSION AND ANALYSIS

I. BUSINESS REVIEW

As part of our commitment to provide affordable and high-quality biomedicines for patients worldwide, the Group has been dedicated to the continuous innovation and layout of the three major segments of R&D, production and commercialisation. During the Reporting Period, we have worked to promote the efficient development of the global commercialisation of product pipeline and implement production capacity deployment for the biomedicines with high economic benefit based on international standards. With great achievements in clinical development and drug registration of pipeline products, the Group completed the transformation from Biotech model to Biopharma model that is more scaled up and highly competitive in the market. As at 24 March 2023, being the latest practicable date for the publication of this announcement (the "**Latest Practicable Date**"), 3 indications of HANSIZHUANG, the first self-developed innovative monoclonal antibody, have been successively approved for marketing, which currently are used for the treatment of MSI-H solid tumours, squamous non-small cell lung cancer (sqNSCLC) and extensive-stage small cell lung cancer (ES-SCLC). During the Reporting Period, with a great deal of effort from the Group's in-house commercialisation team, HANQUYOU and HANSIZHUANG have achieved impressive sales results; HANLIKANG, HANDAYUAN and other products have provided stable income when partners continued to facilitate; several products have reached global cooperation including Abbott Operations Uruguay S.R.L. ("**Abbott**"), Organon LLC and other well-known enterprises, and the launch of domestic sales and internationalised layout has been accelerated. During the Reporting Period, the Group made significant progress in 17 clinical trials, and received approvals for multiple clinical trials worldwide for 9 products and 5 combination therapies, fully demonstrating the Group's strength in innovation and R&D.

As at the Latest Practicable Date, 5 products (18 indications) of the Group have been successfully marketed in Mainland China, 1 product has been successfully marketed in Europe and Australia and other counties/regions. The new drug application (NDA) for the forth indication (esophageal squamous cell carcinoma (ESCC)) of HANSIZHUANG submitted in Mainland China (excluding Hong Kong, Macau and Taiwan regions of the People's Republic of China (the "**PRC**") ("**Mainland China**") has been accepted; the marketing authorisation application (MAA) for the indications of extensive-stage small cell lung cancer (ES-SCLC) was also validated in EU; and the biologics license application (BLA) of HANQUYOU has been accepted in the U.S..

(I) Strong global product commercialisation capability

During the Reporting Period, the Group actively implemented the concept of excellent commercialisation bearing patients' needs in mind. Our commercialisation team comprises of five major segments, namely market promotion, channel management, pricing and market access, domestic sales and strategic planning, covering the whole process of commercialisation, in order to achieve continuous growth in sales scale of products. As at the end of the Reporting Period, the Group has over 1,000 people of commercialisation team, and nearly doubled comparing with that of the end of 2021. Following the launch of HANLIKANG, the first monoclonal antibody approved in China in accordance with the Guidelines for the R&D and Evaluation of Biosimilars (Trial) (the "**Guidelines for Biosimilars**") in 2019, several core products of the Group such as HANQUYOU, HANDAYUAN, HANBEITAI and HANSIZHUANG have successively been approved for marketing in Mainland China and put forward its commercialisation in a well-regulated way. During the Reporting Period, the Group has also established cooperation with several internationally renowned partners for HANLIKANG, HANQUYOU, HANDAYUAN, HANBEITAI, HLX11 (recombinant anti-HER2 domain II humanised monoclonal antibody injection), HLX14 (recombinant anti-RANKL human monoclonal antibody injection) and HANSIZHUANG, obtaining impressive achievements in internationalization for self-developed products.

International commercialisation process of HANQUYOU (trastuzumab for injection, European brand name: Zercepac®) (a therapeutic product for breast cancer and gastric cancer)

– Commercial sales of HANQUYOU in Mainland China

HANQUYOU is the core product of the Group in the field of anti-tumour therapy, and also the first product sold and promoted by the Group's in-house commercialisation team in Mainland China. As at the end of the Reporting Period, we hired more than 550 professional marketing personnel for the sales of HANQUYOU, with an aim to penetrate into the Mainland China market with efficient execution capacity. HANQUYOU (150mg) was launched for commercial sales since August 2020, and completed the tendering process on the procurement platform and was included into the medical insurance procurement platform for all provinces in Mainland China in the first half of 2021. Since its approval for marketing in August 2021, HANQUYOU (60mg) was included into the medical insurance procurement platform in all provinces in Mainland China and completed the tendering process on the procurement platform in 29 provinces as at the end of the Reporting Period. In addition to the efficient market and access providing a strong foundation for the overall sales growth of HANQUYOU, the flexible dose portfolio of 150mg and 60mg also brings personalised and more economical treatment options for patients with different weight ranges. It can also enhance clinical safety with its "ready-to-use" feature. During the Reporting Period, the Group cooperated with relevant enterprises in respect of physician education, medical big data, HER2 testing, innovative payment, patient management and education and has gained a good market reputation in the construction of diagnosis and treatment ecosystem for patients with HER2-positive breast cancer and gastric cancer, and conducted care action on pandemic response for patients with patients education organization during Shanghai's pandemic lockdown, to do its best to care for patients in such a special time.

In April 2022, drug substance west line and east line (with a production capacity of 24,000L), drug product line and packaging line for the production of HANQUYOU in Songjiang First Plant passed the GMP compliance inspection, indicating that Songjiang First Plant has a quality management system that meets the requirements of China's GMP regulations. In May 2022, HANQUYOU was approved by the National Medical Products Administration ("**NMPA**") to change its production site, improve its production process and expand the scale of preparation, and Songjiang First Plant was approved to adopt enhanced new production techniques to conduct the commercial production of HANQUYOU in Mainland China. So far, the full capacity of Songjiang First Plant of 24,000L can be used for the commercial production of HANQUYOU, providing strong support for the production increase of HANQUYOU.

– Commercialisation process of HANQUYOU in Europe, Australia, U.S. and other places

- Based on the Company's cooperation with Accord Healthcare Limited("**Accord**"), the business partner, HANQUYOU (European trade name: Zercepac®) was approved for marketing in the European Union (the "**EU**") in July 2020. As the first "Chinese" monoclonal antibody biosimilar drug approved for sale in the EU, Zercepac® has been sold in United Kingdom, Germany, Spain, France, Italy, Switzerland and approximately 20 European countries.

- In June 2022, trastuzumab for injection granted by the Company to its business partner PT Kalbio Global Medika for commercial purpose in part of Southeast Asian countries was approved for marketing in Cambodia under the brand name of Hertumab®. In October 2022, trastuzumab for injection was approved for marketing in Singapore under the brand name of Trazher®.

- In July 2022, trastuzumab for injection granted by the Company to its business partner Cipla Limited for commercial purpose in Australia and other regions was approved for marketing in Australia under the brand name of Tuzucip®and Trastucip®.

- In October 2022, trastuzumab for injection granted by the Company to its business partner Laboratorio ELEA Phoenix S.A. (The license right was transferred by original licensee Mabxience Research, S.L. to Laboratorio ELEA Phoenix S.A.) for commercial purpose in Argentina and other regions was approved for marketing in Argentina under the brand name of Dafex®.

- In February 2023, the biologics license application (BLA) for trastuzumab for injection for (1) the adjuvant treatment for HER2 overexpressing breast cancer; (2) the treatment for HER2 overexpressing metastatic breast cancer; and (3) the treatment for HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma submitted by the affiliates of the Company's business partner Intas Pharmaceuticals Limited ("**Intas**"), was accepted by the United States Food and Drug Administration (FDA).

HANQUYOU is a trastuzumab developed and manufactured by the Group in accordance with relevant laws and regulations of China and the EU on biosimilars. Focused on HANQUYOU, the Group prospectively has drawn up an internationally commercialised layout, cooperated with many world-class biomedicine enterprises to fully boost market share in the U.S., Canada, Europe and many emerging countries and markets, covering approximately over 100 countries and regions around the world. As a representative domestic biologic to "go global", HANQUYOU has successfully been approved for marketing in over 30 countries and regions.

Three indications of HANSIZHUANG (serplulimab injection) were approved for marketing, currently using for the therapy for the MSI-H solid tumours, squamous non-small cell lung cancer(sqNSCLC) and extensive-stage small cell lung cancer (ES-SCLC)

In March 2022, the first indication of PD-1 monoclonal antibody product HANSIZHUANG, a core innovative product self-developed by the Group, was approved for marketing. Following that, the Company immediately started the relevant commercialisation process. Despite the special period of epidemic containment at that time, the first prescription came into use and the first batch of shipments was successfully delivered in Mainland China within about a week after the approval. As at the end of the Reporting Period, HANSIZHUANG has completed the tendering process on the procurement platform in 27 provinces in Mainland China. The professional marketing personnels, who are capable of professional communication and have considerable experience of marketing in tumours market, were approximately 400 after expansion. Covering over 23,000 professional doctors specializing in treating lung cancer, gastrointestinal tumour and other diseases of thousands of domestic hospitals, the Company adopts the meticulous management model to thereof, and successfully made HANSIZHUANG a competitive PD-1/PD-L1 product focusing on small cell lung cancer through effective differentiated competitive strategy within nine months after the marketing. As at the Latest Practicable Date, HANSIZHUANG has obtained the marketing approval for the three indications, and the new drug application (NDA) for another indication was received, strongly supporting continued deep expansion of commercialisation and ensuring more patients benefit from HANSIZHUANG.

— First indication approved: Microsatellite Instability-High (MSI-H) solid tumours, covering a wide range of patient groups

  In March 2022, PD-1 monoclonal antibody product HANSIZHUANG, a core innovative product self-developed by the Group, for the treatment of adult patients with advanced unresectable or metastatic Microsatellite Instability-High (MSI-H) solid tumours that have failed to respond to the standard therapy was conditionally approved by the NMPA, offering new immunotherapy option for patients. The indication is screened by specific MSI-H tumour markers rather than by cancer type, covering a wide range of patient groups.

– Second indication approved: locally advanced or metastatic squamous non-small cell lung cancer (sqNSCLC), benefiting more patients

  In October 2022, the new drug application (NDA) for indication of HANSIZHUANG in combination with carboplatin and albumin-bound paclitaxel for the first-line treatment of unresectable locally advanced or metastatic squamous non-small cell lung cancer (sqNSCLC), has been approved by the NMPA. Squamous non-small cell lung cancer (sqNSCLC) is the second subtype of non-small cell lung cancer (NSCLC), and has a great demand for clinical drugs. It's expected that more patients will benefit from the marketing for such indication in clinical practices.

– Third indication approved: extensive-stage small cell lung cancer (ES-SCLC), the first monoclonal antibody drug targeting PD-1 approved for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC) around the world

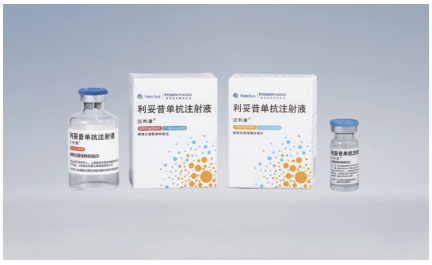
  In January 2023, the new drug application (NDA) for new indication of HANSIZHUANG in combination with carboplatin and etoposide for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC) has been approved by the NMPA. Accordingly, HANSIZHUANG has became the first monoclonal antibody drug targeting PD-1 approved for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC) around the world, making breakthroughs in the treatment of lung cancer. During the Reporting Period, the oral presentation of results of a phase 3 study of the indication was made by principal investigator at the annual meetings of American Society of Clinical Oncology (ASCO) and European Society for Medical Oncology Asia (ESMO Asia) Congress, respectively in 2022, and the results were published online in The Journal of American Medical Association (JAMA, impact factor of 157.3), one of the top four medical journals in the world. As the first monoclonal antibody targeting PD-1 for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC) with positive results around the world, it attracted much attention from and was highly recognized by the global academic communities. In March 2023, the marketing authorisation application (MAA) of the indication submitted by the Group was validated by the European Medicines Agency.

– Fourth indication submitted: esophageal squamous cell carcinoma (ESCC), further covering the field of gastrointestinal tumours

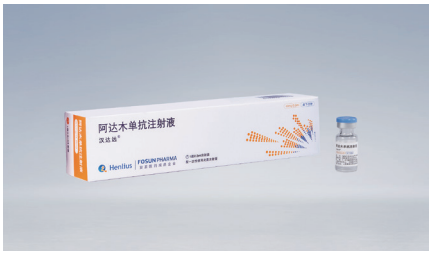
  In May 2022, the phase 3 clinical study of HANSIZHUANG in combination with chemotherapy (Cisplatin + 5-FU) as a first-line treatment for locally advanced/metastatic esophageal squamous cell carcinoma (ESCC), met the co-primary endpoints of progression-free survival (PFS) and overall survival (OS) in a planned interim analysis, evaluated by the Independent Data Monitoring Committee. In August 2022, the new drug application (NDA) of this indication was accepted by the Centre for Drug Evaluation of the NMPA and was the fourth indication for HANSIZHUANG submitted in Mainland China.

  The results of the phase 3 clinical study of indication successively were presented orally at annual meetings of the Chinese Society of Clinical Oncology (CSCO), the European Society for Medical Oncology Asia (ESMO Asia) Congress, and were published officially in Nature Medicine (Impact factors: 87.241), the international prestigious publication in February 2023.

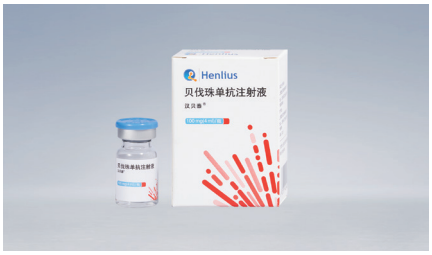
Steady progress of the commercial sales of HANLIKANG (rituximab injection) and HANDAYUAN (adalimumab injection) (therapeutic products for hematological tumours and autoimmune diseases) contributed to the continuous revenue



Jiangsu Fosun Pharmaceutical Sales Co., Ltd. ("**Jiangsu Fosun**"), a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd. ("**Fosun Pharma**"), the controlling shareholder of the Company, was responsible for the domestic commercial sale of HANLIKANG. As the first monoclonal antibody drug approved for marketing under the Guidelines for Biosimilars in China in 2019, HANLIKANG has been approved for marketing for three years, and has benefited approximately 160,000 patients in total in China. As at the end of the Reporting Period, the specifications of HANLIKANG covered 100mg/10ml and 500mg/50ml. HANLIKANG (100mg/10ml) has been included into the medical insurance procurement platform in 30 provinces in Mainland China, and has completed the tendering process on the procurement platform in all provinces, and was procured by more than 70% of major hospitals; HANLIKANG (500mg/50ml) has completed the tendering process on the procurement platform in 28 provinces and was included into the medical insurance procurement platform in 14 provinces in Mainland China. In February 2022, HANLIKANG for the treatment of the innovative indication of rheumatoid arthritis (RA) was approved for marketing, which has advantages of less dosing frequency and lasting medicine effect and is expected to improve patients' compliance and enhance patients' quality of life as well as alleviate their medical burden. Accordingly, as at the end of the Reporting Period, HANLIKANG's indications approved for marketing were further expanded to the field of autoimmune diseases on the basis of covering all the indications of the original drug approved in Mainland China in the field of hematology oncology. The implementation of both types of indications will cover more patient groups.



Jiangsu Wanbang Biopharmaceutical (Group) Co., Ltd. ("**Jiangsu Wanbang**"), a subsidiary of Fosun Pharma, the controlling shareholder of the Company, was responsible for the domestic commercial sale of HANDAYUAN. HANDAYUAN is the third product of the Group marketed in Mainland China, it has been approved for the indications of rheumatoid arthritis, ankylosing spondylitis, psoriasis and uveitis in Mainland China. As at the Latest Practicable Date, HANDAYUAN has completed the tendering process on the procurement platform and was included into the medical insurance procurement platform in all provinces in Mainland China.



Additionally, as at the end of the Reporting Period, HANBEITAI, the fourth biosimilar product of the Group approved for marketing, had covered metastatic colorectal cancer, advanced, metastatic or recurrent non-small cell lung cancer, recurrent glioblastoma, cervical cancer, as well as indications of epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer. The Group began to establish a professional sales team for HANBEITAI and made market layout accordingly during the Reporting Period. As at the end of the Reporting Period, HANBEITAI has been included into the medical insurance procurement platform in 30 provinces and has completed the tendering process on the procurement platform in 24 provinces in Mainland China.

(II) Great success in the licensing cooperation during the Reporting Period

During the Reporting Period, by adhering to the internationalisation strategy, the Group established commercial cooperation globally with international partners, such as Abbott and Organon LLC in respect of HANLIKANG, HANQUYOU, HANDAYUAN, HANBEITAI, HLX11(recombinant anti-HER2 domain II humanised monoclonal antibody injection), HLX14 (recombinant anti-RANKL human monoclonal antibody injection) and HANSIZHUANG, resulting in an upfront payment of over RMB1.5 billion throughout the year.

- In February 2022, the Group has entered into an agreement with Getz Pharma (Private) Limited and its affiliates, Getz Pharma International FZ-LLC (collectively, "**Getz Pharma**"), pursuant to which, the Group agreed to grant a license to Getz Pharma to commercialise HANDAYUAN in Pakistan, Philippines, Vietnam and other regions. According to the agreement, the Company is entitled to receive an upfront payment of $500,000, and a milestone payment of up to $7.5 million.

- In May 2022, the Company entered into an agreement with Eurofarma Laboratorios S.A. ("**Eurofarma**"), pursuant to which, the Company agreed to grant a license to Eurofarma to commercialise HANLIKANG, HANQUYOU and HANBEITAI in Brazil and surrounding regions. According to the agreement, the Company is entitled to receive an upfront payment of $4.5 million, and a milestone payment of up to $46.0 million.

- In May 2022, the Company entered into an agreement with Abbott, pursuant to which, the Company agreed to grant a license to Abbott to commercialise HANLIKANG and HANQUYOU in Brazil. According to the agreement, the Company is entitled to receive an upfront payment of $3.0 million, and a milestone payment of up to $1.4 million.

- In June 2022, the Company entered into an agreement with Organon LLC, pursuant to which, the Company agreed to grant a license to Organon LLC and its affiliates to commercialise HLX11 (recombinant anti-HER2 domain II humanised monoclonal antibody injection) and HLX14 (recombinant anti-RANKL human monoclonal antibody injection) globally except for Mainland China, Hong Kong, Macau and Taiwan regions. According to the agreement, the Company is entitled to receive an upfront payment of $70.0 million, and a milestone payment of up to $468.0 million.

- In December 2022, the Company reached a business cooperation with Shanghai Fosun Pharma Industrial Development Co., Ltd.(上海復星醫藥產業發展有限公司) ("**Fosun Pharma Industrial Development**"), pursuant to which, the Company agreed to grant a license to Fosun Pharma Industrial Development to commercialise HANSIZHUANG in the United States. According to the agreement, the Company is entitled to receive an upfront payment of RMB1.0 billion, and a milestone payment of up to $700 million, as well as a tiered royalty ranging from 10% to 18% of the annual net sales in the licensed territory.

During the Reporting Period, the Group also actively accelerated the creation of innovative technology platforms and the expansion of innovative product pipelines through licensing introduction, cooperative development and other approaches.

- In June 2022, the Company entered into a collaboration and license agreement with Palleon Pharmaceuticals Inc. ("**Palleon**") for the global joint development and commercialisation of a bifunctional HER2-sialidase fusion protein and another tumour-related target-sialidase bifunctional fusion protein. The Company will obtain the exclusive commercialisation rights of two bifunctional antibody-sialidase fusion protein products in Mainland China, Hong Kong, Macau and Taiwan regions under the agreement, and the first collaborative product, a bifunctional HER2-sialidase fusion protein, is expected to enter clinical trial support studies soon.

- In 2022, the Group has reached cooperation consensuses with Novacyte Therapeutics Biomedical Technology (Beijing) Co., Ltd.* (諾靈生物醫藥科技(北京)有限公司) and MediLink Therapeutics (Suzhou) Co., Ltd.* (蘇州宜聯生物醫藥有限公司), respectively on the introduction of ADC platform technology and the cooperative development of ADC products.

Meanwhile, after the comprehensive consideration of the actual situation in the R&D, the market conditions and other factors, the Group terminated the licensing introduction with Galaxy Biotech, LLC and Chiome Bioscience, Inc. to terminate the cooperation on the HLX56 and TROP2 targeted antibodies.

(III) Sustainable global clinical development capability on medical products

During the Reporting Period, based on clinical needs, the Group has orderly organised the development of innovative products. Clinical trials on indication for products are in further process, including HANSIZHUANG (PD-1) and related combination therapies, HLX301 (PD-L1 x TIGIT), HLX35 (EGFR x 4-1BB), HLX208 (BRAF V600E inhibitor), HLX53 (anti-TIGIT Fc fusion protein), HLX60 (GARP), HLX22 (HER2) for the treatment of solid tumours, lymphomas, small cell lung cancer (SCLC), adult Langerhans cell histiocytosis (LCH) and Erdheim-Chester disease (ECD), esophageal squamous cell carcinoma, gastric cancer and hepatocellular carcinoma.

As at the end of the Reporting Period, the Group, synergising R&D centres in China and the United States, has established a global product development team with approximately 450 staffs for advancing the clinical study and drug registration of many candidate drugs across the world, and achieved significant progress in 17 clinical trials and multiple global clinical trial approvals for 9 products and 5 combination therapies during the Reporting Period.

1. Continuous and efficient advancement on clinical research product

As at the Latest Practicable Date, the Group has carried out a total of more than 30 clinical trials for 15 products and 13 combination therapies in an orderly manner in various countries/regions.

Progress of international clinical study projects

– Progress of HANSIZHUANG (serplulimab injection)

  - In March 2022, the phase 3 investigational new drug application (IND) of HANSIZHUANG in combination with chemotherapy (carboplatin/cisplatin-etoposide) and concurrent radiotherapy for the treatment of limited-stage small cell lung cancer (LS-SCLC) was approved by the NMPA. The first patient has been dosed in May 2022 in an international multi-centre phase 3 clinical study in Mainland China and the first patient in the United States has been dosed in January 2023. As at the Latest Practicable Date, such studies have been approved successively to commence in Australia, Spain, Germany and other countries.

- In April 2022 and December 2022, HANSIZHUANG has been granted Orphan-Drug Designation for the treatment of small cell lung cancer (SCLC) by the United States Food and Drug Administration (FDA) and European Commission (EC), respectively.

- In August 2022, the phase 1 clinical trial of HLX60 (recombinant humanised anti-GARP monoclonal antibody injection) in combination with HANSIZHUANG for the treatment of advanced or metastatic solid tumours has been approved to commence in Australia, and the first patient has been dosed in December 2022.

- In November 2022, the first patient has been dosed in a bridging study in the United States for HANSIZHUANG in combination with chemotherapy(carboplatin-etoposide) for first-line treatment of extensive-stage small cell lung cancer (ES-SCLC).

– Progress of other products

- In February 2022, the first patient has been dosed in a phase 1 clinical trial of HLX301 (recombinant anti-PD-L1 and anti-TIGIT bispecific antibody injection) for the treatment of locally advanced or metastatic solid tumours in Australia.

- In April 2022, the first patient has been dosed in an international multi-centre phase 3 clinical study of HLX11 (recombinant anti-HER2 domain II humanised monoclonal antibody injection) for the neoadjuvant therapy of HER2-positive, HR-negative early-stage or locally advanced breast cancer in Mainland China. As at the Latest Practicable Date, such study has been approved to commence in Spain, Bulgaria, Poland and other countries.

- In April 2022, the first patient has been dose in an international multi-centre phase 3 clinical trial of HLX04-O (recombinant anti-VEGF humanised monoclonal antibody injection) for the treatment of wet age-related macular degeneration (wAMD) in Latvia, Australia and other countries. In February 2023, the first patient in the United States has been dosed in such study.

- In April 2022, the phase 1 clinical trial of HLX20 (recombinant fully human anti-PD-L1 monoclonal antibody injection) conducted in patients with advanced solid tumours was completed in Australia, and HLX20 has demonstrated its good safety and tolerability in this trial.

- In June 2022, the first patient has been dosed in an international multi-centre phase 3 clinical study of HLX14 (recombinant anti-RANKL human monoclonal antibody injection) for the treatment of postmenopausal osteoporosis in women with high fracture risks in Mainland China. In July 2022, this international multi-centre phase 3 clinical study was approved to commence in Australia and the first patient in Australia has been dosed in November 2022.

- In August 2022, the phase 2 investigational new drug application (IND) of HLX07 (recombinant anti-EGFR humanised monoclonal antibody injection) for the treatment of locally advanced or metastatic cutaneous squamous cell carcinoma (CSCC) was accepted by the United States Food and Drug Administration (FDA) and was approved in September 2022.

Progress of domestic clinical study projects

– Progress of HANSIZHUANG (serplulimab injection)

- In February 2022, the phase 2 investigational new drug application (IND) of HANSIZHUANG in combination with HLX07 (recombinant anti-EGFR humanised monoclonal antibody injection) and HANBEITAI for the first-line treatment of unresectable or metastatic hepatocellular carcinoma (HCC) was accepted by the NMPA and approved in April 2022.

- In April 2022, the phase 1 investigational new drug application (IND) of HLX26 (recombinant anti-LAG-3 humanised monoclonal antibody injection) in combination with HANSIZHUANG for the treatment of advanced/metastatic solid tumours or lymphomas was approved by the NMPA. In August 2022, the first patient has been dosed in a phase 1 clinical trial of HLX26 in combination with HANSIZHUANG for the treatment of advanced/metastatic solid tumours in Mainland China. In February 2023, the phase 2 investigational new drug application (IND) of HLX26 in combination with HANSIZHUANG and chemotherapy for the first-line treatment of advanced non-small cell lung cancer (NSCLC) was accepted by the NMPA.

- In May 2022, the phase 3 clinical study of HANSIZHUANG in combination with chemotherapy (Cisplatin + 5-FU) for the first-line treatment of patients with locally advanced/metastatic esophageal squamous cell carcinoma (ESCC), met the co-primary endpoints of progression-free survival (PFS) and overall survival (OS) in a planned interim analysis, evaluated by the Independent Data Monitoring Committee.

- In June 2022, the enrollment of subjects was completed in the phase 3 clinical study of HANSIZHUANG in combination with HANBEITAI in combination with chemotherapy (carboplatin-pemetrexed) for the first-line treatment of advanced non-squamous, non-small cell lung cancer (nsNSCLC) in Mainland China.

- In August 2022, the phase 2 investigational new drug application (IND) of HLX22 (anti-human epidermal growth factor receptor-2 (HER2) humanised monoclonal antibody injection) in combination with HANSIZHUANG and in combination with the standard therapy (Trastuzumab in combination with chemotherapy) for the first-line treatment of locally advanced/metastatic gastric cancer (GC) was accepted by the NMPA and was approved in October 2022.

- In November 2022, the phase 1b/2 investigational new drug application (IND) of HLX208 (BRAF V600E inhibitor) in combination with HANSIZHUANG and its combination therapies for the treatment of BRAF V600E or BRAF V600 mutation-positive advanced solid tumours was approved by the NMPA. In February 2023, the first patient has been dosed in a phase 1b/2 clinical trial of HLX208 (BRAF V600E inhibitor) in combination with HANSIZHUANG for the treatment of non-small cell lung cancer (NSCLC) in Mainland China.

– Progress of other products

- In January 2022, the phase 1b/2 investigational new drug application (IND) of HLX208 (BRAF V600E inhibitor) monotherapy or in combination therapy for the treatment of BRAF V600E or BRAF V600 mutation-positive advanced solid tumours was approved by the NMPA. In the same month, the first patient has been dosed in the phase 2 clinical trial of HLX208 (BRAF V600E inhibitor) for the treatment of adult Langerhans Cell Histiocytosis (LCH) and Erdheim-Chester disease (ECD) with BRAF V600E mutation in Mainland China.

- In January 2022, the investigational new drug application (IND) of HLX35 (recombinant humanised anti-EGFR and anti-4-1BB bispecific antibody injection) for the treatment of advanced malignant solid tumours was approved by the NMPA. In June 2022, the first patient has been dosed in the phase 1 clinical trial of HLX35 for the treatment of advanced or metastatic solid tumours in Mainland China.

- In March 2022, the investigational new drug application (IND) of HLX301 (recombinant anti-PD-L1 and anti-TIGIT bispecific antibody injection) for the treatment of advanced tumours has been approved by the NMPA. In July 2022, the first patient has been dosed in a phase 1/2 clinical trial of HLX301 for the treatment of locally advanced/metastatic solid tumours or lymphomas in Mainland China.

- In June 2022, the phase 1 investigational new drug application (IND) of HLX53 (anti-TIGIT Fc fusion protein) for the treatment of advanced solid tumours or lymphomas was approved by the NMPA, and the first patient has been dosed in such trial in December 2022.

- In September 2022, the phase 1 clinical trial of the HLX22 (anti-human epidermal growth factor receptor-2 (HER2) humanised monoclonal antibody injection) has been completed in Mainland China, which has demonstrated the good safety and tolerability of HLX22 in the phase 1 clinical trial conducted in patients with HER2 overexpressing advanced solid tumours.

- In October 2022, the phase 1 investigational new drug application (IND) of HLX60 (recombinant humanised anti-GARP monoclonal antibody injection) for the treatment of solid tumours and lymphomas was approved by the NMPA, and the first patient has been dosed in such trial in December 2022.

- In February 2023, the first subject has been dosed in a phase 1 clinical study of HLX15 (recombinant anti-CD38 human monoclonal antibody injection) in healthy Chinese male subjects.

- In February 2023, the phase 1b/2 clinical trial of HLX07 (recombinant anti-EGFR humanised monoclonal antibody injection) in combination with chemotherapy has been completed in Mainland China, which has demonstrated its good safety and tolerability in the phase 1b/2 clinical trial conducted in patients with advanced solid tumours.

2. Efficient advancement on IND application for pre-clinical development projects

The Group attached great importance to the pre-clinical project pipeline, multiple global clinical trial approvals for 9 products and 5 combination therapies were granted during the Reporting Period, projects covering targets including EGFR×4-1BB, PD-L1×TIGIT, GARP, LAG-3, TIGIT, etc., of which the investigational new drug applications (IND) were successfully approved, has entered into clinical study stage. In addition, in January 2023, the investigational new drug application (IND) of HLX51 (recombinant anti–OX40 humanised monoclonal antibody for injection) for the treatment of advanced/metastatic solid tumours and lymphomas was accepted by NMPA and was approved in March 2023.

The clinical and pre-clinical application results of the Group's products from the beginning of 2022 up to the Latest Practicable Date:

Product name (targets)	Indications	Progress as at the Latest Practicable Date
Efficient advancement on international clinical study projects		
HANSIZHUANG in combination with chemotherapy concurrent radiotherapy (PD-1)	Limited-stage small cell lung cancer (LS-SCLC)	In March 2022, the phase 3 investigational new drug application was approved by the NMPA In May 2022, the first patient dosing was completed in an international multi-centre phase 3 clinical study in Mainland China In October 2022, an international multi-centre phase 3 clinical study was approved to commence in Australia In November 2022, an international multi-centre phase 3 clinical study was approved to commence in Spain In January 2023, the first patient in the United States has been dosed in an international multi-centre phase 3 clinical study
HANSIZHUANG (PD-1)	Small cell lung cancer (SCLC)	In April 2022, the United States Food and Drug Administration (FDA) granted Orphan-drug Designation In December 2022, the European Commission (EC) granted Orphan-drug Designation

Product name (targets)	Indications	Progress as at the Latest Practicable Date
HLX60 in combination with HANSIZHUANG (GARP+PD-1)	Solid tumour	In August 2022, the phase 1 clinical study was approved to commence in Australia In December 2022, the first patient dosing was completed in a phase 1 clinical trial in Australia
HANSIZHUANG in combination with chemotherapy (PD-1)	Extensive-stage small cell lung cancer (ES-SCLC)	In November 2022, the first patient dosing was completed in a bridging study in the United States
HLX301 (PD-L1×TIGIT)	Solid tumour	In February 2022, the first patient dosing was completed in a phase 1 clinical trial in Australia
HLX11 (HER2)	Neoadjuvant treatment of breast cancer	In April 2022, the first patient dosing was completed in an international multi-centre phase 3 clinical trial in Mainland China In October 2022, an international multi-centre phase 3 clinical study was approved to commence in Spain
HLX04-O (VEGF)	Wet age-related macular degeneration (wAMD)	In April 2022, the first patient dosing was completed in an international multi-centre phase 3 clinical study in Latvia, Australia, etc. In February 2023, the first patient in the United States has been dosed in an international multi-centre phase 3 clinical study
HLX20 (PD-L1)	Solid tumour	In April 2022, a phase 1 clinical study was completed in Australia

Product name (targets)	Indications	Progress as at the Latest Practicable Date
HLX14 (RANKL)	Osteoporosis (OP)	In June 2022, the first patient dosing was completed in an international multi-centre phase 3 clinical study in Mainland China In July 2022, an international multi-centre phase 3 clinical study was approved to commence in Australia In November 2022, the first patient in Australia has been dosed in an international multi-centre phase 3 clinical study
HLX07 (EGFR)	Cutaneous squamous cell carcinoma (CSCC)	In August 2022, the phase 2 investigational new drug application was accepted by the United States Food and Drug Administration (FDA) In September 2022, the phase 2 investigational new drug application was approved by the United States Food and Drug Administration (FDA)
Smooth progress of domestic clinical projects		
HANSIZHUANG in combination with HLX07 and HANBEITAI (PD-1+EGFR+VEGF)	Hepatocellular carcinoma (HCC)	In February 2022, the phase 2 investigational new drug application was accepted by the NMPA In April 2022, the phase 2 investigational new drug application was approved by the NMPA
HLX26 in combination with HANSIZHUANG (LAG-3+PD-1)	Solid tumour	In April 2022, the phase 1 investigational new drug application was approved by the NMPA In August 2022, the first patient dosing was completed in a phase 1 clinical trial In February 2023, the phase 2 investigational new drug application for the treatment of advanced non-small cell lung cancer (NSCLC) was accepted by the NMPA

Product name (targets)	Indications	Progress as at the Latest Practicable Date
HANSIZHUANG in combination with chemotherapy (PD-1)	Esophageal squamous cell carcinoma (ESCC)	In May 2022, the phase 3 clinical trial met the primary endpoint
HANSIZHUANG in combination with HANBEITAI and in combination with chemotherapy (PD-1+VEGF)	non-squamous, non-small cell lung cancer (nsNSCLC)	In June 2022, the enrollment of subjects was completed in a phase 3 clinical trial
HLX22 in combination with HANSIZHUANG and in combination with the standard therapy (Trastuzumab and chemotherapy) (HER2+PD-1+HER2)	Gastric cancer (GC)	In August 2022, the phase 2 investigational new drug application was accepted by the NMPA In October 2022, the phase 2 investigational new drug application was approved by the NMPA
HLX208 in combination with HANSIZHUANG and its combination therapies (BRAF V600E+PD-1)	Solid tumour	In November 2022, the phase 1b/2 investigational new drug application was approved by the NMPA In February 2023, the first patient dosing was completed in a phase 1b/2 clinical trial for the treatment of non-small cell lung cancer (NSCLC)
HLX208 (BRAF V600E)	Solid tumour, adult Langerhans Cell Histiocytosis (LCH) and Erdheim-Chester disease (ECD)	In January 2022, a phase 1b/2 investigational new drug application in monotherapy or in combination therapy was approved by the NMPA In January 2022, the first patient dosing was completed in a phase 2 clinical trial
HLX35 (EGFR × 4-1BB)	Solid tumour	In January 2022, the investigational new drug application was approved by the NMPA In June 2022, the first patient dosing was completed in a phase 1 clinical trial

Product name (targets)	Indications	Progress as at the Latest Practicable Date
HLX301 (PD-L1 × TIGIT)	Solid tumour, lymphomas	In March 2022, the investigational new drug application was approved by the NMPA In July 2022, the first patient dosing was completed in a phase 1/2 clinical trial
HLX53 (TIGIT)	Solid tumour, lymphomas	In June 2022, the phase 1 investigational new drug application was approved by the NMPA In December 2022, the first patient dosing was completed in a phase 1 clinical trial
HLX22 (HER2)	Solid tumour	In September 2022, a phase 1 clinical study was completed
HLX60 (GARP)	Solid tumour, lymphomas	In October 2022, the phase 1 investigational new drug application was approved by the NMPA In December 2022, the first patient dosing was completed in a phase 1 clinical trial
HLX15 (CD38)	Multiple myeloma (MM)	In February 2023, the first subject dosing was completed in a phase 1 clinical trial
HLX07 in combination with chemotherapy (EGFR)	Solid tumour	In February 2023, a phase 1b/2 clinical study was completed
Efficient advancement on IND application for pre-clinical development projects		
HLX35 (EGFR × 4-1BB)	Solid tumour	In January 2022, the investigational new drug application was approved by the NMPA (Already in clinical phase)
HLX208 (BRAF V600E)	Solid tumour, adult Langerhans Cell Histiocytosis (LCH) and Erdheim-Chester disease (ECD)	In January 2022, a phase 1b/2 investigational new drug application in monotherapy or in combination therapy was approved by the NMPA (Already in clinical phase)

Product name (targets)	Indications	Progress as at the Latest Practicable Date
HLX301 (PD-L1 × TIGIT)	Solid tumour, lymphomas	In January 2022, the investigational new drug application was accepted by the NMPA In March 2022, the investigational new drug application was approved by the NMPA (Already in clinical phase)
HLX26 in combination with HANSIZHUANG (LAG-3+PD-1)	Solid tumour	In February 2022, the investigational new drug application was accepted by the NMPA In April 2022, the investigational new drug application was approved by the NMPA (Already in clinical phase)
HLX53 (TIGIT)	Solid tumour, lymphomas	In April 2022, the investigational new drug application was accepted by the NMPA In June 2022, the investigational new drug application was approved by the NMPA (Already in clinical phase)
HLX60 in combination with HANSIZHUANG (GARP+PD-1)	Solid tumour	In June 2022, the phase 1 investigational new drug application was submitted in Australia In August 2022, the phase 1 clinical study was approved to commence in Australia (Already in clinical phase)

Product name (targets)	Indications	Progress as at the Latest Practicable Date
HLX60 (GARP)	Solid tumour, lymphomas	In August 2022, the investigational new drug application was accepted by the NMPA In October 2022, the investigational new drug application was approved by the NMPA (Already in clinical phase)
HLX208 in combination with HANSIZHUANG and its combination therapies (BRAF V600E+PD-1)	Solid tumour	In August 2022, the phase 1b/2 investigational new drug application was accepted by the NMPA In November 2022, the phase 1b/2 investigational new drug application was approved by the NMPA (Already in clinical phase)
HLX51 (OX40)	Solid tumour, lymphomas	In January 2023, the investigational new drug application was accepted by the NMPA In March 2023, the investigational new drug application was approved by the NMPA

(IV) Orientation toward clinical value and injecting impetus toward the pipeline

With clinical-value-oriented early study, coordinated with early R&D teams from China and the U.S., based on new discovery driven by deep data and accelerated biocomputing of molecular design technology, the Group has been assiduously cultivating the field of solid tumours, and further expanding into non-oncology disease areas including metabolic, cardiovascular, renal and nervous system disease, and rare diseases where clinical needs are barely met, so that impetus toward the pipeline can be injected. Being independently innovated, the Group has carried out cooperation with external cutting-edge, leading scientific research institutions, and introduced Tumour-Related Target-Sialidase Bifunctional Fusion Protein, ADC platform technology during the Reporting Period, in order to early incubate the cutting-edging ground-breaking science and technologies, bolstering the strength of independent innovation efficiently.

As at the Latest Practicable Date, the Group has 57 molecules (including 10 biosimilar drugs and 47 innovative drugs) in its pipeline, with the form of drug covering monoclonal antibody, bispecific antibody, polyclonal antibody, antibody-drug conjugates(ADC), small molecule-drug conjugates and recombinant protein, etc.

(V) Layout of industrialisation base for biomedicines with high economic benefit based on international standards

As at the end of the Reporting Period, the Group, with a total commercial production capacity of 48,000L (including Xuhui Facility with commercial production capacity of 24,000L and Songjiang First Plant with commercial production capacity of 24,000L), has fully supported the commercialisation needs of domestic and overseas approved marketing products. Meanwhile, the production capacity of 96,000L was under construction (Songjiang Second Plant Phase I Project), and it is expected to be completed by 2026, increasing the total production capacity of the Group to 144,000L. Xuhui Facility, the Group's first biopharmaceutical production base in Shanghai Caohejing Hi-Tech Park has been granted with Chinese and EU GMP certificates and achieved normalised supply in China and the EU markets. In addition, both Songjiang First Plant and Songjiang Second Plant of the Group in Songjiang District, Shanghai also made significant progress during the Reporting Period.

Songjiang First Plant (approved for the production of HANQUYOU with commercial production capacity of 24,000L)

Songjiang First Plant has a commercial production capacity of 24,000L, including the liquid fill line and lyophilised preparation line. In April 2022, the Songjiang First Plant, in which the drug substance west line and east line (with a total production capacity of 24,000L), drug product line and packaging line for the production of HANQUYOU, has passed the drug GMP compliance inspection and it has a quality management system that meets the requirements of China's GMP regulations. In May 2022, HANQUYOU for production site change, production process optimization and production scale expansion of drug product, etc. were approved by the NMPA. The Songjiang First Plant was approved to commence commercial production of HANQUYOU under the optimized new production process in Mainland China. Besides, during the Reporting Period, the Songjiang First Plant has passed certification by Qualified Person (QP) from the EU, indicating that the Songjiang First Plant and its supporting quality management system meet the requirements of EU's GMP regulations, and its products including HLX04-O, HLX11, HLX14 and others were able to conduct clinical trials in Europe.

Songjiang Second Plant (with total planned land area of 200 acres and designed production capacity for Phase I project of 96,000L)

In order to meet the Group's long-term demand on commercial production capacity, the construction of the Phase I project of Songjiang Second Plant, with a total planned land area of 200 acres was started in 2019. The designed production capacity for the first and second stages of this project is totaled 36,000L. Two main production buildings have completed construction, process equipment installation, public system and the adjustment of primary liquid production line in the second half of 2022, and QC laboratory was put into service. The designed production capacity of the third stage of the Phase I project of Songjiang Second Plant was 60,000L (covering a drug substance line consisting of four 15,000L stainless steel reactors) with its piling works, the construction of building envelope and the slab foundation were completed during the Reporting Period, and purchasing process for large equipment was put into use.

(VI) Social responsibility, environmental policies and performance

Adhering to the philosophy of "Affordable Innovation, Reliable Quality", the Group has been committed to providing more affordable and higher quality medicines for global patients, and has actively fulfilled its responsibilities toward stakeholders such as patients, employees, partners, and communities. The Group has placed the legality and compliance as its core operating principle by strictly abiding by the relevant laws and regulations in the regions where it operates by restricting its own behavior. Also, the Group attaches great importance to the establishment and maintenance of relationships with its stakeholders and establishes close relationship with stakeholders through diversified means of communication. During the Reporting Period, the Group sent a questionnaire to stakeholders to have an in-depth knowledge of internal and external stakeholders' assessment and expectations for material ESG related issues, and responded accordingly based on the results of the questionnaire. The Group took corporate social responsibilities as its own duty and gave full play to its own advantages to actively devote to patients public welfare and public health emergency response. During the Reporting Period, the Group initiated a public welfare program named "To the Time to Life" for cancer patients, with the intention of casting light on cancer patients' recovery journeys through arts. It continued the "Excellent Medical Assistance" program and provided support to rural medical development. Amid the resurgence of Covid-19, the Group took quick action to integrate resources to stabilise production, ensure the supply of products and protect the interests of patients, so as to input more resources to communities. In terms of environmental management, the Group continued to improve environmental management system and put multiple management measures into practice under the guidance of environmental objectives. During the Reporting Period, there were no events that led to any major penalties from relevant departments due to environmental issues.

Further information on the Group's social responsibility, environmental policies and performance will be set out in the Environmental, Social and Governance Report to be published by the Company in due course.

II. OUTLOOK FOR 2023

In 2023, the Group will continue to devote to oncology, auto-immune diseases and other fields, and it will explore innovation drugs with clinical orientation by leveraging on its own innovation and R&D strength combined with external cooperation and license-in while maximizing the commercial value of biosimilars at home and abroad, so as to consolidate the internationalised capability of "integrating research, production and marketing", and achieve steady development at a larger, international and more profitable Biopharma stage.

(I) Capitalise on first-entrant advantages and increase the global market coverage of products

As one of the leading biomedicine companies in China, the Group will continue to advance the successful marketing of more products in an all-round efficient commercial operation way, providing global patients with biological drugs of affordable price and high-quality.

HANQUYOU is the Group's first core anti-tumour product promoted and sold within Mainland China as led by its self-built commercialisation team. In 2023, the Group will take further actions to promote the inclusion of HANQUYOU (both 150mg and 60mg) into medical insurance procurement platforms, and continue to optimize the diagnosis and treatment ecosystem for HER2-positive patients. It will also enhance the development of patient's management and education platform, and build a follow-up platform for patients through external cooperation, provide some facilitation measures for HANQUYOU patients, including reminder for return visit and online simple consultation, enabling more patients to have access to standardized treatment.

HANSIZHUANG is one of the Group's core innovative monoclonal antibody products. In 2023, the Group plans to further expand the sales team of HANSIZHUANG, and set up a dedicated sales team for gastrointestinal tumours in advance, so as to prepare for the potential marketing of HANSIZHUANG for the treatment of esophageal squamous cell carcinoma (ESCC) indication in the near future, thereby grasping the market potential of HANSIZHUANG to the maximum extent possible. While making marketing and sales planning, the Group will team up with business partners to develop full process solutions for the management of patients, and further explore commercial insurance and the feasibility of innovative payments, thus improving medication compliance and standard treatment rate of patients.

In 2023, the Group will establish a dedicated sales team to sell HANBEITAI, covering cities adopting dual-channel medical insurance payment.

Jiangsu Fosun and Jiangsu Wanbang, subsidiaries of Fosun Pharma, the controlling shareholder of the Company, are responsible for the domestic commercial sale of HANLIKANG and HANDAYUAN, respectively. In 2023, the Group will maintain close cooperation with Jiangsu Fosun and Jiangsu Wanbang to capture the first mover advantage of the two drugs in China, thereby promoting the sustained growth of sales.

While actively expanding the domestic market, the Group will constantly promote the business cooperation of its self-developed products in the international market. With the continuous advancement of the R&D and registration of pipeline products of the Group and the gradual recognition of the Group's products of the international market, the Group will continue to seek business cooperations with more international leading pharmaceutical companies to jointly promote the expansion of our products into broader international markets, especially emerging markets with huge unmet medical needs for affordable drugs, which will benefit patients overseas.

(II) Continue to facilitate the approvals of more products for new indications

HANSIZHUANG is the core innovative monoclonal antibody product of the Group, which is also the first commercial innovation of the Group. The Group promotes the marketing of HANSIZHUANG for other indications and combination therapies related to HANSIZHUANG while pushing the launch of other innovative products with experiences gained along the way.

- The new drug application (NDA) for HANSIZHUANG in combination with chemotherapy for the first-line treatment of new indication of locally advanced/recurrent or metastatic esophageal squamous cell carcinoma (ESCC) is expected to be approved in Mainland China in the second half of 2023.

- The new drug application (NDA) for HANSIZHUANG in combination with chemotherapy for the first-line treatment of metastatic non-squamous non-small cell lung cancer (nsNSCLC) is scheduled to be submitted in Mainland China in the second half of 2023.

- The marketing authorisation application (MAA) for HANSIZHUANG in combination with chemotherapy for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) is expected to be approved in EU in the first half of 2024.

- The biologics license application (BLA) for HANSIZHUANG in combination with chemotherapy for the treatment of the indication of extensive-stage small cell lung cancer (ES-SCLC) is scheduled to be submitted in the United States in the first half of 2024.

In 2023, the Group will also proactively cooperate with international partners to facilitate the marketing approval process in terms of HANQUYOU, HANSIZHUANG, HANLIKANG, HANDAYUAN and HANBEITAI in the United States, Singapore, Brazil, Indonesia and other regions. The biologics license application (BLA) for HANQUYOU for adjuvant treatment of HER2 overexpressing breast cancer, the treatment of HER2 overexpressing metastatic breast cancer and the treatment of HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma is expected to be approved in the United States in late 2023.

(III) Continue to build innovative product pipeline through iterating R&D capabilities

The Group will continue to leverage international resources and advantages to explore cutting-edge innovative products with clinical value, and deepen the early R&D results, with a view to addressing unmet clinical needs as soon as possible. In 2023, some of the early-stage innovative products in Group's pipeline are expected to be further promoted:

- The phase 1 investigational new drug application (IND) of HLX42 (antibody-drug conjugate targeting EGFR) for the treatment of solid tumours is expected to be submitted to the NMPA in the second half of 2023.

- The phase 1 investigational new drug application (IND) of HLX43 (antibody-drug conjugate targeting PD-L1) for the treatment of solid tumours is expected to be submitted to the NMPA in the second half of 2023.

- The phase 1 investigational new drug application (IND) of HLX6018 (monoclonal antibody targeting the GARP/TGFβ1 complex) for the treatment of chronic inflammatory diseases is expected to be submitted to the NMPA in the second half of 2023.

(IV) Maintain the international high quality standards and continue to promote industrialisation deployment

The Group proactively plans the construction of production bases and the expansion of production capacity in accordance with the process of product R&D and marketing, providing a strong guarantee for the commercial sales of products. The Group's Xuhui Facility will continue to adopt a series of lean management and process optimization measures in 2023 to ensure the stability and efficiency of international commercial production, and plan to complete the GMP compliance inspection before the launch of HANSIZHUANG in the EU in 2023. In 2023, Songjiang First Plant will continuously improve the international standard quality system and plan to complete the GMP compliance inspection of HANQUYOU before its launch in the United States.

The verification work of facilities and equipment for the two main production buildings in the first and second stage of the Songjiang Second Plant Phase I Project are expected to be completed in the first half of 2023. The first batch production of the Songjiang Second Plant project is expected to be completed in 2023. The topping of the main structure of the third stage of the Songjiang Second Plant Phase I project is expected to be completed in 2023. The Group will promote the construction and operation of the Songjiang Second Plant as soon as possible. When completed, the Songjiang Second Plant will become the monoclonal antibody biological drug R&D, pilot test and production base of the Group. This will further enhance the market competitiveness of the Group in its core business areas and meet the global commercial production needs of the Group's products.

III. FINANCIAL REVIEW

(I) Revenue

During the Reporting Period, the Group capitalised on its first-mover advantages and expanded the market coverage of products, actively improved the commercialisation layout aligning with multiple and targeted market strategies and the keen and efficient capacity for selling products to build a powerful commercialisation capability, and to lay the solid foundation for successful commercialisation of later products and high-quality treatment options for more patients. During the Reporting Period, HANQUYOU, the first core product of the Group in the field of anti-tumour therapy that was promoted and sold by the Group's in-house commercialisation team in Mainland China, continued to rise in its sales at a high speed with encouraging results; HANSIZHUANG, the first self-developed and approved bio-innovative drugs of the Group, was approved for marketing in Mainland China in March 2022, and recorded substantial sales revenue during the Reporting Period.

With continuous advancement of the R&D and registration of rich and diversified pipeline products of the Group, and the increasing understanding and full recognition of the Group's products from the international market, the Group worked hard to march into the mainstream biologics market in Europe and the United States. Meanwhile, the Group focused on its expansion into emerging markets in its globalization strategy, proactively promoting internationalised layout, quickening the pace of international operation strategy, and keeping efforts on innovation. During the Reporting Period, the Group cooperated with partners and continued to expand overseas markets to deliver benefits to the patients around the world and brought in considerable licensing income and R&D service income.

During the Reporting Period, the Group realised an operating income of RMB3,214.7 million, representing an increase of 91.1% compared to the same period in the last year, and the main revenue components are as follows:

1) Revenue from product sales:

HANQUYOU was the first domestic trastuzumab approved for marketing independently developed by the Group and was also the first product of the Group to adopt its in-house team to conduct commercialisation promotion. It was commercially available in the domestic market in August 2020. During the Reporting Period, HANQUYOU recorded a sales revenue of approximately RMB1,694.4 million, representing a dramatic increase of approximately RMB826.4 million or approximately 95.2% as compared to the same period in the last year. Meanwhile, drug substance of trastuzumab recorded sales revenue of approximately RMB1.5 million in Mainland China.

HANSIZHUANG (serplulimab) was the first self-developed and approved bio-innovative drugs of the Group and was commercially available in the domestic market in March 2022. The approval of HANSIZHUANG will further enrich the Group's commercial product line and will also bring more treatment options for domestic patients. During the Reporting Period, HANSIZHUANG recorded sales revenue of approximately RMB339.1 million.

In respect of HANLIKANG (rituximab), according to the cooperation agreement with Fosun Pharma, Fosun Pharma would reimburse all the expenses related to the clinical trials of HANLIKANG incurred by the Group after the relevant cooperation agreement was signed, and the Group was responsible for the production of HANLIKANG in China and the supply of HANLIKANG to Fosun Pharma after the commercialisation of HANLIKANG, and shall share the profits from the sales of HANLIKANG in China. During the Reporting Period, the Group recorded sales revenue of approximately RMB553.9 million, and licensing income of approximately RMB20.9 million under the aforementioned profit-sharing arrangement with its partners.

In respect of HANDAYUAN (adalimumab), according to the cooperation agreement with Fosun Pharma, Fosun Pharma will reimburse all the expenses related to the clinical trials of HANDAYUAN incurred by the Group after the relevant cooperation agreement is signed, and the Group is responsible for the production of HANDAYUAN in China and the supply of HANDAYUAN to Fosun Pharma after the commercialisation of HANDAYUAN, and shall share the profits from the sales of HANDAYUAN in China. During the Reporting Period, HANDAYUAN recorded sales revenue of approximately RMB51.2 million and licensing income of approximately RMB2.6 million under the aforementioned profit-sharing arrangement with its partners.

Zercepac® (trastuzumab, European brand name) recorded revenue of approximately RMB26.5 million during the Reporting Period, and drug substance of trastuzumab recorded sales revenue of approximately RMB8.8 million in international market.

2) Revenue from joint development and technology transfer/commercialisation licensing

The Group has focused on clinical needs for a long time, proactively promoted internationalised layout, and quickened the pace of international operation strategy with persistence. The Group has built an integrated biopharmaceutical platform with innovative capabilities throughout the entire industry chain of R&D, production and commercial operations. Meanwhile, with the continuous improvement of the R&D system and innovation capabilities of the Group, our influence in the international market is growing, the number and overall amount of licensed-out projects are constantly expanding. During the Reporting Period, the Group also carried out business cooperation with many partners around the world based on various projects, including intellectual property licensing, joint development, commercial authorisation etc., which further improved the accessibility and influence of Company's products in global market, bringing hope to more patients.

In June 2018, the Group entered into a license agreement with Accord in relation to HANQUYOU (European brand name: Zercepac®), granting Accord exclusive commercialisation rights in special territories as agreed therein. In July 2020, the marketing authorisation application of Zercepac® submitted by a wholly-owned subsidiary of Accord was approved. Since then, Zercepac® has been the first "Chinese" monoclonal antibody biosimilar drug approved for sale in the EU. The Group has recognised licensing revenue and revenue from R&D services of approximately RMB4.7 million for the 12 months ended 31 December 2022.

In September 2019, the Group entered into a co-development and commercialisation agreement with PT Kalbe Genexine Biologics in relation to HANSIZHUANG (serplulimab). With the continuous advancement of R&D services, the Group has recognised revenue from R&D services of approximately RMB6.2 million for the 12 months ended 31 December 2022.

In October 2020, the Group entered into a co-development and exclusive license agreement with Essex Bio-Investment Limited and Zhuhai Essex Bio-Pharmaceutical Co., Ltd. *(珠海億勝生物製藥有限公司) in relation to the HLX04-O (recombinant humanised anti-VEGF monoclonal antibody injection) independently developed by the Group. The Group has recognised revenue from R&D services of approximately RMB116.3 million for the 12 months ended 31 December 2022.

In November 2020, the Group entered into a license and co-development agreement with Binacea Pharma Inc. in relation to HLX35 (recombinant humanised anti-EGFR and anti-4-1BB bispecific antibody injection) independently developed by the Group. The Group has recognized licensing revenue of approximately RMB19.0 million for the 12 months ended 31 December 2022.

In January 2021, the Group entered into a license agreement with Intas in relation to HANQUYOU (European brand name: Zercepac®), granting Intas exclusive developing and commercial rights in special territories as agreed therein. The Group has recognised licensing revenue of approximately RMB163.9 million for the 12 months ended 31 December 2022.

In June 2022, the Group entered into a license and supply agreement with Organon LLC, granting Organon LLC and its affiliates exclusive right to commercialise two products independently developed by the Group, being HLX11 (recombinant anti-HER2 domain II humanised monoclonal antibody injection) and HLX14 (recombinant anti-RANKL human monoclonal antibody injection) worldwide except for China, fully covering the U.S., EU, Japan and other major biomedicine markets and many emerging markets. The Group has recognised revenue from R&D services of approximately RMB143.1 million for the 12 months ended 31 December 2022.

3) Revenue from other R&D service businesses

In February 2022, the Group entered into a technical service contract with Shanghai Zhenge Biotech Co., Ltd.* (上海臻格生物技術有限公司) in relation to the study and production of freeze-dried formulation at IND stage, an antibody drug under development. With the continuous advancement of technical service, the Group recognised revenue from R&D service of approximately RMB2.6 million for the 12 months ended 31 December 2022.

In March 2022, the Group entered into a Fosun Pharma industrial technical services agreement with Fosun Pharma Industrial Development in relation to provision of CMC and pre-clinical toxicology research services to Fosun Pharma Industrial Development for an antibody drug FS2101 under development. The Group recognised revenue from R&D services of approximately RMB30.7 million for the 12 months ended 31 December 2022.

In March 2022, Fosun Pharma Industrial Development was in the process of licensing the antibody drug FS2101 to Zhejiang Xinghao Pengbo Pharmaceutical Co., Ltd.* (浙江星浩澎博醫藥有限公司) ("**Xinghao Pengbo**"), a subsidiary of Fosun Pharma. In anticipation of such license and to ensure seamless services to be provided in respect of FS2101, the Group entered into the Technical Services Agreement with Xinghao Pengbo, pursuant to which the Group agreed to provide additional CMC and preclinical bioanalysis technical services to Xinghao Pengbo in relation to FS2101. For the 12 months ended 31 December 2022, the Group recognised revenue from R&D services of approximately RMB5.6 million.

In November 2022, the Group entered into the Clinical Trial Research Services Agreement with Henan Genuine Biotech Co., Ltd.* (河南真實生物科技有限公司) and Fosun Pharma Industrial Development in relation to provision of clinical trial research services regarding the prevention of SARS-Cov-2 of Azvudine. For the 12 months ended 31 December 2022, the Group recognised revenue from R&D service of approximately RMB18.0 million.

(II) Cost of sales

Cost of sales of the Group primarily represents reagents and consumables, employee compensation, outsourcing expenses, utilities expenses and depreciation and amortisation. For the 12 months ended 31 December 2022, the Group recorded cost of sales of approximately RMB844.6 million, representing an increase of approximately RMB321.9 million as compared with that for the 12 months ended 31 December 2021, due to the increase of the sales volume of the key commercial product markets.

(III) Gross profit

For the 12 months ended 31 December 2022, the Group recorded a gross profit of approximately RMB2,370.1 million, representing an increase of approximately RMB1,210.4 million, as compared with that for the 12 months ended 31 December 2021, mainly due to the continuous growth of sales from HANQUYOU and HANSIZHUANG, the key commercial products of the Group.

(IV) Other income and gains

Other income of the Group mainly included government grants, exchange gains and bank interest income. Government grants included (1) government grants for capital expenditure in relation to the purchase of machinery and equipment (recognised over the useful life of the relevant assets); (2) incentives for R&D activities and other grants (recognised after satisfying certain conditions imposed by the government).

During the Reporting Period, the Group recognised other income and gains of approximately RMB105.6 million.

	Year ended 31 December	
	2022	2021
	RMB'000	*RMB'000*
Government grants	**69,043**	41,896
Exchange gains	**32,919**	–
Interest income	**3,571**	2,686
Others	**19**	509
Total	**105,552**	45,091

(V) R&D expenditure

	Year ended 31 December	
	2022	2021
	RMB'000	*RMB'000*
Expensed R&D expenses		
R&D employee salaries	**460,783**	338,988
Outsourcing fees	**296,959**	152,730
Clinical trials	**212,151**	90,850
Reagents and consumables	**134,850**	92,712
Depreciation and amortisation	**94,059**	87,171
Consulting expense	**51,430**	24,709
Technology expense	**45,288**	136,808
Utilities expenses	**19,161**	15,822
Share-based compensation	**1,446**	13,188
Others	**78,387**	70,953
Total expensed R&D expenses	**1,394,514**	1,023,930

	Year ended 31 December	
	2022	2021
	RMB'000	*RMB'000*
Capitalised R&D expenses		
Clinical trials	**519,408**	420,143
R&D employee salaries	**153,850**	195,413
Outsourcing fees	**24,227**	4,593
Depreciation and amortisation	**23,890**	37,669
Reagents and consumables	**15,020**	36,849
Consulting expense	**3,263**	2,858
Utilities expenses	**1,380**	28,650
Share-based compensation	**707**	4,519
Others	**46,943**	9,100
Total capitalised R&D expenses	**788,688**	739,793

For the 12 months ended 31 December 2022, the Group recognised R&D expenses of approximately RMB2,183.2 million, representing an increase of approximately RMB419.5 million as compared with that of approximately RMB1,763.7 million for the 12 months ended 31 December 2021. The increase in R&D expenses was mainly due to the increase of investment in innovative R&D projects to accelerate the Group's innovation and transformation.

(VI) Administrative expenses

Administrative expenses mainly included administrative staff costs, office administrative expenses, depreciation and amortisation, audit and consulting fees, etc.

For the 12 months ended 31 December 2022, the Group recognised administrative expenses of approximately RMB354.0 million as compared with that of approximately RMB280.6 million for the 12 months ended 31 December 2021, representing an increase of approximately RMB73.4 million. The increase in administrative expenses of the Group was mainly due to: (1) the increase in the cost of the administrative staff resulted from the expansion of the operations and development of the Group and its higher requirements for compliance; and (2) the corresponding increase in office administrative expenses, depreciation costs and software expenses to accelerate its drift to digits and improve operational efficiency.

(VII) Selling and distribution expenses

Selling and distribution expenses of the Group mainly included salaries, promotional expenses and other expenses, etc.

For the 12 months ended 31 December 2022, the Group recognised selling and distribution expenses of approximately RMB1,049.3 million, which were mainly the marketing expenses incurred in continuous sales growth of HANQUYOU and the marketing and selling of HANSIZHUANG. Among which, the marketing expenses ratio of HANQUYOU in domestic market has been decreasing over the years, and to below 40% by 2022.

(VIII) Other expenses

For the 12 months ended 31 December 2022, the Group recognised other expenses of approximately RMB264.4 million, which mainly included: (1) investment loss related to the entrusted investment management services by AMTD Global Markets Limited; (2) expenses on pharmaceutical donations; and (3) loss on devaluation of inventories of raw materials, semi-finished products and finished products.

(IX) Income tax expense

For the 12 months ended 31 December 2022, the Group incurred income tax expense of approximately RMB1.4 million.

(X) Loss for the year

In view of the above, loss of the Group decreased by approximately RMB288.8 million from approximately RMB984.1 million for the year ended 31 December 2021 to approximately RMB695.3 million for the year ended 31 December 2022.

(XI) Liquidity and capital resources

As of 31 December 2022, cash and bank balances of the Group were approximately RMB680.5 million, mainly denominated in Renminbi ("**RMB**"), United States Dollars ("**USD**"), New Taiwan Dollars ("**NTD**"), Hong Kong Dollars ("**HKD**") and Euro ("**EUR**"), compared to cash and bank balances of the Group approximately RMB707.3 million as of 31 December 2021, representing a decrease of approximately RMB26.8 million. Such decrease was mainly due to the daily R&D expenses of the Group.

As of 31 December 2022, the current assets of the Group were approximately RMB2,191.5 million, including cash and cash equivalents of approximately RMB673.5 million, pledged deposits of approximately RMB7.0 million, inventories were approximately RMB757.3 million, trade receivables were approximately RMB455.5 million, and other receivables were approximately RMB138.0 million, and financial assets at fair value through profit or loss amounted to approximately RMB160.2 million.

As at 31 December 2022, the current liabilities of the Group were approximately RMB5,001.6 million, including trade payables of approximately RMB713.6 million, other payables and accruals of approximately RMB1,443.4 million, contract liabilities of RMB322.4 million and interest-bearing bank and other borrowings of approximately RMB2,522.2 million.

As at 31 December 2022, the bank balances in foreign exchange were as follows:

	RMB'000
RMB	552,890
HKD	7,060
USD	115,725
EUR	385
NTD	4,418

	Original amount '000
RMB	552,890
HKD	7,904
USD	16,612
EUR	52
NTD	19,439

(XII) Inventories

Inventories of the Group increased from approximately RMB420.1 million as at 31 December 2021 to approximately RMB757.3 million as at 31 December 2022, mainly due to (1) the increased purchases of raw materials and consumables in line with the clinical trial progress and preparation for commercialised production; (2) more safety stock is prepared with the increasing demand for key commercial products.

(XIII) Trade receivables

As at 31 December 2021 and 31 December 2022, trade receivables from customer contracts were approximately RMB295.7 million and RMB455.5 million, respectively. There were no changes in accounting estimates or key assumptions made in both years.

	As at 31 December	
	2022	2021
	RMB'000	*RMB'000*
Within 3 months	**373,226**	295,741
3 to 6 months	**114**	–
6 to 12 months	**20,877**	–
1 to 2 years	**61,292**	–
Total	**455,509**	295,741

(XIV) Interest-bearing bank and other borrowings

As of 31 December 2022, borrowings from bank and other institutions (exclusive of lease liabilities) of the Group were approximately RMB3,416.0 million. The Group incurred new borrowings for the following reasons: ongoing clinical research trials and preclinical research for drug candidates, selling expenses of commercialisation of products, plant construction and normal operating expenses. The borrowings of the Group were denominated in RMB and USD.

Such borrowings bear interest at fixed annual and floating interest rates. There is no significant seasonal impact on the Group's borrowing requirements.

(XV) Maturity structure of outstanding debts

The following table sets forth the maturity structure of outstanding debts as at 31 December 2022 and 31 December 2021, of which lease liabilities were initially recognised upon the adoption of IFRS 16 – Leases on 1 January 2017.

	As at 31 December	
	2022	2021
	RMB'000	*RMB'000*
Within one year	**2,522,155**	1,570,674
In the second year	**155,864**	318,790
In the third to fifth year (inclusive)	**704,137**	177,956
Over five years	**294,939**	555,517
Total	**3,677,095**	2,622,937

(XVI) Collateral and pledged assets

As at 31 December 2022, the Group's pledged assets in relation to borrowings included property, plant and equipment of approximately RMB664.9 million and land use right of approximately RMB196.8 million. The Group had a deposit of approximately RMB7.0 million due to issuance of letter of guarantee.

(XVII) Key financial ratios

	31 December 2022	31 December 2021
Current ratio[(1)]:	**43.8%**	55.7%
Quick ratio[(2)]:	**28.7%**	41.5%
Gearing ratio[(3)]:	**64.7%**	51.8%

Notes:

(1) Current ratio is calculated as current assets divided by current liabilities as at the same day.

(2) Quick ratio is calculated as current assets minus inventories and then divided by current liabilities as of the same day.

(3) Gearing ratio is calculated as net debt divided by equity attributable to owners of the parent plus net debt, multiplied by 100%. Net debt represents the balance of indebtedness less cash and cash equivalents as at the end of the period.

(XVIII) Material investment

In order to satisfy the expected market demand for drug candidates, the Group is currently constructing a new manufacturing facility in Shanghai, the Songjiang Second Plant, to significantly increase our overall production capacity. We designed the Songjiang Second Plant to incorporate substantially similar manufacturing equipment, technologies and processes as those being used and to be implemented at our Xuhui Facility. This project is expected to become the monoclonal antibody biological drug R&D, pilot test and production base of the Group when completed, which is conducive to further strengthening the Group's R&D capabilities in the field of biomedicine (especially monoclonal antibody biomedicine) and meeting the global commercial production needs of the Group's biosimilar and bioinnovative products.

The Group is expected to invest not more than RMB2.54 billion for the construction of the Phase I project of the Songjiang Second Plant (first stage, second stage and third stage). As at the end of the Reporting Period, the facility is under construction and the subsequent stages of construction will be gradually carried out based on the strategy of the Group. The capital expenditure of the construction of the Songjiang Second Plant will be mainly funded through debt financing.

(XIX) Capital commitments and capital expenditures

	As at 31 December	
	2022	2021
	RMB'000	*RMB'000*
Construction in progress	**624,228**	250,773
Plant and machinery	**45,116**	55,745
Electronic equipment	**29,142**	14,096
Leasehold improvements	**13,754**	45,706
Others	**–**	378
Total	**712,240**	366,698

We had capital commitments for plant and machinery contracted but not provided for of approximately RMB297.2 million as at 31 December 2022. These capital commitments primarily relate to expenditures expected to be incurred for the purchase of machinery, renovation of our existing laboratories and buildings and the R&D expenditure to be capitalised.

(XX) Contingent liabilities

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

(XXI) Material acquisitions and disposals

As of 31 December 2022, the Group did not have any material acquisitions and disposals.

(XXII) Dividends

The Group did not pay or declare any dividend for the year ended 31 December 2022.

IV. RISK MANAGEMENT

(I) Foreign exchange risk

Up until 31 December 2022, the Group was principally engaged in business in the PRC, in which most of the transactions were settled in RMB with no significant foreign exchange risk. No financial instrument for hedging foreign exchange risk or other hedging purposes was employed.

(II) Exchange rate risk

Currently, the major business operation of the Group is in the PRC and most of the revenue and expenses are settled in RMB, which is the Group's reporting currency. With the acceleration of the Group's development in overseas markets, it is expected that the sales revenue and licensing revenue denominated in USD and EUR will increase in the future. Fluctuations in exchange rates may affect the Group's cash flows, revenues, earnings and financial position.

(III) Potential risks

1. Market Risk

The biologics market is highly competitive, and the Group's existing commercialised products and products that may be commercialised in the future face competition from pharmaceutical companies around the world in respect of various factors such as indication treatment, drug novelty, drug quality and reputation, breadth of drug portfolio, manufacturing and distribution capacity, drug price, breadth and depth of customer coverage, consumer behaviour and supply chain relationships. The Group's ability to remain competitive depends to a large extent on our ability to innovate, develop and promote new products and technologies that meet market needs in a timely manner to capture market share. At the same time, in October 2020, in the "Response to the Recommendation of No. 6450 of the Third Session of the 13th NPC", the National Healthcare Security Administration stated that centralised volume-based procurement will commence at an appropriate time, after considering the factors of the biosimilar similarity, production capacity and supply chain stability of companies and the clinical substitutability of specific products. Currently, certain biosimilar has already been included in the application scope of centralised drug procurement at the provincial level. If any of our products are included in the centralised volume-based procurement in the future, our rivals (if they are evaluated on equivalence) may also choose to participate in tenders and be included in centralised procurement, hence bringing potential impact on the pricing of the drugs.

2. Business and Operational Risk

The global biologics market is constantly evolving, and the Group invests significant amounts of human and capital resources for R&D, to develop, enhance or acquire technologies that will allow the Group to expand the scope and improve the quality of the services. Currently, the commercially available products of the Group include: HANLIKANG, HANQUYOU, HANDAYUAN, HANBEITAI and HANSIZHUANG. Most of the Group's drug candidates are still under development and are in the clinical development stages, and the course of clinical development involves a lengthy and expensive process with uncertainties in various aspects, as there can be no assurance from the Group of the development and clinical results. Furthermore, if the clinical development and regulatory approval process of the drug candidates are delayed or terminated, the successful development and commercialisation of the Group's drug candidates in a timely manner may be adversely affected.

3. Potential Risks of COVID-19

After the outbreak of COVID-19, the Group immediately adopted anti-epidemic measures, to secure employees' safety and guarantee to carry out a variety of work duties in an orderly manner. In the first half of 2022, the repeated spread of COVID-19 in Shanghai and other cities in China exerted certain negative impacts on the Group's operations in China. Although the epidemic situation has eased during the second half of 2022, there are still uncertainties on its impacts on China and the world in the future.

4. Force Majeure Risk

Our business, financial condition and results of operations may be materially and adversely affected by natural disasters or other unanticipated catastrophic events such as earthquakes, fires, terrorist attacks and wars. For example, the ability of our facilities to operate may be impaired, our equipment may be damaged, the development timeline of our drug candidates may be prolonged and even there may be a decrease in the demand for our products. The occurrence of any such event could adversely affect our business and financial condition.

V. EMPLOYEES AND REMUNERATION POLICIES

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

Function	**Number of employees**
R&D and technology	1,130
Manufacturing	966
Commercial Operation	1,045
General and administrative	265
Total	**3,406**

The individual employment contracts entered into by the Group with our employees set out terms such as salaries, bonuses, grounds for termination and confidentiality. Employment contracts with our R&D personnel also typically contain a non-competition clause. The Group also provides benefits to our employees as part of their compensation package which we believe are in line with industry norms. For example, PRC-based employees are entitled to employee benefits as mandated by the PRC Social Insurance Law and Regulations on the Administration of Housing Provident Fund, including pension, basic medical insurance, maternity insurance, work-related injury insurance, unemployment insurance and housing provident fund. To stay competitive in the market for talents, we have also adopted share award schemes to give incentives to our employees. The Group emphasises on-the-job training as a constant and ongoing objective for the employees. All employees participate in formal training on an annual basis, where the Group focuses on the latest technical developments and updates in regulatory requirements.

COMMUNICATION WITH SHAREHOLDERS AND INVESTORS

The Group is committed to creating two-way channels of communication between senior management and investors, maintaining close relations with the shareholders through a variety of channels and promoting understanding and communication between investors and the Group. The Company has adopted a shareholders' communication policy to formalise and facilitate the effective and healthy communication between the Company and the shareholders and other stakeholders, which is available on the website of the Group (http://www.henlius.com). The main communication channels with the shareholders include investors' meetings, general meetings, annual reports, interim reports, announcements and circulars, prospectus and the Group's website.

The Group has a dedicated team to maintain contact with investors and handle shareholders' inquiries. Should investors have any inquiries, please contact the Group's investor relationship department (email: ir@henlius.com).

FINAL DIVIDEND

The Board does not recommend the payment of a final dividend for the Reporting Period.

AGM AND PERIOD OF CLOSURE OF REGISTER OF MEMBERS OF H SHARES

The Company will arrange the time of convening the forthcoming annual general meeting (the"**AGM**") as soon as practicable, and the notice of the AGM will be published and dispatched to the shareholders in a timely manner in accordance with the requirements of the Rules Governing the Listing of Securities on the Stock Exchange (the "**Listing Rules**") and the articles of association of the Company (the "**Articles of Association**"). Once the date of the AGM is finalised, the Company will publish the period of closure of the register of members of H shares of the Company in a separate announcement and in the notice of the AGM.

PURCHASE, SALE AND REDEMPTION OF LISTED SECURITIES

During the Reporting Period, neither the Company nor any of its subsidiaries have purchased, sold or redeemed any of the Company's listed securities.

COMPLIANCE WITH CORPORATE GOVERNANCE CODE

The Company's corporate governance practices are based on the principles and code provisions set forth in the Corporate Governance Code (the "**CG Code**") contained in Appendix 14 to the Listing Rules.

Code provision C.2.1 of the CG Code provides that the roles of chairman and chief executive should be separate and should not be performed by the same individual. From 30 November 2021, Mr. Wenjie Zhang assumed the roles of both chairman and chief executive officer, the Company deviated from the requirements set out in code provision C.2.1 of the CG Code. Mr. Wenjie Zhang joined the Company in March 2019 and has successively served in various key positions in the Company, including the chief commercial operation officer and chief strategy officer of the Company, his familiarity with the business operation of the Company and his roles as the Chairman of the Board and the Chief Executive Officer of the Company can facilitate the formulation and implementation of business strategies of the Company. The Board considered that the current structure will not impair the balance of power and authority between the Board and the management of the Company. The Board will make decisions on important matters of the Company within the authority granted by the Articles of Association and its shareholders at the general meetings. In addition, the Board, which currently comprises one executive director, five non-executive directors and four independent non-executive directors, is appropriately structured with a balance of power to provide sufficient checks to protect the interests of the Company and the shareholders as a whole.

Save as disclosed above, during the Reporting Period, the Company has complied with all the principles and code provisions as set out in the CG Code.

COMPLIANCE WITH CODE FOR SECURITIES TRANSACTIONS

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 code of conduct regarding directors' securities transactions. Having made specific enquiries to all of the directors of the Company, all directors of the Company confirmed that they have fully complied with all relevant requirements set out in the Model Code during the Reporting Period.

EXTRACT OF INDEPENDENT AUDITOR'S REPORT ON THE GROUP'S CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2022

Qualified Opinion

In our opinion, except for the effects of the matters described in the "Basis for qualified opinion" section of our report, the consolidated financial statements give a true and fair view of the consolidated financial position of the Group as at 31 December 2022, and of its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with International Financial Reporting Standards ("**IFRSs**") issued by the International Accounting Standards Board ("**IASB**") and have been properly prepared in compliance with the disclosure requirements of the Hong Kong Companies Ordinance.

Basis for qualified opinion

As explained in note 20 to the consolidated financial statements, on 25 September 2019, the Company entered into an investment management agreement (the "**IMA**") with AMTD Global Markets Limited ("**AMTD**"). Pursuant to the IMA, the Company deposited a total amount of USD117,000,000 into the investment portfolio account with AMTD (the "**AMTD Account**") and engaged AMTD to provide investment management services. During the years ended 31 December 2020 and 2021, the Company redeemed in total of USD30,640,000 from AMTD and a provision of USD30,000,000 (equivalent to RMB191,271,000) was provided for potential losses based on the Company's best estimate, with the assistance of an external legal counsel, in the year ended 31 December 2021. As at 31 December 2021, the outstanding balance in the AMTD Account amounted to USD86,360,000 (equivalent to RMB550,610,000) and was recorded in restricted cash and bank balances and the provision was recorded in other payables and accruals.

The management of the Company represented that during the year ended 31 December 2022, the Company entered into notes purchase agreements to purchase promissory notes issued by three private entities (collectively, the "**Notes**") with the total principal amounts of USD86,360,000 (equivalent to RMB550,610,000) through the AMTD Account, which was recorded in financial assets at fair value through profit or loss. The Company has engaged an independent valuer to assess the fair value of the Notes and concluded that the fair value of the Notes as at 31 December 2022 was USD23,000,000 (equivalent to RMB160,186,000) giving rise to a total fair value loss of RMB390,424,000.

The management of the Company provided us with the AMTD Account statement as at 31 December 2022 obtained from AMTD. However, the management of the Company were unable to provide us with the signed notes purchase agreements or other adequate evidence to support the existence and valuation of the Notes. We were not able to obtain the necessary corroborative evidence from the counterparties of the Notes neither. Because of the above scope limitations, and there were no alternative audit procedures that we could perform, we are unable to satisfy ourselves as to whether any adjustments are necessary to the following accounts and disclosures in the consolidated financial statements: i) the financial assets at fair value through profit or loss amounted to RMB160,186,000 as at 31 December 2022 as stated in consolidated statement

of financial position and disclosed in note 20 to the consolidated financial statements; ii) other expenses amounted to RMB199,153,000 representing the additional net fair value losses charged to the consolidated statement of profit and loss for the year ended 31 December 2022 and disclosed in note 7 to the consolidated financial statements; and iii) "Changes in restricted cash for investments" amounted to RMB550,610,000 and "Purchase of investment measured at fair value through profit or loss" amounted to RMB550,610,000 as stated in the statement of consolidated cashflow for the year ended 31 December 2022. Any adjustments to the figures as described above might have a consequential effect on the Group's financial performance and cash flows for the year ended 31 December 2022 and the financial position of the Group as at 31 December 2022 and the related disclosures thereof in the consolidated financial statements.

We conducted our audit in accordance with Hong Kong Standards on Auditing ("**HKSAs**") issued by the Hong Kong Institute of Certified Public Accountants ("**HKICPA**"). Our responsibilities under those standards are further described in the *Auditor's responsibilities for the audit of the consolidated financial statements* section of our report. We are independent of the Group in accordance with the HKICPA's *Code of Ethics for Professional Accountants* (the "**Code**"), and we have fulfilled our other ethical responsibilities in accordance with the Code. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our qualified opinion.

AUDIT COMMITTEE

The audit committee of the Company has reviewed the Group's 2022 annual results and the financial statements for the year ended 31 December 2022 prepared in accordance with the IFRSs.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS

Year ended 31 December 2022

	Notes	**2022** ***RMB'000***	2021 *RMB'000*
REVENUE	*3*	**3,214,730**	1,682,472
Cost of sales		**(844,621)**	(522,748)
Gross profit		**2,370,109**	1,159,724
Other income and gains	*4*	**105,552**	45,091
Selling and distribution expenses		**(1,049,292)**	(520,261)
Administrative expenses		**(354,038)**	(280,606)
Impairment losses on financial assets, net		**(1,638)**	(174)
Research and development expenses		**(1,394,514)**	(1,023,930)
Other expenses		**(264,394)**	(251,763)
Finance costs	*6*	**(105,672)**	(84,820)
LOSS BEFORE TAX	*5*	**(693,887)**	(956,739)
Income tax expense	*7*	**(1,372)**	(27,313)
LOSS FOR THE YEAR		**(695,259)**	(984,052)
Attributable to:			
Owners of the parent		**(695,259)**	(984,052)
Non-controlling interests		**–**	–
		(695,259)	(984,052)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted (RMB)	*9*	**(1.28)**	(1.83)

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

Year ended 31 December 2022

	2022	2021
	RMB'000	RMB'000
LOSS FOR THE YEAR	**(695,259)**	(984,052)
OTHER COMPREHENSIVE LOSS		
Other comprehensive loss that may be reclassified to profit or loss in subsequent periods:		
Exchange differences:		
Exchange differences on translation of foreign operations	**(3,997)**	(448)
OTHER COMPREHENSIVE LOSS FOR THE YEAR, NET OF TAX	**(3,997)**	(448)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	**(699,256)**	(984,500)
Attributable to:		
Owners of the parent	**(699,256)**	(984,500)
Non-controlling interests	**–**	–
	(699,256)	(984,500)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

Year ended 31 December 2022

	Notes	2022 RMB'000	2021 RMB'000
NON-CURRENT ASSETS			
Property, plant and equipment		**1,817,449**	1,228,885
Intangible assets		**4,332,283**	3,634,931
Right-of-use assets		**412,422**	438,201
Other non-current assets		**170,612**	223,668
Total non-current assets		**6,732,766**	5,525,685
CURRENT ASSETS			
Inventories		**757,312**	420,112
Trade receivables	*10*	**455,509**	295,741
Financial assets at fair value through profit or loss	*11*	**160,186**	–
Prepayments, deposits and other receivables		**138,057**	223,973
Cash and bank balances		**680,478**	707,333
Total current assets		**2,191,542**	1,647,159
CURRENT LIABILITIES			
Trade payables	*12*	**713,552**	383,470
Other payables and accruals		**1,443,451**	867,278
Contract liabilities		**322,420**	138,303
Interest-bearing bank and other borrowings		**2,522,155**	1,570,674
Total current liabilities		**5,001,578**	2,959,725
NET CURRENT LIABILITIES		**(2,810,036)**	(1,312,566)
TOTAL ASSETS LESS CURRENT LIABILITIES		**3,922,730**	4,213,119
NON-CURRENT LIABILITIES			
Interest-bearing bank and other borrowings		**1,154,940**	1,052,263
Other long-term payables		**292,370**	54,425
Contract liabilities		**645,594**	653,934
Deferred income		**193,494**	155,741
Total non-current liabilities		**2,286,398**	1,916,363
Net assets		**1,636,332**	2,296,756
EQUITY			
Share capital		**543,495**	543,495
Reserves		**1,092,837**	1,753,261
Equity attributable to owners of the parent and total equity		**1,636,332**	2,296,756

1.1 BASIS OF PREPARATION

These financial statements have been prepared in accordance with International Financial Reporting Standards ("**IFRSs**"), which comprise all standards and interpretations approved by the International Accounting Standards Board (the "**IASB**"), and International Accounting Standards ("**IASs**") and Standing Interpretations Committee interpretations approved by the International Accounting Standards Committee that remain in effect, and the disclosure requirements of the Hong Kong Companies Ordinance. They have been prepared under the historical cost convention. These financial statements are presented in Renminbi ("**RMB**"), and all values are rounded to the nearest thousand except when otherwise indicated.

The Group had net current liabilities of RMB2,810,036,000 as at 31 December 2022. Having taken into account the unused banking facilities and the expected cash flows from operating, financing and investing activities, the directors consider that it is appropriate to prepare the financial statements on a going concern basis.

Basis of consolidation

The consolidated financial statements include the financial statements of the Company and its subsidiaries (collectively referred to as the "**Group**") for the year ended 31 December 2022. A subsidiary is an entity (including a structured entity), directly or indirectly, controlled by the Company. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee (i.e., existing rights that give the Group the current ability to direct the relevant activities of the investee).

Generally, there is a presumption that a majority of voting rights results in control. When the Company has, directly or indirectly, less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, including:

(a) the contractual arrangement with the other vote holders of the investee;
(b) rights arising from other contractual arrangements; and
(c) the Group's voting rights and potential voting rights.

The financial statements of the subsidiaries are prepared for the same Reporting Period as the Company, using consistent accounting policies. The results of subsidiaries are consolidated from the date on which the Group obtains control and continue to be consolidated until the date that such control ceases.

Profit or loss and each component of other comprehensive income are attributed to the owners of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. All intra-group assets and liabilities, equity, income, expenses, and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

The Group reassesses whether it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control described above. A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

If the Group loses control over a subsidiary, it derecognises (i) the assets (including goodwill) and liabilities of the subsidiary, (ii) the carrying amount of any non-controlling interest and (iii) the cumulative translation differences recorded in equity; and recognises (i) the fair value of the consideration received, (ii) the fair value of any investment retained and (iii) any resulting surplus or deficit in profit or loss. The Group's share of components previously recognised in other comprehensive income is reclassified to profit or loss or retained profits, as appropriate, on the same basis as would be required if the Group had directly disposed of the related assets or liabilities.

1.2 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The Group has adopted the following revised IFRSs for the first time for the current year's 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*
Annual Improvements to IFRS Standards 2018-2020	Amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41

The nature and the impact of the revised IFRSs that are applicable to the Group are described below:

(a) Amendments to IFRS 3 replace a reference to the previous *Framework for the Preparation and Presentation of Financial Statements* with a reference to the *Conceptual Framework for Financial Reporting* (the "**Conceptual Framework**") issued in March 2018 without significantly changing its requirements. The amendments also add to IFRS 3 an exception to its recognition principle for an entity to refer to the Conceptual Framework to determine what constitutes an asset or a liability. The exception specifies that, for liabilities and contingent liabilities that would be within the scope of IAS 37 or IFRIC 21 if they were incurred separately rather than assumed in a business combination, an entity applying IFRS 3 should refer to IAS 37 or IFRIC 21 respectively instead of the Conceptual Framework. Furthermore, the amendments clarify that contingent assets do not qualify for recognition at the acquisition date. The Group has applied the amendments prospectively to business combinations that occurred on or after 1 January 2022. As there were no contingent assets, liabilities and contingent liabilities within the scope of the amendments arising in the business combination that occurred during the year, the amendments did not have any impact on the financial position and performance of the Group.

(b) Amendments to IAS 16 prohibit an entity from deducting from the cost of an item of property, plant and equipment any proceeds from selling items produced while bringing that asset to the location and condition necessary for it to be capable of operating in the manner intended by management. Instead, an entity recognises the proceeds from selling any such items, and the cost of those items as determined by IAS 2 *Inventories*, in profit or loss. The Group has applied the amendments retrospectively to items of property, plant and equipment made available for use on or after 1 January 2021. Since there was no sale of items produced prior to the property, plant and equipment being available for use, the amendments did not have any impact on the financial position or performance of the Group.

(c) Amendments to IAS 37 clarify that for the purpose of assessing whether a contract is onerous under IAS 37, the cost of fulfilling the contract comprises the costs that relate directly to the contract. Costs that relate directly to a contract include both the incremental costs of fulfilling that contract (e.g., direct labour and materials) and an allocation of other costs that relate directly to fulfilling that contract (e.g., an allocation of the depreciation charge for an item of property, plant and equipment used in fulfilling the contract as well as contract management and supervision costs). General and administrative costs do not relate directly to a contract and are excluded unless they are explicitly chargeable to the counterparty under the contract. The Group has applied the amendments prospectively to contracts for which it has not yet fulfilled all its obligations at 1 January 2022 and no onerous contracts were identified. Therefore, the amendments did not have any impact on the financial position or performance of the Group.

(d) *Annual Improvements to IFRS Standards 2018-2020* sets out amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41. Details of the amendments that are applicable to the Group are as follows:

- IFRS 9 *Financial Instruments*: clarifies the fees that an entity includes when assessing whether the terms of a new or modified financial liability are substantially different from the terms of the original financial liability. These fees include only those paid or received between the borrower and the lender, including fees paid or received by either the borrower or lender on the other's behalf. The Group has applied the amendment prospectively from 1 January 2022. As there was no modification or exchange of the Group's financial liabilities during the year, the amendment did not have any impact on the financial position or performance of the Group.

- IFRS 16 *Leases*: removes the illustration of payments from the lessor relating to leasehold improvements in Illustrative Example 13 accompanying IFRS 16. This removes potential confusion regarding the treatment of lease incentives when applying IFRS 16.

1.3 ISSUED BUT NOT YET EFFECTIVE INTERNATIONAL FINANCIAL REPORTING STANDARDS

The Group has not applied the following new and revised IFRSs, that have been issued but are not yet effective, in these financial statements.

Amendments to IFRS 10 and IAS 28	*Sale or Contribution of Assets between an Investor and its Associate or Joint Venture*[3]
Amendments to IFRS 16	*Lease Liability in a Sale and Leaseback*[2]
IFRS 17	*Insurance Contracts*[1]
Amendments to IFRS 17	*Insurance Contracts*[1, 5]
Amendment to IFRS 17	*Initial Application of IFRS 17 and IFRS 9 – Comparative Information*[6]
Amendments to IAS 1	*Classification of Liabilities as Current or Non-current* (the "**2020 Amendments**")[2, 4]
Amendments to IAS 1	*Non-current Liabilities with Covenants* (the "**2022 Amendments**")[2]
Amendments to IAS 1 and IFRS Practice Statement 2	*Disclosure of Accounting Policies*[1]
Amendments to IAS 8	*Definition of Accounting Estimates*[1]
Amendments to IAS 12	*Deferred Tax related to Assets and Liabilities arising from a Single Transaction*[1]

1 Effective for annual periods beginning on or after 1 January 2023
2 Effective for annual periods beginning on or after 1 January 2024
3 No mandatory effective date yet determined but available for adoption
4 As a consequence of the 2022 Amendments, the effective date of the 2020 Amendments was deferred to annual periods beginning on or after January 1, 2024
5 As a consequence of the amendments to IFRS 17 issued in June 2020, IFRS 4 was amended to extend the temporary exemption that permits insurers to apply IAS 39 rather than IFRS 9 for annual periods beginning before January 1, 2023
6 An entity that chooses to apply the transition option relating to the classification overlay set out in this amendment shall apply it on initial application of IFRS 17

Further information about those IFRSs that are expected to be applicable to the Group is described below.

Amendments to IFRS 10 and IAS 28 address an inconsistency between the requirements in IFRS 10 and in IAS 28 in dealing with the sale or contribution of assets between an investor and its associate or joint venture. The amendments require a full recognition of a gain or loss resulting from a downstream transaction when the sale or contribution of assets between an investor and its associate or joint venture constitutes a business. For a transaction involving assets that do not constitute a business, a gain or loss resulting from the transaction is recognised in the investor's profit or loss only to the extent of the unrelated investor's interest in that associate or joint venture. The amendments are to be applied prospectively. The previous mandatory effective date of amendments to IFRS 10 and IAS 28 was removed by the IASB in December 2015 and a new mandatory effective date will be determined after the completion of a broader review of accounting for associates and joint ventures. However, the amendments are available for adoption now.

Amendments to IFRS 16 specify the requirements that a seller-lessee uses in measuring the lease liability arising in a sale and leaseback transaction to ensure the seller-lessee does not recognise any amount of the gain or loss that relates to the right of use it retains. The amendments are effective for annual periods beginning on or after January 1, 2024 and shall be applied retrospectively to sale and leaseback transactions entered into after the date of initial application of IFRS 16 (i.e., January 1, 2019). Earlier application is permitted. The amendments are not expected to have any significant impact on the Group's financial statements.

Amendments to IAS 1 *Classification of Liabilities as Current or Non-current* clarify the requirements for classifying liabilities as current or non-current, in particular the determination over whether an entity has a right to defer settlement of the liabilities for at least 12 months after the Reporting Period. Classification of a liability is unaffected by the likelihood that the entity will exercise its right to defer settlement of the liability. The amendments also clarify the situations that are considered a settlement of a liability. In 2022, the IASB issued the 2022 Amendments to further clarify that, among covenants of a liability arising from a loan arrangement, only those with which an entity must comply on or before the reporting date affect the classification of that liability as current or non-current. In addition, the 2022 Amendments require additional disclosures by an entity that classifies liabilities arising from loan arrangements as non-current when it has a right to defer settlement of those liabilities that are subject to the entity complying with future covenants within 12 months after the Reporting Period. The amendments are effective for annual periods beginning on or after January 1, 2024 and shall be applied retrospectively. Earlier application is permitted. An entity that applies the 2020 Amendments early is required to apply simultaneously the 2022 Amendments, and vice versa. The Group is currently assessing the impact of the amendments and whether existing loan agreements may require revision. Based on a preliminary assessment, the amendments are not expected to have any significant impact on the Group's financial statements.

Amendments to IAS 1 *Disclosure of Accounting Policies* require entities to disclose their material accounting policy information rather than their significant accounting policies. Accounting policy information is material if, when considered together with other information included in an entity's financial statements, it can reasonably be expected to influence decisions that the primary users of general purpose financial statements make on the basis of those financial statements. Amendments to IFRS Practice Statement 2 provide non-mandatory guidance on how to apply the concept of materiality to accounting policy disclosures. Amendments to IAS 1 are effective for annual periods beginning on or after 1 January 2023 and earlier application is permitted. Since the guidance provided in the amendments to IFRS Practice Statement 2 is non-mandatory, an effective date for these amendments is not necessary. The Group is currently revisiting the accounting policy disclosures to ensure consistency with the amendments.

Amendments to IAS 8 clarify the distinction between changes in accounting estimates and changes in accounting policies. Accounting estimates are defined as monetary amounts in financial statements that are subject to measurement uncertainty. The amendments also clarify how entities use measurement techniques and inputs to develop accounting estimates. The amendments are effective for annual reporting periods beginning on or after 1 January 2023 and apply to changes in accounting policies and changes in accounting estimates that occur on or after the start of that period. Earlier application is permitted. The amendments are not expected to have any significant impact on the Group's financial statements.

Amendments to IAS 12 narrow the scope of the initial recognition exception in IAS 12 so that it no longer applies to transactions that give rise to equal taxable and deductible temporary differences, such as leases and decommissioning obligations. Therefore, entities are required to recognise a deferred tax asset (provided that sufficient taxable profit is available) and a deferred tax liability for temporary differences arising from these transactions. The amendments are effective for annual reporting periods beginning on or after 1 January 2023 and shall be applied to transactions related to leases and decommissioning obligations at the beginning of the earliest comparative period presented, with any cumulative effect recognised as an adjustment to the opening balance of retained profits or other component of equity as appropriate at that date. In addition, the amendments shall be applied prospectively to transactions other than leases and decommissioning obligations. Earlier application is permitted. The amendments are not expected to have any significant impact on the Group's financial statements.

2. OPERATING SEGMENT INFORMATION

The Group is engaged in biopharmaceutical R&D, biopharmaceutical services and biopharmaceutical production and sales, which is regarded as a single reportable segment in a manner consistent with the way in which information is reported internally to the Group's senior management for purposes of resource allocation and performance assessment. Therefore, no analysis by operating segment is presented.

Geographical information

(a) Revenue from external customers

	2022	2021
	RMB'000	*RMB'000*
Mainland China	**2,840,567**	1,515,645
Asia Pacific (excluding Mainland China)	**178,971**	57,286
North America	**145,056**	–
Europe	**50,136**	109,541
	3,214,730	1,682,472

The revenue geographical information above is based on the locations of the customers.

(b) Non-current assets

	2022	2021
	RMB'000	*RMB'000*
Mainland China	**6,600,293**	5,430,594
Overseas	**132,473**	95,091
	6,732,766	5,525,685

The non-current asset information above is based on the locations of the assets and excludes financial instruments and deferred tax assets.

Information about major customers

Revenue from customers amounting to over 10% to the total revenue of the Group in the Reporting Period is as follows:

	2022
	RMB'000
Customer A	**1,000,670**
Customer B	**582,908**
	1,583,578

	2021
	RMB'000
Customer A	534,538
Customer B	458,237
	992,775

3. REVENUE

An analysis of revenue is as follows:

	2022 *RMB'000*	2021 *RMB'000*
Revenue from contracts with customers	**3,212,800**	1,682,472
Revenue from other sources		
Gross rental income from operating leases	**1,930**	–
	3,214,730	1,682,472

Revenue from contracts with customers

(a) Revenue information

	2022 *RMB'000*	2021 *RMB'000*
Types of goods or service		
Sales of biopharmaceutical products	**2,675,372**	1,494,639
Research and development services	**325,484**	112,873
The license	**211,016**	74,222
Others	**928**	738
Total revenue from contracts with customers	**3,212,800**	1,682,472
Timing of revenue recognition		
Transferred at a point in time	**2,899,468**	1,495,377
Transferred over time	**313,332**	187,095
Total revenue from contracts with customers	**3,212,800**	1,682,472

The following table shows the amounts of revenue recognised in the current Reporting Period that were included in the contract liabilities at the beginning of the Reporting Period:

	2022 *RMB'000*	2021 *RMB'000*
Revenue recognised that was included in contract liabilities at the beginning of the Reporting Period:		
The license	**182,366**	14,545
Research and development services	**24,375**	107,387
	206,741	121,932

There is no revenue recognised from performance obligations satisfied in previous periods.

(b) Performance obligations

Information about the Group's performance obligations is summarised below:

Sale of biopharmaceutical products
The performance obligation is satisfied upon receipt of the products and payment is generally due within 90 days from the received date.

The license
The performance obligation of commercialisation licenses is generally satisfied over time during the expected commercialisation period after the Group obtains the commercialisation authorisation from the local authorities and payment in advance is normally required. The performance obligation of intellectual property licenses is satisfied at a point in time and payment is billed based on the milestone achieved.

Research and development services

Based on the terms of the contracts, the performance obligation is generally satisfied over time as services are rendered or at the point in time as the services are completed and accepted and payment is billed based on the milestone achieved.

The amounts of transaction prices allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at 31 December are as follows:

	2022	2021
	RMB'000	*RMB'000*
Amounts expected to be recognised as revenue:		
Within one year	**469,966**	232,700
After one year	**726,156**	804,982
	1,196,122	1,037,682

The remaining performance obligations expected to be recognised after one year mainly relate to the transaction prices allocated to the license and research and development services. The revenue from the license is expected to be recognised during the future estimated commercialisation period. The revenue from research and development services is expected to be recognised during the period in which the services are being rendered. The amounts disclosed above do not include variable consideration.

4. OTHER INCOME AND GAINS

	2022	2021
	RMB'000	*RMB'000*
Interest income	**3,571**	2,686
Exchange gains	**32,919**	–
Government grants	**69,043**	41,896
Others	**19**	509
	105,552	45,091

5. LOSS BEFORE TAX

The Group's loss before tax is arrived at after charging/(crediting):

	Notes	2022 RMB'000	2021 RMB'000
Cost of inventories sold		**504,504**	396,900
Cost of services provided		**340,117**	125,848
Depreciation of property, plant and equipment*		**113,828**	83,976
Depreciation of right-of-use assets*		**64,520**	49,607
Amortisation of intangible assets*		**99,255**	66,593
Research and development expenses:			
Current year expenditure		**1,394,514**	1,023,930
Lease payments not included in the measurement of lease liabilities		**5,594**	5,093
Listing expenses		**–**	159
Auditor's remuneration		**3,350**	2,800
Employee benefit expense (including directors' and chief executive's remuneration):			
Wages and salaries		**1,127,336**	709,686
Staff welfare expenses		**227,120**	144,419
Share-based payment expense*		**12,517**	48,417
Foreign exchange (gain)/loss		**(32,919)**	16,662
Impairment of financial assets, net:			
Impairment of trade receivables, net		**1,638**	174
Impairment of deferred development costs, net		**–**	28,848
Write-down of inventories to net realisable value		**24,669**	7,566
Loss on fair value adjustment of financial assets at fair value through profit or loss**	*11*	**199,153**	–
Provision for the contract loss		**–**	191,271
Bank interest income	*4*	**(3,571)**	(2,686)
Loss on disposal of items of property, plant and equipment		**248**	932

* The depreciation of property, plant and equipment, the depreciation of right-of-use assets, the amortisation of intangible assets and the share-based payment expense for the year are included in "Cost of sales", "Research and development expenses", "Selling and distribution expenses" and "Administrative expenses" in the consolidated statement of profit or loss.

** Represented the fair value loss on the financials assets through profit or loss amounted to RMB390,424,000, net off a provision of RMB191,271,000 charged to other expenses in the consolidated statement of profit or loss for the year ended 31 December 2021. Please refer to note 11 for details.

6. FINANCE COSTS

An analysis of finance costs is as follows:

	2022	2021
	RMB'000	*RMB'000*
Interest expense on bank and other borrowings	**115,886**	78,505
Interest expense on lease liabilities	**14,910**	16,649
Less: Interest capitalised	**(25,124)**	(10,334)
	105,672	84,820

7. INCOME TAX

The provision for Chinese Mainland current income tax is based on the statutory rate of 25% (2021: 25%) of the assessable profits of the Group as determined in accordance with the PRC Corporate Income Tax Law which was approved and became effective on 1 January 2008, except for certain group entities in Chinese Mainland, which are taxed at a preferential rate of 15%.

Taxes on profits assessable elsewhere have been calculated at the tax rates prevailing in the jurisdictions in which the Group operates. The provision for current income tax of Hengenix Biotech, Inc. incorporated in the United State and Henlius Industrial Co., Limited incorporated in Hong Kong in the year of 2022, is based on the statutory rates of 29.84% and 8.25%, respectively (2021: 29.84%, 8.25%,respectively).

	2022	2021
	RMB'000	*RMB'000*
Current – Mainland China	**1,372**	27,313
Total tax charged for the year	**1,372**	27,313

8. DIVIDENDS

No dividends have been paid or declared by the Group during the Reporting Period.

9. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic loss per share amounts is based on the loss attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 542,021,455 (2021: 538,836,373) in issue during the year.

The calculation of the diluted loss per share amounts is based on the loss for the year attributable to ordinary equity holders of the parent. The weighted average number of ordinary shares used in the calculation is the number of ordinary shares in issue during the year, as used in the basic loss per share calculation, and the weighted average number of conversion of all dilutive potential ordinary shares into ordinary shares.

The calculations of basic and diluted earnings per share are based on:

	2022	2021
	RMB'000	*RMB'000*
Loss		
Loss attributable to ordinary equity holders of the parent, used in the basic loss per share calculation	**(695,259)**	(984,052)

	Number of shares	
	2022	2021
Shares		
Weighted average number of ordinary shares in issue during the year used in the basic loss per share calculation	**542,021,455**	538,836,373
Effect of dilution – weighted average number of ordinary shares:		
Restricted shares under share award scheme	**–**	–
Weighted average number of ordinary shares in issue during the year in the diluted loss per share calculation	**542,021,455**	538,836,373

Because the diluted loss per share amount is decreased when taking restricted shares issued under the share award scheme into account, the restricted shares had an anti-dilutive effect on the basic loss per share amount for the year and were ignored in the calculation of diluted loss per share.

10. TRADE RECEIVABLES

	2022	2021
	RMB'000	*RMB'000*
Trade receivables	**462,607**	301,201
Impairment	**(7,098)**	(5,460)
	455,509	295,741

The Group's trading terms with its customers are mainly on credit. The credit period is generally three months. The Group seeks to maintain strict control over its outstanding receivables and has a credit control department to minimise credit risk. Overdue balances are reviewed regularly by senior management. Trade receivables are non-interest-bearing.

At 31 December 2022, the amount of Group's trade receivables were pledged as security for the Group's interest-bearing bank and other borrowings was nil (2021: RMB69,444,000).

An ageing analysis of the trade receivables as at the end of each of Reporting Period, based on the invoice date and net of loss allowance, is as follows:

	2022	2021
	RMB'000	*RMB'000*
Within 3 months	**373,226**	295,741
3-6 months	**114**	–
6-12 months	**20,877**	–
1-2 years	**61,292**	–
	455,509	295,741

11. FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT OR LOSS

	2022	2021
	RMB'000	*RMB'000*
Unlisted investment, at fair value	**160,186**	–

On 25 September 2019, the Company entered into an investment management agreement (the "**IMA**") with AMTD Global Markets Limited ("**AMTD**"). Pursuant to the IMA, the Company deposited a total amount of USD117,000,000 into the investment portfolio account with AMTD (the "**AMTD Account**") and engaged AMTD to provide investment management services.

During the years ended 31 December 2020 and 2021, the Company redeemed in total of USD30,640,000 from AMTD and a provision for expected loss of USD30,000,000 (equivalent to RMB191,271,000) was provided based on the Company's best estimate, with the assistance of an external legal counsel, in the year ended 31 December 2021. As at 31 December 2021, the outstanding balance in the AMTD Account amounted to USD86,360,000 (equivalent to RMB550,610,000) was recorded in restricted cash and bank balances and the provision was recorded in other payables and accruals.

During the year ended 31 December 2022, the Company entered into to purchase promissory notes issued by three private entities (collectively, the "**Notes**") with the total principal amounts of USD86,360,000 (equivalent to RMB550,610,000) through the AMTD Account, which was recorded in financial assets at fair value through profit or loss. In February 2023, the Company redeemed the amount of USD20,000,000 from AMTD.

The Company has engaged an independent valuer to assess the fair value of the Notes and concluded that the fair value of the Notes as at 31 December 2022 was USD23,000,000 (equivalent to RMB160,186,000) giving rise to a total fair value loss of RMB390,424,000. As a loss of RMB191,271,000 relating to the AMTD Account had already been recognised for the year ended 31 December 2021, an additional fair value loss of RMB199,153,000 was recognised for other expenses for the year ended 31 December 2022.

12. TRADE PAYABLES

	2022	2021
	RMB'000	*RMB'000*
Trade payables	**713,552**	383,470

Trade payables are non-interest-bearing and are normally settled on terms of three to six months.

An ageing analysis of the trade payables as at the end of each Reporting Period based on the invoice date, is as follows:

	2022	2021
	RMB'000	*RMB'000*
Within 1 year	**713,104**	383,470
1 to 2 years	**448**	–
	713,552	383,470

13. EVENTS AFTER THE REPORTING PERIOD

On 30 March 2023, the Company received a letter from the legal representatives of AMTD, attaching a Writ of Summons issued in relation to a litigation commenced by AMTD against the Company in the Court of First Instance of the High Court of Hong Kong. AMTD alleges that the Company has breached the IMA by withdrawing the USD30,640,000 mentioned in note 11 above without the written consent of AMTD, and not paying management fees for services provided by AMTD. AMTD seeks monetary and declaratory relief, as well as specific performance.

PUBLICATION OF ANNUAL RESULTS AND ANNUAL REPORT

This results announcement is published on the website of the Stock Exchange at http://www. hkexnews.hk and on the website of the Company at http://www.henlius.com. The 2022 annual report containing all the information required by the Listing Rules will be despatched to the shareholders in due course and will be published on the websites of the Company and the Stock Exchange.

APPRECIATION

The Group would like to express its appreciation to all the staff for their outstanding contribution towards the Group's development. The Board wishes to sincerely thank the management for their dedication and diligence, which are the key factors for the Group to continue its success in future. Also, the Group wishes to extend its gratitude for the continued support from its shareholders, customers, and business partners. The Group will continue to deliver sustainable business development, so as to create more values for all its shareholders.

B. DISCLOSEABLE TRANSACTION

The then-management of the Company entered into the Investment Management Agreement (the "**Investment Management Agreement**") with AMTD Global Markets Limited (now renamed as orientiert XYZ Securities Limited, the "**Investment Manager**") on 25 September 2019 to engage the Investment Manager to provide investment management services for the Company's cash, securities, other assets and all related proceeds under the investment portfolio account (collectively, the "**Assets under Management**"). After the signing of the Investment Management Agreement, the Company deposited US$117,000,000 of portion of idle proceeds into the investment portfolio account.

The investment portfolio under the Investment Management Agreement includes: (i) fixed income investment products; and (ii) bonds that may be issued by any product issuer, in each case as recommended by the Investment Manager. The Investment Management Agreement shall be effective from 25 September 2019 (the "**Effective Date**"). However, the Investment Management Agreement contained a provision stating that the Investment Management Agreement's date of termination shall be the day being the second anniversary of the Effective Date, but that it shall be automatically renewed thereafter unless terminated by mutual written consent of both parties. The Company shall have the right to terminate the Investment Management Agreement in the event of a material adverse change in the Investment Manager. Based on the Investment Management Agreement, the relevant management fees for the first two years shall be calculated based on a percentage of the value of the Assets under Management on each anniversary of the Effective Date. From the third year of the Effective Date and each year thereafter (if any), the Company shall also pay certain management fees to the Investment Manager for the relevant years. If the Company fails to pay the management fees on time, the Investment Management Agreement provides that the Investment Manager shall deduct from the Assets under Management (i) the management fees, and (ii) additional administrative fees calculated based on a percentage of the value of the Assets under Management.

Termination of the Investment Management Agreement

On 25 September 2021, as the initial term of the Investment Management Agreement had expired, the Company terminated the Investment Management Agreement by serving a written notice to the Investment Manager and requested the Investment Manager to return the principal and relevant returns accrued under the Investment Management Agreement.

As of the date of the announcement, the Company had already recovered the principal amount of US$50,640,000 (of which: US$30,640,000 in previous years before 2022 and US$20,000,000 in February 2023) and the outstanding principal balance is US$66,360,000.

The Company has been continuously communicating and negotiating with the Investment Manager on termination of the Investment Management Agreement and collection of the principal and relevant returns accrued. In 2021, in light of the prolonged communication with the Investment Manager and based on the opinions by its external attorneys, the Company has made a provision for potential losses of approximately RMB191,271,000 under the contract. As at 31 December 2021, the outstanding balance in the AMTD Account amounted to US$86,360,000 (approximately RMB550,610,000) and was recorded in restricted cash and bank balances. In 2022, based on the information obtained as well as the calculation results of external appraisers, the Company recognized a loss on change in fair value of assets of approximately RMB199,153,000, and by 31 December 2022, this portion of the Assets under Management in the financial statements of the Company had a fair value of US$23,000,000 (approximately RMB160,186,000) (of which US$20,000,000 was recovered subsequent to the Reporting Period). The external auditor of the Company expressed a qualified opinion in relation to the Assets under Management for the year ended 31 December 2022, for the detailed information, please refer to page 45 of this announcement.

On 30 March 2023, the Company received a letter from the legal representatives of the Investment Manager, attaching a Writ of Summons issued in relation to a litigation commenced by the Investment Manager against the Company in the Court of First Instance of the High Court of Hong Kong. The Investment Manager alleges that the Company has breached the Investment Management Agreement by withdrawing the US$30,640,000 mentioned above without the written consent of the Investment Manager, and not paying management fees for services provided by the Investment Manager. The Investment Manager seeks monetary and declaratory relief, as well as specific performance.

The Company is currently seeking legal advice regarding the relevant proceedings. The Company will also consider all options available and make every effort to recover outstanding principal and relevant returns accrued under the Investment Management Agreement. The Company will make further announcement(s) to keep its shareholders and potential investors informed of any significant development of the above proceedings and recovery of outstanding principal and relevant returns accrued as and when appropriate.

LISTING RULES IMPLICATIONS

As the highest applicable percentage ratio in respect of the entering into of the Investment Management Agreement and the transactions contemplated under the Investment Management Agreement (the "**Investment Management Transaction**") is more than 5% but is less than 25%, the entering into of the Investment Management Agreement and the Investment Manager Transaction constituted a discloseable transaction and would be subject to the announcement requirements, but would be exempt from the shareholders' approval requirement under Chapter 14 of the Listing Rules.

INADVERTENT BREACH OF THE RELEVANT RULES

The then-management of the Company failed to consult its compliance adviser before the entering into the Investment Management Agreement pursuant to Rule 3A.23 of the Listing Rules, and conduct the review procedures of the Board and disclose the relevant information in a timely manner pursuant to the requirements of Article 114(12) of the Articles of Association of the Company, Rule 14.34 of the Listing Rules and paragraph 3.13 of Guidance Letter GL86-16 (Part I).

REMEDIAL MEASURES

The Company regrets its non-compliance with the requirements of Article 114(12) of the Articles of Association of the Company, Rules 3A.23 and 14.34 of the Listing Rules and paragraph 3.13 of Guidance Letter GL86-16 (Part I), and would like to stress that the Company had no intention to withhold any information relating to the entering into of the Investment Management Agreement from disclosure.

To prevent the reoccurrence of the current instance of non-compliance, the Company intends to adopt the following measures:

(1) the Company will enhance the training provided to the Directors, the senior management and responsible finance staff, including requesting its legal adviser to provide further trainings on the requirements under the Listing Rules and practical knowledge of notifiable transactions to its staff, so as to reinforce their understanding of and to emphasize the importance of compliance with the Listing Rules; and

(2) the Company will conduct a thorough internal control assessment, improve the internal control process, and strengthen the implementation of its internal control system including but not limited to strengthening the coordination and reporting arrangements for notifiable transactions among the various departments of the Company.

INFORMATION ABOUT THE PARTIES

The Company

The Company is a leading biopharmaceutical company in the PRC with the vision to offer high-quality, affordable and innovative drugs for patients worldwide. The H shares of the Company have been listed on the Main Board of the Stock Exchange since September 2019.

Investment Manager

The Investment Manager is a licensed corporation licensed to carry out type 1 (Dealing in Securities), type 2 (Dealing in Futures Contracts), type 4 (Advising on Securities), type 6 (Advising on Corporate Finance) and type 9 (Asset Management) regulated activities under the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong).

To the best knowledge, information and belief of the Directors having made all reasonable enquiries, the Investment Manager and its ultimate beneficial owners are third parties independent of the Group and its connected persons.

On behalf of the Board
Shanghai Henlius Biotech, Inc.
Wenjie Zhang
Chairman

Hong Kong, 31 March 2023

As at the date of this announcement, the board of directors of the Company comprises Mr. Wenjie Zhang as the chairman and executive director, Mr. Qiyu Chen, Mr. Yifang Wu, Ms. Xiaohui Guan, Mr. Deyong Wen and Mr. Zihou Yan as the non-executive directors, and Mr. Tak Young So, Dr. Lik Yuen Chan, Dr. Guoping Zhao and Dr. Ruilin Song as the independent non-executive directors.