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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)

ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED 31 DECEMBER 2023

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 2023 (the “**Reporting Period**”), prepared under International Financial Reporting Standards (“**IFRSs**”).

FINANCIAL SUMMARY:

1. The Group’s total revenue increased by approximately RMB2,180.2 million or approximately 67.8% to approximately RMB5,394.9 million for the year ended 31 December 2023, compared to approximately RMB3,214.7 million for the year ended 31 December 2022. 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 2023, the Group recognized expensed R&D expenditure of approximately RMB1,118.7 million, representing a decrease of approximately RMB275.8 million as compared to approximately RMB1,394.5 million for the year ended 31 December 2022. During the Reporting Period, the Group continued to deploy scientific and efficient R&D strategy, focus on unmet clinical needs and optimize allocation of pipeline resources.
3. The Group’s total profit was approximately RMB546.0 million for the year ended 31 December 2023, representing an increase of approximately RMB1,241.3 million in profit from a loss of approximately RMB695.3 million for the year ended 31 December 2022, mainly due to increasing commercial sales of the core products and expanding sales volume.
4. The Board does not recommend a final dividend for the Reporting Period.

BUSINESS HIGHLIGHTS:

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

From the beginning of 2023 to date, the marketing authorisation applications of different specifications of HANQUYOU were approved in Cambodia, Singapore, Thailand, Philippines and Brazil, respectively.

In February 2023, the FDA has accepted the biologics license application (BLA) for trastuzumab for injection.

In July 2023, Health Canada accepted the New Drug Submission (NDS) for trastuzumab for injection.

2 HANSIZHUANG (serplulimab injection):

In January 2023, the new drug application (NDA) 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 September 2023, the new drug application (NDA) of HANSIZHUANG in combination with the drug containing fluorouracil and platinum for the first-line treatment of PD-L1 positive, unresectable locally advanced/recurrent or metastatic esophageal squamous cell carcinoma (ESCC) was approved by the NMPA.

In December 2023, the new drug application (NDA) of HANSIZHUANG in combination with chemotherapy for the first-line treatment of locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) has been accepted by the NMPA.

In March 2023, the marketing authorisation application (MAA) of HANSIZHUANG in combination with chemotherapy for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC) has been validated by the EMA.

In December 2023, HANSIZHUANG was approved by the Indonesia's National Agency for Drug and Food Control (BPOM) for the treatment of extensive-stage small cell lung cancer (ES-SCLC) (local brand name: Zerpidio®).

HANSIZHUANG was recommended by 9 guidelines, including the 2023 Guidelines of CSCO for Small-Cell Lung Cancer 《CSCO小細胞肺癌診療指南》, Guidelines of CSCO for Non-small Cell Lung Cancer 《CSCO非小細胞肺癌診療指南》, Guidelines of CSCO for Esophageal Cancer 《(CSCO食管癌診療指南》, Guidelines of CSCO for Colorectal Cancer 《CSCO結直腸癌診療指南》 and Guidelines of CSCO for Immune Checkpoint Inhibitor Clinical Practice 《CSCO免疫檢查點抑制劑臨床應用指南》.

3 HANLIKANG (rituximab injection), HANDAYUAN (adalimumab injection) and HANBEITAI (bevacizumab injection):

As at the end of the Reporting Period, HANLIKANG has benefited over 230,000 patients in total in Mainland China.

In February 2024, the supplemental new drug applications for new indications of HANDAYUAN such as polyarticular juvenile idiopathic arthritis, pediatric plaque psoriasis have been accepted by the NMPA.

As at the Latest Practicable Date, HANBEITAI has been included in the medical insurance procurement platform in all provinces and has completed the tendering process on the procurement platform in 28 provinces in Mainland China.

4 Business Expansion:

In April 2023, the Company entered into an agreement with Boston Oncology, LLC, agreeing to grant a license, to commercialise HANLIKANG in the Middle East and North Africa such as Saudi Arabia, Egypt and Bahrain.

In August 2023, the Company entered into an agreement with FBD Biologics Limited, agreeing to grant a license, to use the anti-PD-L1 VHH sequence to develop, manufacture, commercialise HCB301 worldwide.

In August 2023, the Company entered into an agreement with PT Kalbe Genexine Biologics, agreeing to grant a license, to commercialise HANSIZHUANG in the Middle East and North Africa such as Saudi Arabia, the United Arab Emirates and Egypt.

In October 2023, the Company entered into an agreement with Intas Pharmaceuticals Ltd., agreeing to grant a license, to commercialise HANSIZHUANG in the agreed European region and India.

5 Efficient Advancement on Clinical Study Projects both Domestically and Internationally:

– Progress of international clinical study projects

- In January 2023, the first patient in the United States has been dosed in an international multi-centre phase 3 clinical study of HANSIZHUANG in combination with chemotherapy (carboplatin/cisplatin-etoposide) and concurrent radiotherapy for the treatment of limited-stage small cell lung cancer (LS-SCLC). The first patient in Australia and the EU also have been dosed in such international multi-centre phase 3 clinical study in April and October 2023, respectively.
- As at the Latest Practicable Date, 81 sites have been set for the bridging study in the United States for HANSIZHUANG in combination with chemotherapy (carboplatin-etoposide) for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC), and the recruitment of subjects is underway.

- In February 2023, the first patient in the United States has been dosed in an international multi-centre phase 3 clinical study of HLX04-O (recombinant anti-VEGF humanised monoclonal antibody injection) for the treatment of wet age-related macular degeneration (wAMD). As at the Latest Practicable Date, in addition to the United States, the first patient has been dosed in an international multi-centre phase 3 clinical study in Mainland China, EU, Australia and other countries/regions.
- Progress of domestic clinical study projects: HANSIZHUANG (serplulimab injection)
- In February 2023, the first patient has been dosed in a phase 1b/2 clinical study of HLX208 (BRAF V600E inhibitor) in combination with HANSIZHUANG for the treatment of non-small cell lung cancer (NSCLC) in Mainland China.
 - In April 2023, the phase 2 investigational new drug application (IND) of HLX26 (recombinant anti-LAG-3 humanised monoclonal antibody injection) in combination with HANSIZHUANG and chemotherapy for the first-line treatment of advanced non-small cell lung cancer (NSCLC) was approved by the NMPA, and the first patient has been dosed in such clinical trial in August 2023.
 - In June 2023, the first patient has been dosed in a phase 2 clinical trial of HLX26 (recombinant anti-LAG-3 humanised monoclonal antibody injection) in combination with HANSIZHUANG for the treatment of patients with metastasis colorectal cancer (mCRC) who had previously received third-line treatment in Mainland China.
 - In October 2023, the phase 3 clinical study of HANSIZHUANG in combination with chemotherapy for the first-line treatment of advanced non-squamous non-small cell lung cancer (nsNSCLC) has met the primary study endpoint and its results showed that HANSIZHUANG in combination with chemotherapy (carboplatin-pemetrexed) demonstrated the good efficacy and safety in patients with advanced non-squamous non-small cell lung cancer.
- Progress of domestic clinical study projects: other products
- In February 2023, the first subject has been dosed in a 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 demonstrated good safety and tolerability of HLX07 in the phase 1b/2 clinical study conducted in patients with advanced solid tumours.
 - In April 2023, HLX208 (BRAF V600E inhibitor) for the treatment of adult Langerhans Cell Histiocytosis (LCH) and Erdheim-Chester disease (ECD) with BRAF V600E mutation has been officially granted the Breakthrough Therapy Designation by the Center for Drug Evaluation (CDE) of the NMPA.

- In June and November 2023, the investigational new drug applications (IND) of a biosimilar of Ipilimumab HLX13 (recombinant anti-CTLA-4 fully human monoclonal antibody injection) were approved by the NMPA, respectively. In December 2023, the first subject has been dosed in a phase 1 clinical trial of HLX13 in healthy Chinese male subjects.
- In July 2023, the phase 1/2 clinical study of HLX04-O (recombinant anti-VEGF humanised monoclonal antibody injection) in patients with wet age-related macular degeneration (wAMD) demonstrated good safety and tolerability, and demonstrated its preliminary efficacy.
- In October 2023, the phase 1 investigational new drug application (IND) of HLX42 for injection (antibody-drug conjugate targeting EGFR with novel DNA topoisomerase I inhibitor) for the treatment of advanced/metastatic solid tumours was approved by the NMPA, and the first patient has been dosed in such trial in March 2024. In November 2023, the phase 1 investigational new drug application (IND) of HLX42 for injection for the treatment of advanced/metastatic solid tumours was approved by the FDA. In December 2023, HLX42 for injection for the treatment of patients with advanced or metastatic EGFR-mutated non-small cell lung cancer whose disease has progressed on a third-generation EGFR tyrosine kinase inhibitor has been granted the Fast Track Designation by the FDA.
- In October 2023, the phase 1 investigational new drug application (IND) of HLX43 for injection (antibody-drug conjugate targeting PD-L1 with novel DNA topoisomerase I inhibitor) for the treatment of advanced/metastatic solid tumours was approved by the NMPA, and the first patient has been dosed in such trial in November 2023. In November 2023, the phase 1 investigational new drug application (IND) of HLX43 for injection for the treatment of advanced/metastatic solid tumours was approved by the FDA.
- In January 2024, the phase 1 clinical study of a biosimilar of denosumab HLX14 (recombinant anti-RANKL human monoclonal antibody injection) in healthy Chinese male subjects was successfully completed. The results of the study demonstrate that HLX14 has highly similar pharmacokinetics and pharmacodynamics, as well as comparable safety, tolerability and immunogenicity to the US-, EU-, and CN-sourced denosumab. This study met all of the pre-specified endpoints.

6 Efficient Advancement on Pre-Clinical Development Projects:

- 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.

- In December 2023, the investigational new drug application (IND) of HLX6018 (recombinant anti-GARP/TGF-β1 humanised monoclonal antibody for injection) for the treatment of idiopathic pulmonary fibrosis was accepted by the NMPA and approved in March 2024.
- In March 2024, the investigational new drug applications (IND) of an innovative small molecular HLX99 tablets for the treatment of amyotrophic lateral sclerosis (ALS) were accepted by NMPA.

7 Orientation toward Clinical Value and Injecting Impetus toward the Pipeline:

By centering on patients' needs, with the clinical value-oriented early R&D, the Group coordinated with early R&D teams in China and the United States, based on new drug discovery platforms driven by deep data and biocomputing accelerated molecular design technology, to continue to develop high-quality and affordable innovative drugs to treat complex diseases with the help of network biology and polypharmacology. By employing a comprehensive antibody drug technology platform to empower the development of innovative therapies, the Group was eyeing the next-generation innovative antibody drugs and antibody-based drugs. In terms of the development of antibody-drug conjugates (ADC), the Group's R&D platform Hanjugator has the ability to develop ADC products with high safety, high selectivity and high efficacy, and is able to effectively expand the application scenarios of ADC products, providing strong support for the Group in developing ADC products with differentiation advantage and significant clinical value. As at the Latest Practicable Date, the Group has a total of 59 molecules (including 48 innovative drugs and 11 biosimilar drugs) in its pipeline and 18 R&D platforms, with the forms of drug covering monoclonal antibody, bispecific antibody, ADC, recombinant protein and small molecule-drug conjugates, etc..

8 Layout of Industrialisation Base for Biomedicines with High Economic Benefit based on International Standards:

The total commercial production capacity of the Group is 48,000L (including the Xuhui Facility with a commercial production capacity of 24,000L and Songjiang First Plant with a commercial production capacity of 24,000L). During the Reporting Period, the production lines of HANSIZHUANG, HANLIKANG and HANQUYOU in the Xuhui Facility have successively passed the pre-approval GMP inspection of related products by the drug and health supervision agencies in Indonesia, Brazil and the Netherlands; Songjiang First Plant accepted the Pre-License Inspection (PLI) of HANQUYOU by the FDA; the installation and commissioning of equipment in two main production buildings of the first and second stages of the Phase I project of Songjiang Second Plant including production lines of drug substance and drug product and Prefilled Syringes System (PFS), and part of equipment verification work have been completed. The construction of the underground structure of the third stage of the Phase I project of Songjiang Second Plant was completed, and the construction of the aboveground structure began.

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.

PRODUCT PORTFOLIO AND PIPELINE

Phase	Product	Indication	Notes
In-Market	HANSIZHUANG (serplulimab) ⁽¹⁾	PD-1 MSI-H solid tumours, sqNSCLC, ES-SCLC, ESCC	
	HANBEITAI (bevacizumab) ⁽⁶⁾	VEGF mCRC, advanced, metastatic or recurrent NSCLC, GBM, etc.	
NDA	HLX10 ⁽¹⁾ (serplulimab)+Chemo	PD-1 ES-SCLC 1L	
	HLX10 ⁽¹⁾ (serplulimab)+Chemo	PD-1 rsNSCLC 1L	
Phase 3	HLX10 ⁽¹⁾ (serplulimab)+Chemo	PD-1 ES-SCLC 1L	
	HLX10 ⁽¹⁾ (serplulimab)+Chemo	PD-1 Neo/adjuvant treatment for GC	
	HLX10 ⁽¹⁾ (serplulimab)+Chemo+Radio	PD-1 LS-SCLC 1L	
	HLX04-O ⁽⁷⁾	VEGF Wet AMD	
Phase 2	HLX11 (pertuzumab) ⁽⁸⁾	HER2 Neoadjuvant treatment of breast cancer	
	HLX14 (denosumab) ⁽⁹⁾	RANKL Osteoporosis	
	HLX78 (Lasofoxifene) ⁽¹⁰⁾	SERM Breast cancer	
	HLX10 ⁽¹⁾ (serplulimab)+ HANBEITAI	PD-1+VEGF mCRC 1L	
Phase 1	HLX22 + HANQUYOU	HER2+HER2 GC	
	HLX10 ⁽¹⁾ (serplulimab)+ HLX07	PD-1+EGFR HNSCC, NPC, GC, ESCC, sqNSCLC	
	HLX208 ⁽¹²⁾	BRAF V600E LCH/ECD, solid tumours (i.e. MEL, thyroid cancer, mCRC, NSCLC)	
	HLX208 ⁽¹²⁾ + HLX10 ⁽¹⁾ (serplulimab)	BRAF V600E + PD-1 NSCLC	
Phase 1	HLX10 ⁽¹⁾ (serplulimab)+ HLX60 ⁽¹³⁾	PD-1+GARP Solid tumours	
	HLX42 ⁽¹⁵⁾	EGFR ADC Solid tumours	
	HLX53	TIGIT Solid tumours, lymphomas	
IND	HLX43 ⁽¹⁴⁾	PD-L1 ADC Solid tumours	
	HLX05 (cetuximab) ⁽¹⁶⁾	EGFR mCRC, HNSCC	
	HLX15 (daratumumab)	CD38 Multiple myeloma	
	HLX17 (pembrolizumab)	PD-1 Melanoma, NSCLC, EC, HNSCC, CRC, HCC, TNBC	
	HLX51	OX40 Solid tumours, lymphomas	
	HLX6018	GARP/TGF-β1 IPF	
	HLX99	Polypharmacology ALS	

- Innovative mAb
- Innovative fusion protein
- Biosimilar mAb
- Innovative ADC
- Innovative small molecule
- Bridging study in United States
- BLA under FDA review
- Global multi-centre clinical trial
- MAA under EMA review
- The first Chinese mAb biosimilar launched in both China and the EU

HANSIZHUANG, HANLIKANG, HANQUYOU, HANDAYUAN and HANBEITAI, the core products of the Company, were all successfully launched.

- (1) Approved in China and Indonesia. Business partners: KGbio, Fosun Pharma and Intas.
- (2) The first biosimilar approved in China. Business partners: Fosun Pharma, Farma de Colombia, Eurofarma, Abbott and Boston Oncology.
- (3) The first rituximab approved for the indication in China.
- (4) Approved for marketing in 40+ countries, including China, the UK, Germany, France and Australia, trade name registered in Europe: Zerceptac®, trade name registered in Australia: Tuzucip® and Trastucip®. Business partners: Accord, Cipla, Jacobson, Elea, Eurofarma, Abbott and KGbio.
- (5) Business partners: Wanbang and Getz Pharma.
- (6) Business partner: Eurofarma.
- (7) IND approvals obtained in China, Australia, the United States, Singapore and EU countries, etc. Business partner: Essex.
- (8) IND approvals obtained in China and EU. Business partner: Organon.
- (9) IND approvals obtained in China, EU and Australia. Business partner: Organon.
- (10) Exclusive license obtained in China. Phase 3 MRCT enrolling globally.
- (11) IND approvals obtained in China and the United States.
- (12) Exclusive license obtained in China.
- (13) IND approvals obtained in Australia.
- (14) IND approvals obtained in China and the United States.
- (15) IND approvals obtained in China and the United States and granted Fast Track Designation by FDA.
- (16) 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 improvement of the establishment and layout of the integrated platform of R&D, production and commercialisation in 2023. With its continuous accumulation and improvement of “profitability”, the Company managed to achieve good results in the first semi-annual profit and the first annual profit during the Reporting Period. Thanks to the continuous growth of sales revenue of HANQUYOU and HANSIZHUANG, our core products, favorable results in cost control of the Company’s meticulous management measures, plus the orderly progress of clinical development and drug registration of pipeline products and international production capacity, the business of the Company continued to be driven into a positive cycle and with high-quality development.

As at 19 March 2024, being the latest practicable date for the publication of this announcement (the “**Latest Practicable Date**”), 5 products (19 indications) of the Group have been successfully marketed in Mainland China (excluding Hong Kong, Macau and Taiwan regions of the People’s Republic of China (the “**PRC**”) (“**Mainland China**”)), and 2 products have been successfully marketed in Europe, Australia, Indonesia and other counties/regions. During the Reporting Period, the third and fourth indications for extensive-stage small cell lung cancer (ES-SCLC) and esophageal squamous cell carcinoma (ESCC) of HANSIZHUANG applied for marketing in Mainland China have been approved; the new drug application for extensive-stage small cell lung cancer (ES-SCLC) indication was accepted by the European Medicines Agency (“**EMA**”) and approved by the Indonesia’s National Agency for Drug and Food Control (BPOM) during the Reporting Period, which demonstrated the successful exploration in the international market had opened a new chapter in HANSIZHUANG benefiting patients worldwide. Since the beginning of 2023, the overseas commercialisation of HANQUYOU managed to include the markets of Thailand, the Philippines and Brazil, and its new drug applications in the United States and Canada have also been accepted.

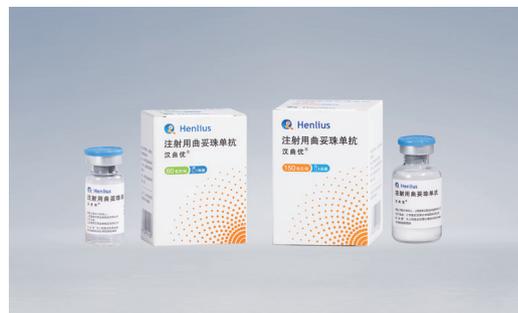
(I) Strong global product commercialisation capability

During the Reporting Period, the Group insisted on starting from clinical needs, actively creating a comprehensive and innovative business operation model, and continuously optimizing the commercialisation layout, achieving remarkable results. As at the end of the Reporting Period, the Group’s commercialisation team was of nearly 1,500 people, promoting the commercialisation of five products, including HANQUYOU and HANSIZHUANG, in an orderly manner in Mainland China. Meanwhile, leveraging on the foresighted R&D strategy and commercialisation layout, HANQUYOU and HANSIZHUANG continue to deploy and expand overseas markets, further benefiting patients worldwide.

International commercialisation process of HANQUYOU (trastuzumab for injection, European trade 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, the professional marketing personnel for the sales of HANQUYOU continued to penetrate the Mainland China market with efficient execution capabilities. Since the marketing of HANQUYOU, its efficient market and access provided a strong foundation for the 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 medical education, medical big data, HER2 testing, innovative payment 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.



– Commercialisation process of HANQUYOU in international markets

HANQUYOU is a trastuzumab independently developed by the Group in accordance with relevant laws and regulations of China, the European Union (the “EU”) and the United States on biosimilars. Focused on HANQUYOU, the Group has prospectively drawn up an internationally commercialised layout, cooperated with internationally renowned biomedicine enterprises, including Abbott Operations Uruguay S.R.L., Accord Healthcare Limited (“**Accord**”), Eurofarma Laboratorios S.A., PT Kalbio Global Medika, Laboratorio ELEA Phoenix S.A., etc., to fully boost market share in Europe, the United States, Canada, and other regions, as well as many emerging markets in country level, covering approximately 100 countries and regions around the world. As a representative domestic biologic to “go global”, HANQUYOU has successfully been approved for marketing in over 40 countries and regions, including the United Kingdom, Germany, Spain, France, Italy, Switzerland, Australia, Singapore, Argentina, Brazil, etc..



From the beginning of 2023 to date, the marketing authorisation applications of different specifications of HANQUYOU were approved in Cambodia, Singapore, Thailand, Philippines and Brazil, respectively. In addition, in February 2023, United States Food and Drug Administration (“FDA”) has accepted the biologics license application (BLA) for trastuzumab for injection. In July 2023, Health Canada accepted the New Drug Submission (NDS) for trastuzumab for injection, laying a foundation for the further development of HANQUYOU in overseas markets.

Four indications of HANSIZHUANG (serplulimab injection) were approved for marketing, using for the therapy for the MSI-H solid tumours, squamous non-small cell lung cancer (sqNSCLC), extensive-stage small cell lung cancer (ES-SCLC) and esophageal squamous cell carcinoma (ESCC), with a new chapter in overseas sales opened during the Reporting Period.

– Commercial sales of HANSIZHUANG in Mainland China

In Mainland China, the PD-1 monoclonal antibody product HANSIZHUANG, a core innovative product self-developed by the Group, has covered four indications since it was approved for marketing in 2022. It has become the first monoclonal antibody drug targeting PD-1 approved for first-line treatment of extensive-stage small cell lung cancer (ES-SCLC) around the world, and its differentiated advantages of focusing on



small cell lung cancer are uniquely competitive in the PD-1 market. As at the end of the Reporting Period, HANSIZHUANG has completed the tendering process on the procurement platform in all provinces in Mainland China. The sales team is capable of professional communication and has considerable experience in marketing in the tumours market, which adopts meticulous management modes covering approximately 36,000 professional doctors specializing in treating lung cancer, gastrointestinal tumour and other diseases in approximately 1,800 domestic hospitals. Meanwhile, HANSIZHUANG was recommended by 9 guidelines for its excellent clinical efficacy in lung cancer, esophageal cancer, intestinal cancer and other fields, including the 2023 Guidelines of Chinese Society of Clinical Oncology (“CSCO”) for Small-Cell Lung Cancer (《CSCO小細胞肺癌診療指南》), Guidelines of CSCO for Non-small Cell Lung Cancer (《CSCO非小細胞肺癌診療指南》), Guidelines of CSCO for Esophageal Cancer (《CSCO食管癌診療指南》), Guidelines of CSCO for Colorectal Cancer (《CSCO結直腸癌診療指南》) and Guidelines of CSCO for Immune Checkpoint Inhibitor Clinical Practice (《CSCO免疫檢查點抑制劑臨床應用指南》), and received widespread attention therefrom.

After the approvals for two indications for Microsatellite Instability-High (MSI-H) solid tumours and locally advanced or metastatic squamous non-small cell lung cancer (sqNSCLC) were obtained successively in 2022, the new drug application (NDA) for the third 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 National Medical Products Administration (“NMPA”) in January 2023. In September 2023, the new drug application (NDA) for the fourth indication of HANSIZHUANG in combination with drugs containing fluorouracil and platinum for the first-line treatment of PD-L1 positive, unresectable locally advanced/recurrent or metastatic esophageal squamous cell carcinoma (ESCC) was approved by NMPA. In February 2023, the results of the phase 3 clinical study of this indication were officially published in Nature Medicine (impact factors: 82.9), an international prestigious publication. HANSIZHUANG as the treatment for this indication is also listed in the I catalogue under the strength of recommendation (evidence type: 1A) in the 2023 Guidelines of CSCO for Esophageal Cancer (《CSCO食管癌診療指南》) and Guidelines of CSCO for Immune Checkpoint Inhibitor Clinical Practice (《CSCO免疫檢查點抑制劑臨床應用指南》). In December 2023, the new drug application (NDA) of HANSIZHUANG in combination with chemotherapy for the first-line treatment of locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) has been accepted by the NMPA, this is the fifth indication of HANSIZHUANG applied for marketing in Mainland China. The Company will continue to deepen the multi-tumour differentiated layout of HANSIZHUANG in order to benefit more patients.

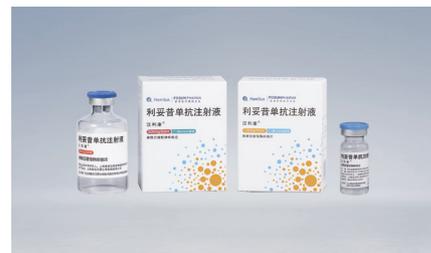
– Commercialisation process of HANSIZHUANG in the international market

With its excellent efficacy and data quality, HANSIZHUANG has also been widely acknowledged in the international market. As its licenses-out covering the United States, Europe, Southeast Asia, the Middle East and North Africa and India, the international commercialisation has been carried out in an orderly manner.

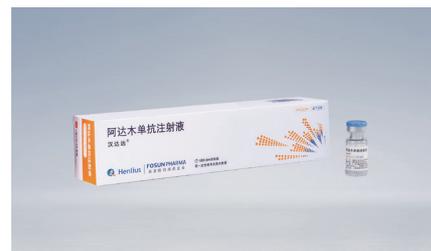
- In March 2023, the marketing authorisation application (MAA) of HANSIZHUANG in combination with chemotherapy for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC) has been validated by the EMA. In December 2023, the production lines of drug substance and drug product of HANSIZHUANG passed the GMP certification of the Netherlands, an EU Member State, these production lines have complied with the EU GMP standards, laying a solid foundation for the Group to further expand the overseas market of HANSIZHUANG. In addition, an Innovation Passport designation has been awarded to HANSIZHUANG for the treatment of extensive stage small cell lung cancer (ES-SCLC) by the United Kingdom Innovative Licensing and Access Pathway Steering Group including the Medicines & Healthcare products Regulatory Agency (MHRA) in January 2024.
- In December 2023, HANSIZHUANG was approved by Indonesia’s National Agency for Drug and Food Control (BPOM) for the treatment of extensive-stage small cell lung cancer (ES-SCLC) (local brand name: Zerpidio®). This is the first time that HANSIZHUANG has been approved for marketing in the overseas market, and accordingly, HANSIZHUANG has also become the first China-made anti-PD-1 mAb approved for marketing in Southeast Asian countries. During the Reporting Period, the Group also cooperated with our business partners to submit the marketing authorisation applications of HANSIZHUANG in Thailand, Singapore, Malaysia and other countries, which further promotes the progress of commercialisation of HANSIZHUANG within Southeast Asia regions.

Steady progress of the commercial sales of HANLIKANG (rituximab injection), HANDAYUAN (adalimumab injection) and HANBEITAI (bevacizumab injection) (therapeutic products for solid tumours, 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 the R&D and Evaluation of Biosimilars (Trial) 《生物類似藥研發與評價技術指導原則(試行)》 in China in 2019, HANLIKANG has benefited over 230,000 patients in total in Mainland China. HANLIKANG’s indications 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 coverage of both types of indications will serve 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. In February 2024, the supplemental new drug applications for new indications of HANDAYUAN of polyarticular juvenile idiopathic arthritis, pediatric plaque psoriasis and etc. have been accepted by the NMPA.



Additionally, as at the end of the Reporting Period, HANBEITAI, the fourth biosimilar product of the Group approved for marketing and had commercialised sales, 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. As at the Latest Practicable Date, HANBEITAI has been included in the medical insurance procurement platform in all provinces and has completed the tendering process on the procurement platform in 28 provinces in Mainland China.



Further promote the overseas commercialisation process of products through the licensing cooperation

The Group adhered to the internationalisation strategy. In April 2023, the Company entered into an agreement with Boston Oncology, LLC, agreeing to grant a license, to commercialise HANLIKANG in the Middle East and North Africa such as Saudi Arabia, Egypt and Bahrain. In August 2023, the Company entered into an agreement with FBD Biologics Limited, agreeing to grant a license to use the anti-PD-L1 VHH sequence to develop, manufacture,

commercialise HCB301 worldwide. In August 2023, the Company entered into an agreement with PT Kalbe Genexine Biologics, agreeing to grant a license, to commercialise HANSIZHUANG in the Middle East and North Africa such as Saudi Arabia, the United Arab Emirates and Egypt. In October 2023, the Company entered into an agreement with Intas Pharmaceuticals Ltd. (“**Intas**”), agreeing to grant a license, to commercialise HANSIZHUANG in the agreed European region and India. The Group also continued to promote the commercialisation of existing overseas cooperation during the Reporting Period.

Meanwhile, after the comprehensive consideration of the market conditions and commercial viability, the Group entered into the termination agreement with Chiome Bioscience, Inc. during the Reporting Period in terms of terminating cooperation on the TROP2 targeted antibodies.

(II) 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 the indication for products are in further process, including HANSIZHUANG (PD-1) and related combination therapies, HLX07 (recombinant anti-EGFR humanised monoclonal antibody injection), HLX04-O (recombinant anti-VEGF humanised monoclonal antibody injection), HLX42 for injection (antibody-drug conjugate targeting EGFR with novel DNA topoisomerase I inhibitor), HLX43 for injection (antibody-drug conjugate targeting PD-L1 with novel DNA topoisomerase I inhibitor) for the treatment of solid tumours, lymphomas, small cell lung cancer (SCLC), non-small cell lung cancer (NSCLC), metastatic colorectal cancer(mCRC), wet age-related macular degeneration (wAMD).

As at the end of the Reporting Period, the Group, synergising R&D centers in China and the United States, the global product development team has proceeded with its advancement over the clinical study and drug registration of many candidate drugs across the world, and achieved significant progress in 11 clinical trials and obtained 8 clinical trial approvals during the Reporting Period.

1. Continuous and efficient advancement of clinical research product

As at the Latest Practicable Date, the Group has carried out a total of more than 30 clinical trials in an orderly manner in various countries/regions across the world.

Progress of international clinical study projects

- In January 2023, the first patient in the United States has been dosed in an international multi-centre phase 3 clinical study of HANSIZHUANG in combination with chemotherapy (carboplatin/cisplatin-etoposide) and concurrent radiotherapy for the treatment of limited-stage small cell lung cancer (LS-SCLC). The first patient in Australia and the EU also have been dosed in such international multi-centre phase 3 clinical study in April and October 2023, respectively.
- As at the Latest Practicable Date, 81 sites have been set up for the bridging study in the United States for HANSIZHUANG in combination with chemotherapy (carboplatin-etoposide) for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC), and the recruitment of subjects is ongoing.

- In February 2023, the first patient in the United States has been dosed in an international multi-centre phase 3 clinical study of HLX04-O (recombinant anti-VEGF humanised monoclonal antibody injection) for the treatment of wet age-related macular degeneration (wAMD). As at the Latest Practicable Date, in addition to the United States, the first patient has been dosed in such international multi-centre phase 3 clinical study in Mainland China, EU, Australia and other countries/regions.

Progress of domestic clinical study projects

- Progress of HANSIZHUANG (serplulimab injection)
 - In February 2023, the first patient has been dosed in a phase 1b/2 clinical study of HLX208 (BRAF V600E inhibitor) in combination with HANSIZHUANG for the treatment of non-small cell lung cancer (NSCLC) in Mainland China.
 - In April 2023, the phase 2 investigational new drug application (IND) of HLX26 (recombinant anti-LAG-3 humanised monoclonal antibody injection) in combination with HANSIZHUANG and chemotherapy for the first-line treatment of advanced non-small cell lung cancer (NSCLC) was approved by the NMPA, and the first patient has been dosed in such trial in August 2023.
 - In June 2023, the first patient has been dosed in a phase 2 clinical trial of HLX26 (recombinant anti-LAG-3 humanised monoclonal antibody injection) in combination with HANSIZHUANG for the treatment of patients with metastasis colorectal cancer (mCRC) who had previously received third-line treatment in Mainland China.
 - In October 2023, the phase 3 clinical study of HANSIZHUANG in combination with chemotherapy for the first-line treatment of advanced non-squamous non-small cell lung cancer (nsNSCLC) met the primary study endpoint and its results showed that HANSIZHUANG in combination with chemotherapy (carboplatin-pemetrexed) demonstrated good efficacy and safety in patients with advanced non-squamous non-small cell lung cancer.
- Progress of other products
 - In February 2023, the first subject has been dosed in a 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 demonstrated good safety and tolerability of HLX07 in the phase 1b/2 clinical study conducted in patients with advanced solid tumours.
 - In April 2023, HLX208 (BRAF V600E inhibitor) for the treatment of adult Langerhans Cell Histiocytosis (LCH) and Erdheim-Chester disease (ECD) with BRAF V600E mutation has been officially granted the Breakthrough Therapy Designation by the Center for Drug Evaluation (CDE) of the NMPA.

- In June and November 2023, the investigational new drug applications (IND) of a biosimilar of Ipilimumab HLX13 (recombinant anti-CTLA-4 fully human monoclonal antibody injection) were approved by the NMPA, respectively. In December 2023, the first subject has been dosed in a phase 1 clinical trial of HLX13 in healthy Chinese male subjects.
- In July 2023, the phase 1/2 clinical study of HLX04-O (recombinant anti-VEGF humanised monoclonal antibody injection) in patients with wet age-related macular degeneration (wAMD) demonstrated good safety and tolerability and demonstrated its preliminary efficacy.
- In October 2023, the phase 1 investigational new drug application (IND) of HLX42 for injection (antibody-drug conjugate targeting EGFR with novel DNA topoisomerase I inhibitor) for the treatment of advanced/metastatic solid tumours was approved by the NMPA, and the first patient has been dosed in such trial in March 2024. In November 2023, the phase 1 investigational new drug application (IND) of HLX42 for injection for the treatment of advanced/metastatic solid tumours was approved by the FDA. In December 2023, HLX42 for injection for the treatment of patients with advanced or metastatic EGFR-mutated non-small cell lung cancer whose disease has progressed on a third-generation EGFR tyrosine kinase inhibitor has been granted the Fast Track Designation by the FDA.
- In October 2023, the phase 1 investigational new drug application (IND) of HLX43 for injection (antibody-drug conjugate targeting PD-L1 with novel DNA topoisomerase I inhibitor) for the treatment of advanced/metastatic solid tumours was approved by the NMPA, and the first patient has been dosed in such trial in November 2023. In November 2023, the phase 1 investigational new drug application (IND) of HLX43 for injection for the treatment of advanced/metastatic solid tumours was approved by the FDA.
- In January 2024, the phase 1 clinical study of a biosimilar of denosumab HLX14 (recombinant anti-RANKL human monoclonal antibody injection) in healthy Chinese male subjects was successfully completed. The results of the study demonstrate that HLX14 has highly similar pharmacokinetics and pharmacodynamics, as well as comparable safety, tolerability and immunogenicity to the US-, EU-, and CN-sourced denosumab. This study met all of the pre-specified endpoints.

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

The Group attached great importance to the pre-clinical project pipeline and proactively proceeded with the investigational new drug application (IND) for products during the Reporting Period.

- 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 the NMPA and approved in March 2023.

- In December 2023, the investigational new drug application (IND) of HLX6018 (recombinant anti-GARP/TGF-β1 humanised monoclonal antibody for injection) for the treatment of idiopathic pulmonary fibrosis was accepted by the NMPA and approved in March 2024.
- In March 2024, the investigational new drug applications (IND) of an innovative small molecular HLX99 tablet for the treatment of amyotrophic lateral sclerosis (ALS) were accepted by NMPA.

The clinical and pre-clinical application results of the Group's products from the beginning of 2023 to the Latest Practicable Date.

Product name (targets)	Indications	Progress as at the Latest Practicable Date
Efficient advancement on international clinical projects		
HANSIZHUANG in combination with chemotherapy concurrent radiotherapy (PD-1)	Limited-stage small cell lung cancer (LS-SCLC)	<p>In January 2023, the first patient in the United States has been dosed in an international multi-centre phase 3 clinical study</p> <p>In April 2023, the first patient in Australia has been dosed in an international multi-centre phase 3 clinical study</p> <p>In October 2023, the first patient in the EU has been dosed in an international multi-centre phase 3 clinical study</p>
HANSIZHUANG in combination with chemotherapy (PD-1)	Extensive-stage small cell lung cancer (ES-SCLC)	As at the Latest Practicable Date, the bridging study in the United States has set up 81 sites and recruitment of subjects is ongoing
HLX04-O (VEGF)	Wet age-related macular degeneration (wAMD)	In February 2023, the first patient in the United States has been dosed in an international multi-centre phase 3 clinical study

Product name (targets)	Indications	Progress as at the Latest Practicable Date
Smooth progress of domestic clinical projects		
HLX208 in combination with HANSIZHUANG (BRAF V600E+PD-1)	Non-small cell lung cancer (NSCLC)	In February 2023, the first patient has been dosed in a phase 1b/2 clinical trial
HLX26 in combination with HANSIZHUANG and chemotherapy (LAG-3+PD-1)	Non-small cell lung cancer (NSCLC)	In April 2023, the phase 2 investigational new drug application was approved by the NMPA In August 2023, the first patient has been dosed in a phase 2 clinical trial
HLX26 in combination with HANSIZHUANG (LAG-3+PD-1)	Metastatic colorectal cancer (mCRC)	In June 2023, the first patient has been dosed in a phase 2 clinical trial
HANSIZHUANG in combination with chemotherapy (PD-1)	Non-squamous non-small cell lung cancer (nsNSCLC)	In October 2023, the phase 3 clinical study met the primary study endpoint
HLX15 (CD38)	Multiple myeloma (MM)	In February 2023, the first subject has been dosed 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
HLX208 (BRAF V600E)	Adult Langerhans Cell Histiocytosis (LCH) and Erdheim-Chester disease (ECD)	In April 2023, the Center for Drug Evaluation (CDE) of the NMPA granted the Breakthrough Therapy Designation officially
HLX13 (CTLA-4)	Melanoma, renal cell carcinoma, colorectal cancer, hepatocellular carcinoma, non-small cell lung cancer, malignant pleural mesothelioma and esophageal squamous-cell carcinoma	In June 2023, the investigational new drug application for the treatment of liver cancer was approved by the NMPA In November 2023, the investigational new drug application was approved by the NMPA In December 2023, the first subject has been dosed in a phase 1 clinical trial
HLX04-O (VEGF)	wet age-related macular degeneration (wAMD)	In July 2023, the phase 1/2 clinical study was completed

Product name (targets)	Indications	Progress as at the Latest Practicable Date
HLX42 (EGFR ADC)	Solid tumour	In October 2023, the phase 1 investigational new drug application was approved by the NMPA In March 2024, the first patient has been dosed in a phase 1 clinical trial
HLX43 (PD-L1 ADC)	Solid tumour	In October 2023, the phase 1 investigational new drug application was approved by the NMPA In November 2023, the first patient has been dosed in a phase 1 clinical trial
HLX14 (RANKL)	Osteoporosis (OP)	In January 2024, the phase 1 clinical study conducted in healthy Chinese male subjects was completed
Efficient advancement of IND application for pre-clinical development projects		
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
HLX13 (CTLA-4)	Melanoma, renal cell carcinoma, colorectal cancer, hepatocellular carcinoma, non-small cell lung cancer, malignant pleural mesothelioma and esophageal squamous-cell carcinoma	In April 2023, the investigational new drug application for the treatment of liver cancer was accepted by the NMPA In June 2023, the investigational new drug application for the treatment of liver cancer was approved by the NMPA In August 2023, the investigational new drug application was accepted by the NMPA In November 2023, the investigational new drug application was approved by the NMPA (Already in clinical phase)

Product name (targets)	Indications	Progress as at the Latest Practicable Date
HLX42 (EGFR ADC)	Solid tumour	<p>In August 2023, the phase 1 investigational new drug application was accepted by the NMPA</p> <p>In October 2023, the phase 1 investigational new drug application was approved by the NMPA</p> <p>In October 2023, the phase 1 investigational new drug application was accepted by the FDA</p> <p>In November 2023, the phase 1 investigational new drug application was approved by the FDA</p> <p>In December 2023, the treatment of patients with advanced or metastatic EGFR-mutated non-small cell lung cancer whose disease has progressed on a third-generation EGFR tyrosine kinase inhibitor has been granted the Fast Track Designation by the FDA</p> <p>(Already in clinical phase in Mainland China)</p>
HLX43 (PD-L1 ADC)	Solid tumour	<p>In August 2023, the phase 1 investigational new drug application was accepted by the NMPA</p> <p>In October 2023, the phase 1 investigational new drug application was approved by the NMPA</p> <p>In October 2023, the phase 1 investigational new drug application was accepted by the FDA</p> <p>In November 2023, the phase 1 investigational new drug application was approved by the FDA</p> <p>(Already in clinical phase in Mainland China)</p>

Product name (targets)	Indications	Progress as at the Latest Practicable Date
HLX6018 (GARP/TGF-β1)	Idiopathic pulmonary fibrosis (IPF)	In December 2023, the investigational new drug application was accepted by the NMPA In March 2024, the investigational new drug application was approved by the NMPA
HLX99 (Polypharmacology)	Amyotrophic lateral sclerosis (ALS)	In March 2024, the investigational new drug applications were accepted by the NMPA

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

By centering on patients' needs, with the clinical value-oriented early R&D, the Group coordinated with early R&D teams in China and the United States, based on new drug discovery platforms driven by deep data and biocomputing accelerated molecular design technology, to continue to develop high-quality and affordable innovative drugs to treat complex diseases with the help of network biology and polypharmacology. By employing a comprehensive antibody drug technology platform to empower the development of innovative therapies, the Group was eyeing the next-generation innovative antibody drugs and antibody-based drugs. In terms of the development of antibody-drug conjugates (ADC), the Group's R&D platform Hanjugator has the ability to develop ADC products with high safety, high selectivity and high efficacy, and is able to effectively expand the application scenarios of ADC products, providing strong support for the Group in developing ADC products with differentiation advantage and significant clinical value.

As at the Latest Practicable Date, the Group has a total of 59 molecules (including 48 innovative drugs and 11 biosimilar drugs) in its pipeline and 18 R&D platforms, with the forms of drug covering monoclonal antibody, bispecific antibody, ADC, recombinant protein and small molecule-drug conjugates, etc.

(IV) 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 the Xuhui Facility with a commercial production capacity of 24,000L and Songjiang First Plant with a commercial production capacity of 24,000L), has fully supported the commercialisation needs of products approved for marketing in Mainland China and overseas.

- Xuhui Facility, the Group's first biopharmaceutical production base in Shanghai Caohejing Hi-Tech Park has been granted with the Chinese and EU GMP certificates and achieved normalised supply in China and the EU markets. From October to December 2023, the production lines of HANSIZHUANG, HANLIKANG and HANQUYOU in the Xuhui Facility have successively passed the pre-approval GMP inspection of related products by the drug and health supervision agencies in Indonesia, Brazil and the Netherlands. Among them, the production lines of drug substance and

drug product of HANSIZHUANG have passed the GMP certification of the Netherlands, an EU Member State, marking that such production lines have met the EU GMP standards, which laid a solid foundation for the Group to further expand the overseas market of HANSIZHUANG.

- Songjiang First Plant of the Group in Songjiang District, Shanghai has a commercial production capacity of 24,000L, including the liquid fill line and lyophilized preparation line. During the Reporting Period, at Songjiang First Plant, the Process Performance Qualification (PPQ) batches productions of products such as HLX04-O, HLX11 and HLX14 drug substance were completed, and the product commercialisation process was steadily advanced. Songjiang First Plant also accepted the Pre-License Inspection (PLI) of HANQUYOU by the FDA during the Reporting Period.
- In order to meet the Group's long-term demand for commercial production capacity, the construction of the Phase I project of Songjiang Second Plant, with a total planned land area of 200 acres started in 2019. The designed production capacity for the first and second stages of this project is totaled 36,000L. The installation and commissioning of equipment in two main production buildings including production lines of drug substance and drug product and Prefilled Syringes System (PFS), and part of equipment verification work have been completed, while the remaining verification work will be implemented expeditiously. During the Reporting Period, the construction of the underground structure of the third stage of the Phase I project of Songjiang Second Plant was completed, and the construction of the aboveground structure began.

(V) 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 high-quality medicines for global patients, and has actively fulfilled its responsibilities toward stakeholders such as patients, employees, partners, and communities. The Group took an active approach to implement the ESG management strategy, and focused its ESG efforts on corporate governance, product, talent, environment and the society. In terms of corporate governance, the Group continued to establish sound and compliant management systems, strictly restrict the conduct of businesses, and improve risk management and control ability. In terms of product, by upholding the principle of “Quality First”, the Group strictly abided by high-quality standards in production and development, and was devoted to improving the affordability and accessibility of products with medical security, patient assistance programs and product layout globalisation. In terms of talents, the Group resolutely protected the legitimate rights and interests and welfare of employees. By providing staff with an all-around, three-dimensional talent training platform, coupled with a well-conceived and reasonable promotion incentive mechanism, the Group enabled its staff to grow in multiple fields. In terms of environment, the Group continued to monitor the progress of its environmental targets, and has put multiple environmental management measures into practice. On the social front, the Group continued to push ahead with “To the Time to Life”, a public welfare program for cancer patients and “Rural Medical Service”, a public welfare activity regarding rural medical care during the Reporting Period. It is devoted to upholding the “Patient-oriented” concept throughout the full life cycle of products and assists partners along the value chain in creating a sustainable supply chain, to actively advance industry cooperation and development.

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 2024

In 2024, based on clinical needs, the Group will continue to devote itself to oncology, auto-immune diseases and other fields, and deepen product innovation, market expansion and international cooperation so that we can 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 biopharma companies in Mainland China, the Group will continue to advance the successful commercialisation of more products in an all-round efficient commercial operation model, 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 in-house commercialisation team. In 2024, with the current market strength, the Group will consolidate the market share and continuously develop market potential at all levels based on dual-specification (both 150mg and 60mg) of HANQUYOU with international quality.
- HANSIZHUANG is one of the Group’s core innovative monoclonal antibody products. In 2024, the Group plans to further expand the sales team of HANSIZHUANG, and set up a dedicated sales team for gastrointestinal tumours in response to the latest approved indication of esophageal squamous cell carcinoma (ESCC), thereby grasping the market potential of HANSIZHUANG in gastrointestinal tumours market 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 the standard treatment rate of patients.
- The Group commenced the commercial sales of HANBEITAI since 2023 and would further promote and implement the sales of it in 2024.
- 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 2024, the Group will maintain close cooperation with Jiangsu Fosun and Jiangsu Wanbang, 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 progress made in the R&D and registration of pipeline products of the Group and the gradual recognition of the Group’s products in the international market, the Group will continuously depend on the commercial capability of international partners in their own field to jointly expand our products into broader international markets, especially emerging markets with huge unmet medical needs for affordable drugs, which will benefit patients overseas.

In August 2023, the Company and Baodao Pharmaceutical Co., Ltd. (“**Baodao Pharmaceutical**”) entered into the Framework Agreement in relation to the Acquisition of DDL Licensed Company, pursuant to which, the Company plans to acquire 100% equity interests of the subsidiary with a pharmaceutical business license, which is wholly-owned by Baodao Pharmaceutical. Upon the completion of the transaction, the Company will be able to commercialise more in-licensing products in Mainland China and is expected to bring more business opportunities to the Company.

(II) Continue to facilitate the approvals of pipeline products worldwide

As at the Latest Practicable Date, 5 products of the Group have been successfully marketed in Mainland China, Europe, Australia, Indonesia and other countries/regions. In 2024, the Group will continuously promote the marketing approval process of more products in the global market with experiences gained along the way.

- 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 the EU in 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 2024.
- 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 2024.
- New Drug Submission (NDS) for HANQUYOU with the treatment for the indications including HER2-positive early-stage breast cancer, is expected to be approved in Canada in 2024.
- In 2024, the Group will also proactively cooperate with international partners to facilitate the marketing approval process in terms of HANLIKANG, HANDAYUAN, HANBEITAI, HLX04-O, HLX11, HLX14 in the United States, EU, Canada, Saudi Arabia, Brazil and other countries and regions.

(III) Continue to expand product pipeline based on patients’ needs 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, while rapidly empowering and expanding the pipeline of the Group by project cooperation, with a view to addressing unmet clinical needs as soon as possible. In 2024, the Group’s pipeline products are expected to be further promoted and expanded:

- The investigational new drug applications (IND) of HLX99 tablets, innovative small molecules, for the treatment of amyotrophic lateral sclerosis (ALS) are expected to be approved by the NMPA in the first half of 2024.

- The investigational new drug application (IND) of HLX78 (Lasofixifene) is expected to be approved by the NMPA in the first half of 2024. The Group licensed-in the product from Sermonix Pharmaceuticals, Inc. in January 2024 to acquire the rights of development, production and commercialisation in Mainland China and for intended treatment of breast cancer.

(IV) Maintain 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 to ensure the stability and efficiency of international commercial production. In 2024, Songjiang First Plant will continuously improve the international standard quality system and plans to complete the GMP compliance inspection of HLX14 before its launch in the EU and the inspection for drug manufacturing of HLX04-O and HLX11 in Mainland China.

Songjiang Second Plant Phase I Project is expected to complete completion acceptance in 2024 and its batch production of Second Generation Process performance qualification (PPQ) of HANSIZHUANG is expected to be completed in 2024. Verification of facilities at each stage of the Songjiang Second Plant Phase I Project will be gradually facilitated based on the business needs of the Group. 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 R&D, pilot test and production base for monoclonal antibody biological drugs 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 gradually enlarged its competitive advantages by leveraging its first-mover advantages and differentiated layout in innovative research and development. With the professional and efficient commercialisation team actively promoting the all-round innovative business operation model, the Group has achieved excellent commercialisation results, which has also demonstrated the value of the Group's integrated research, production and marketing platform and its self-sustaining cash flow. During the Reporting Period, HANQUYOU and HANSIZHUANG, the two core products 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, led the continuous rapid growth of the Group's revenue.

As an international and innovative biopharmaceutical company, the Group continued to implement its innovation strategy. Through strengthening cooperation with first-class academic institutions around the world and building more new strategic partnerships to jointly explore technological innovation and the application of cutting-edge technologies, the Group expanded the global R&D layout, and accelerated the transformation and application of more innovative achievements through "both internal and external development". During the Reporting Period, the Group cooperated with partners to expand overseas markets

with remarkable results in delivering benefits to patients around the world, brought in considerable R&D service income and licensing income, and opened up new growth space for internationalization.

During the Reporting Period, the Group realised an operating income of RMB5,394.9 million, representing an increase of 67.8% compared to the same period in the last year, and the main revenue components are as follows:

1) Revenue from product sales:

HANQUYOU (trastuzumab for injection) 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 inhouse 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 RMB2,644.4 million, representing a rapid increase of approximately RMB950.0 million or approximately 56.1% as compared to the same period in the last year.

HANSIZHUANG (serplulimab) was the first self-developed and approved bioinnovative drug 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 RMB1,119.8 million, representing a dramatic increase of approximately RMB780.7 million or approximately 230.2% as compared to the same period in the last year.

HANBEITAI (bevacizumab) is the fourth biosimilar product of the Group approved for marketing in Mainland China and commercialised by the Group's in-house team. It was commercially available in the domestic market in January 2023. During the Reporting Period, HANBEITAI recorded sales revenue of approximately RMB119.4 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 RMB518.6 million, and licensing income of approximately RMB21.9 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 would reimburse all the expenses related to the clinical trials of HANDAYUAN incurred by the Group after the relevant cooperation agreement was signed, and the Group was 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 RMB58.6 million under the aforementioned profit-sharing arrangement with its partners.

Zercepac[®] (trastuzumab, European brand name) recorded revenue of approximately RMB69.5 million during the Reporting Period, and drug substance of trastuzumab recorded sales revenue of approximately RMB23.1 million in international market.

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

Since its establishment, the Group has adhered to an international vision and focused on clinical needs. While deepening the differentiated innovation strategy, the Group has gradually established an international standard quality control system and accumulated extensive experience in international registration in large-scale international multi-centre phase 3 clinical trials. With the continuous implementation of the internationalization and innovation strategy, the Group's 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.

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 of approximately RMB6.0 million for the 12 months ended 31 December 2023.

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 RMB59.6 million for the 12 months ended 31 December 2023.

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 RMB112.7 million for the 12 months ended 31 December 2023.

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 United States., EU, Japan and other major biomedicine markets and many emerging markets. The Group has recognised revenue from R&D services of approximately RMB311.8 million for the 12 months ended 31 December 2023.

In November 2022, the Group entered into a license agreement 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**”), granting it the equity of exclusive commercialisation of HANSIZHUANG (serplulimab) independently developed by the Group in the United States. The Group has recognised revenue from R&D services of approximately RMB171.6 million for the 12 months ended 31 December 2023.

In October 2023, the Group entered into a license agreement with Intas in relation to HANSIZHUANG (serplulimab), granting Intas exclusive developing and commercial rights in special territories as agreed therein. The Group has recognized licensing revenue of approximately RMB111.1 million for the 12 months ended 31 December 2023.

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 RMB1.0 million for the 12 months ended 31 December 2023.

In September 2022, the Group entered into a technical service contract with Shanghai KangaBio Co., Ltd. in relation to CMC services such as cell library construction and toxicology research for an innovative drug being developed by it. With the continuous advancement of technical services, the Group recognised revenue from R&D services of approximately RMB9.5 million for the 12 months ended 31 December 2023.

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 2023, the Group recognised revenue from R&D service of approximately RMB30.3 million.

In June 2023, the Group entered into the CMC Technical Services Framework Agreement with Fosun Pharma Industrial Development. With the continuous advancement of technical services, the Group recognised revenue from R&D services of approximately RMB1.1 million for the 12 months ended 31 December 2023.

(II) Cost of sales

Cost of sales of the Group primarily represents reagents and consumables, employee compensation, outsourcing fees, utilities expenses and depreciation and amortisation. For the 12 months ended 31 December 2023, the Group recorded cost of sales of approximately RMB1,476.1 million, representing an increase of approximately RMB631.5 million as compared with that for the 12 months ended 31 December 2022, due to the increase in the cost of R&D services and the increase of the sales volume of the key commercial product markets during the Reporting Period as the continuous advancement of R&D services.

(III) Gross profit

For the 12 months ended 31 December 2023, the Group recorded a gross profit of approximately RMB3,918.8 million, representing an increase of approximately RMB1,548.7 million as compared with that for the 12 months ended 31 December 2022, 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 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 RMB68.9 million.

	Year ended 31 December	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Government grants	59,814	69,043
Exchange gains	(1,421)	32,919
Interest income	8,146	3,571
Others	2,375	19
Total	68,914	105,552

(V) R&D expenses

	Year ended 31 December	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Expensed R&D expenses		
R&D employee salaries	333,275	460,783
Outsourcing fees	120,180	296,959
Clinical trials	299,424	212,151
Reagents and consumables	128,878	134,850
Depreciation and amortisation	65,661	94,059
Consulting expense	25,676	51,430
Technology expense	62,020	45,288
Utilities expenses	11,640	19,161
Share-based compensation	161	1,446
Others	71,817	78,387
Total expensed R&D expenses	1,118,732	1,394,514

	Year ended 31 December	
	2023	2022
	RMB'000	RMB'000
Capitalised R&D expenses		
Clinical trials	84,333	519,408
R&D employee salaries	125,791	153,850
Outsourcing fees	27,852	24,227
Depreciation and amortisation	21,217	23,890
Reagents and consumables	29,849	15,020
Consulting expense	677	3,263
Utilities expenses	4,668	1,380
Share-based compensation	38	707
Others	20,486	46,943
	<hr/>	<hr/>
Total capitalised R&D expenses	314,911	788,688
	<hr/> <hr/>	<hr/> <hr/>

For the 12 months ended 31 December 2023, the Group recognised R&D expenses of approximately RMB1,433.6 million, representing a decrease of approximately RMB749.6 million as compared to approximately RMB2,183.2 million for the 12 months ended 31 December 2022, mainly due to (1) the development expenditures under the contracts are included in cost of R&D service after certain projects were licensed out, thereby reducing their own R&D expenses; and (2) during the Reporting Period, the Group continued to deploy scientific and efficient R&D strategy, focus on unmet clinical needs and optimize allocation of pipeline resources. Such R&D expenses was mainly due to advancing technology platform innovation, IND application and clinical trials for new drugs 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 2023, the Group recognised administrative expenses of approximately RMB383.8 million, representing an increase of approximately RMB29.8 million as compared with that of approximately RMB354.0 million for the 12 months ended 31 December 2022. The increase in administrative expenses of the Group was mainly due to: (1) the increase in the cost of the administrative staff with the expansion of the operations and development of the Group; and (2) the corresponding increase in depreciation costs, lease payments, travel expenses and conference expenses to improve operational efficiency.

(VII) Selling and distribution expenses

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

For the 12 months ended 31 December 2023, the Group recognised selling and distribution expenses of approximately RMB1,754.2 million, which were mainly the marketing expenses incurred in continuous sales growth of HANQUYOU, HANSIZHUANG and the marketing and selling of HANBEITAI. Among which, the marketing expenses ratio of HANQUYOU in domestic market has been decreasing over the years, reaching 30% in 2023.

(VIII) Other expenses

For the 12 months ended 31 December 2023, the Group recognised other expenses of approximately RMB20.5 million, which mainly included provision for 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 2023, the Group incurred income tax expense of approximately RMB23.6 million.

(X) Profit for the year

In view of the above, the Group recorded an increase of approximately RMB1,241.3 million in profit from a loss of approximately RMB695.3 million for the year ended 31 December 2022 to a profit of approximately RMB546.0 million for the year ended 31 December 2023.

(XI) Liquidity and capital resources

As of 31 December 2023, cash and bank balances of the Group were approximately RMB987.7 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 of approximately RMB680.5 million as of 31 December 2022, representing an increase of approximately RMB307.2 million.

As of 31 December 2023, the current assets of the Group were approximately RMB2,676.0 million, including cash and cash equivalents of approximately RMB867.7 million, fixed time deposits of approximately RMB120.0 million, inventories of approximately RMB757.4 million, trade receivables of approximately RMB647.8 million, contract assets of approximately RMB82.4 million, and other receivables of approximately RMB200.7 million.

As of 31 December 2023, the current liabilities of the Group were approximately RMB5,067.4 million, including trade payables of approximately RMB544.8 million, other payables and accruals of approximately RMB1,255.3 million, contract liabilities of RMB466.9 million and interest-bearing bank and other borrowings of approximately RMB2,800.4 million.

As at 31 December 2023, the bank balances in foreign exchange were as follows:

	<i>RMB'000</i>
RMB	575,536
HKD	5,719
USD	399,755
EUR	2,868
NTD	3,787
	<u> </u>

	<i>Original amount</i> <i>'000</i>
RMB	575,536
HKD	6,311
USD	56,434
EUR	365
NTD	16,364
	<u><u> </u></u>

(XII) Inventories

Inventories of the Group amounted to approximately RMB757.4 million as at 31 December 2023, basically in line with approximately RMB757.3 million as at 31 December 2022.

(XIII) Trade receivables

As at 31 December 2022 and 31 December 2023, trade receivables from customer contracts were approximately RMB455.5 million and RMB647.8 million, respectively. There were no changes in accounting estimates or key assumptions made in both years.

	As at 31 December	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Within 3 months	635,950	373,226
3 to 6 months	11,878	114
6 to 12 months	–	20,877
1 to 2 years	–	61,292
	<u> </u>	<u> </u>
Total	<u><u>647,828</u></u>	<u><u>455,509</u></u>

(XIV) Interest-bearing bank and other borrowings

As of 31 December 2023, borrowings from bank and other institutions (exclusive of lease liabilities) of the Group were approximately RMB3,819.6 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.

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 2023 and 31 December 2022, of which lease liabilities were recognised in accordance with IFRS 16 – Leases.

	As at 31 December	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Within one year	2,800,377	2,522,155
In the second year	213,288	155,864
In the third to fifth year (inclusive)	899,218	704,137
Over five years	180,168	294,939
Total	4,093,051	3,677,095

(XVI) Collateral and pledged assets

As at 31 December 2023, the Group's pledged assets in relation to borrowings included property, plant and equipment of approximately RMB907.5 million and land use right of approximately RMB192.6 million.

(XVII) Key financial ratios

	31 December 2023	31 December 2022
Current ratio ⁽¹⁾ :	52.8%	43.8%
Quick ratio ⁽²⁾ :	37.9%	28.7%
Gearing ratio ⁽³⁾ :	59.5%	64.7%

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 at 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	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Construction in progress	472,846	624,228
Plant and machinery	52,046	45,116
Electronic equipment	11,574	29,142
Leasehold improvements	35,589	13,754
Total	572,055	712,240

We had capital commitments for plant and machinery contracted but not provided for of approximately RMB209.3 million as at 31 December 2023. 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 at 31 December 2023, the Group did not have any material contingent liabilities.

(XXI) Material acquisitions and disposals

As at 31 December 2023, the Group did not have any material acquisitions and disposals.

(XXII) Dividends

The Group did not pay or declare any dividends for the year ended 31 December 2023.

IV. RISK MANAGEMENT

(I) Foreign exchange risk

As at 31 December 2023, 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, revenue, 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. In March 2023, the National Healthcare Security Administration issued the "Notice on Improving the Centralised Procurement and Price Management of Pharmaceuticals in 2023", proposing to continue to expand the coverage of centralised drug procurement, focusing on varieties that have not been included or evaluated in the national centralised procurement in respect of the centralised drug procurement at the provincial level, actively exploring the "blank" variety centralised procurement that has not yet been included in the national or provincial centralised procurement, and encouraging price linkage with volume for varieties that have already been centralised at the provincial level and have sufficient price competition. Currently, certain monoclonal antibody (mAb) biosimilars have already been included in the scope of centralised drug procurement at some provincial levels, but centralised drug procurement at the national level has not been conducted on monoclonal antibody (mAb) biosimilars. If any of our products and products of our competitors were chosen to participate in tenders and be included in centralised volume-based procurement, it may have a potential impact on the pricing of the drugs to some extent.

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 for 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. 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 2023:

Function	Number of employees
R&D and technology	1,035
Manufacturing	889
Commercial Operation	1,445
General and administrative	268
Total	<u>3,637</u>

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 agreement. 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, the Group has also adopted share award schemes to give incentives to our employees. The Group emphasizes 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 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 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 C1 to the Listing Rules.

CG Code provision C.2.1 provides that the roles of chairman and chief executive should be separate and should not be performed by the same individual. From the beginning of the Reporting Period to 17 July 2023, Mr. Wenjie Zhang assumed the roles of both chairman of the Board and chief executive officer. The Company deviated from the code provision. 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 chief executive officer of the Company can facilitate the formulation and implementation of business strategies of the Company. In addition, from the beginning of the Reporting Period to 17 July 2023, the Board, which 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 their shareholders as a whole. With effect from 17 July 2023, Mr. Zhu Jun was appointed as the chief executive officer of the Company following the resignation of Mr. Wenjie Zhang as the chief executive officer. Accordingly, from 17 July 2023 to the Latest Practicable Date, the Company has complied with all applicable 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 C3 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.

AUDIT COMMITTEE

The audit committee of the Company has reviewed the Group's 2023 annual results and the financial statements for the year ended 31 December 2023 prepared in accordance with the IFRSs.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS*Year ended 31 December 2023*

	<i>Notes</i>	2023 RMB'000	2022 RMB'000
REVENUE	<i>3</i>	5,394,909	3,214,730
Cost of sales		<u>(1,476,112)</u>	<u>(844,621)</u>
Gross profit		3,918,797	2,370,109
Other income and gains	<i>4</i>	68,914	105,552
Selling and distribution expenses		(1,754,241)	(1,049,292)
Administrative expenses		(383,840)	(354,038)
Impairment losses on financial assets, net		(30,280)	(200,791)
Research and development expenses		(1,118,732)	(1,394,514)
Other expenses		(20,501)	(65,241)
Finance costs	<i>6</i>	<u>(110,539)</u>	<u>(105,672)</u>
PROFIT/(LOSS) BEFORE TAX	<i>5</i>	569,578	(693,887)
Income tax expense	<i>7</i>	<u>(23,559)</u>	<u>(1,372)</u>
PROFIT/(LOSS) FOR THE YEAR		<u>546,019</u>	<u>(695,259)</u>
Attributable to:			
Owners of the parent		546,019	(695,259)
Non-controlling interests		<u>–</u>	<u>–</u>
		<u>546,019</u>	<u>(695,259)</u>
EARNINGS/(LOSS) PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic			
– For profit/(loss) for the year (RMB)	<i>9</i>	<u>1.01</u>	<u>(1.28)</u>
Diluted			
– For profit/(loss) for the year (RMB)	<i>9</i>	<u>1.00</u>	<u>(1.28)</u>

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

Year ended 31 December 2023

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
PROFIT/(LOSS) FOR THE YEAR	<u>546,019</u>	<u>(695,259)</u>
OTHER COMPREHENSIVE INCOME/(LOSS)		
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:		
Exchange differences:		
Exchange differences on translation of foreign operations	<u>17</u>	<u>(3,997)</u>
OTHER COMPREHENSIVE INCOME/(LOSS) FOR THE YEAR, NET OF TAX	<u>17</u>	<u>(3,997)</u>
TOTAL COMPREHENSIVE INCOME/(LOSS) FOR THE YEAR	<u>546,036</u>	<u>(699,256)</u>
Attributable to:		
Owners of the parent	<u>546,036</u>	<u>(699,256)</u>
Non-controlling interests	<u>–</u>	<u>–</u>
	<u>546,036</u>	<u>(699,256)</u>

CONSOLIDATED STATEMENT OF FINANCIAL POSITION
31 December 2023

	<i>Notes</i>	2023 RMB'000	2022 RMB'000
NON-CURRENT ASSETS			
Property, plant and equipment		2,237,768	1,817,449
Intangible assets		4,510,729	4,332,283
Right-of-use assets		414,886	412,422
Other non-current assets		64,156	170,612
Total non-current assets		7,227,539	6,732,766
CURRENT ASSETS			
Inventories		757,359	757,312
Trade receivables	<i>10</i>	647,828	455,509
Prepayments, deposits and other receivables	<i>11</i>	200,761	298,243
Contract assets		82,419	–
Cash and bank balances		987,665	680,478
Total current assets		2,676,032	2,191,542
CURRENT LIABILITIES			
Trade payables	<i>12</i>	544,815	713,552
Other payables and accruals		1,255,363	1,443,451
Contract liabilities		466,878	322,420
Interest-bearing bank and other borrowings		2,800,377	2,522,155
Total current liabilities		5,067,433	5,001,578
NET CURRENT LIABILITIES		(2,391,401)	(2,810,036)
TOTAL ASSETS LESS CURRENT LIABILITIES		4,836,138	3,922,730
NON-CURRENT LIABILITIES			
Interest-bearing bank and other borrowings		1,292,674	1,154,940
Other long-term payables		172,071	292,370
Contract liabilities		949,044	645,594
Deferred income		230,048	193,494
Total non-current liabilities		2,643,837	2,286,398
Net assets		2,192,301	1,636,332
EQUITY			
Share capital		543,495	543,495
Reserves		1,648,806	1,092,837
Equity attributable to owners of the parent and total equity		2,192,301	1,636,332

NOTES TO FINANCIAL STATEMENTS

Year ended 31 December 2023

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 RMB2,391,401,000 as at 31 December 2023. 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 2023. 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, 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 the related assets (including goodwill), liabilities, any non-controlling interest and the exchange fluctuation reserve; and recognises the fair value of any investment retained and 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 new and revised IFRSs for the first time for the current year's financial statements.

IFRS 17	<i>Insurance Contracts</i>
Amendments to IAS 1 and IFRS Practice Statement 2	<i>Disclosure of Accounting Policies</i>
Amendments to IAS 8	<i>Definition of Accounting Estimates</i>
Amendments to IAS 12	<i>Deferred Tax related to Assets and Liabilities arising from a Single Transaction</i>
Amendments to IAS 12	<i>International Tax Reform – Pillar Two Model Rules</i>

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

- (a) Amendments to IAS 1 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 *Making Materiality Judgements* provide non-mandatory guidance on how to apply the concept of materiality to accounting policy disclosures. The amendments did not have any impact on the measurement, recognition or presentation of any items in the Group's financial statements.
- (b) 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. Since the Group's approach and policy align with the amendments, the amendments had no impact on the Group's financial statements.
- (c) Amendments to IAS 12 *Deferred Tax related to Assets and Liabilities arising from a Single Transaction* 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.

Upon the application of the amendments, the Group has determined the temporary differences arising from right-of-use assets and lease liabilities separately. However, they did not have any material impact on the overall deferred tax balances presented in the consolidated statement of financial position as the related deferred tax balances qualified for offsetting under IAS 12.

- (d) Amendments to IAS 12 *International Tax Reform – Pillar Two Model Rules* introduce a mandatory temporary exception from the recognition and disclosure of deferred taxes arising from the implementation of the Pillar Two model rules published by the Organisation for Economic Co-operation and Development. The amendments also introduce disclosure requirements for the affected entities to help users of the financial statements better understand the entities' exposure to Pillar Two income taxes, including the disclosure of current tax related to Pillar Two income taxes separately in the periods when Pillar Two legislation is effective and the disclosure of known or reasonably estimable information of their exposure to Pillar Two income taxes in periods in which the legislation is enacted or substantively enacted but not yet in effect. The Group has applied the amendments retrospectively. Since the major entities comprising the Group are operating in jurisdictions in which the Pillar Two tax law has not yet been enacted, the amendments did not have any significant impact to the Group. The Group will disclose known or reasonably estimable information related to its exposure to Pillar Two income taxes in the consolidated financial statements by the time when the Pillar Two tax law has been enacted or substantively enacted and will disclose separately the current tax expense or income related to Pillar Two income taxes when it is in effect.

1.3 ISSUED BUT NOT YET EFFECTIVE INTERNATIONAL FINANCIAL REPORTING STANDARDS

The Group has not applied the following revised IFRSs, that have been issued but are not yet effective, in these financial statements. The Group intends to apply these revised IFRSs, if applicable, when they become effective.

Amendments to IFRS 10 and IAS 28	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture</i> ³
Amendments to IFRS 16	<i>Lease Liability in a Sale and Leaseback</i> ¹
Amendments to IAS 1	<i>Classification of Liabilities as Current or Non-current (the “2020 Amendments”)</i> ¹
Amendments to IAS 1	<i>Non-current Liabilities with Covenants (the “2022 Amendments”)</i> ¹
Amendments to IAS 7 and IFRS 7	<i>Supplier Finance Arrangements</i> ¹
Amendments to IAS 21	<i>Lack of Exchangeability</i> ²

¹ Effective for annual periods beginning on or after 1 January 2024

² Effective for annual periods beginning on or after 1 January 2025

³ No mandatory effective date yet determined but available for adoption

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 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. 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.

The 2020 Amendments clarify the requirements for classifying liabilities as current or non-current, including what is meant by a right to defer settlement and that a right to defer must exist at the end of the reporting period. Classification of a liability is unaffected by the likelihood that the entity will exercise its right to defer settlement. The amendments also clarify that a liability can be settled in its own equity instruments, and that only if a conversion option in a convertible liability is itself accounted for as an equity instrument would the terms of a liability not impact its classification. 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. Additional disclosures are required for non-current liabilities that are subject to the entity complying with future covenants within 12 months after the reporting period. The amendments shall be applied retrospectively with earlier application 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 7 and IFRS 7 clarify the characteristics of supplier finance arrangements and require additional disclosure of such arrangements. The disclosure requirements in the amendments are intended to assist users of financial statements in understanding the effects of supplier finance arrangements on an entity's liabilities, cash flows and exposure to liquidity risk. Earlier application of the amendments is permitted. The amendments provide certain transition reliefs regarding comparative information, quantitative information as at the beginning of the annual reporting period and interim disclosures. The amendments are not expected to have any significant impact on the Group's financial statements.

Amendments to IAS 21 specify how an entity shall assess whether a currency is exchangeable into another currency and how it shall estimate a spot exchange rate at a measurement date when exchangeability is lacking. The amendments require disclosures of information that enable users of financial statements to understand the impact of a currency not being exchangeable. Earlier application is permitted. When applying the amendments, an entity cannot restate comparative information. Any cumulative effect of initially applying the amendments shall be recognised as an adjustment to the opening balance of retained profits or to the cumulative amount of translation differences accumulated in a separate component of equity, where appropriate, at the date of initial application. 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

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Chinese Mainland	4,810,621	2,840,567
Asia Pacific (excluding Chinese Mainland)	193,988	178,971
North America	314,789	145,056
South America	19,144	–
Europe	56,367	50,136
Total revenue	<u>5,394,909</u>	<u>3,214,730</u>

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

(b) Non-current assets

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Chinese Mainland	7,087,635	6,600,293
Overseas	139,904	132,473
Total non-current assets	<u>7,227,539</u>	<u>6,732,766</u>

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:

	2023 RMB'000
Customer A	1,932,173
Customer B	<u>552,068</u>
	<u>2,484,241</u>
	2022 RMB'000
Customer A	1,000,670
Customer B	<u>582,908</u>
	<u>1,583,578</u>

3. REVENUE

An analysis of revenue is as follows:

	2023 RMB'000	2022 RMB'000
<i>Revenue from contracts with customers</i>	5,392,189	3,212,800
<i>Revenue from other sources</i>		
Gross rental income from operating leases	<u>2,720</u>	<u>1,930</u>
Total revenue	<u>5,394,909</u>	<u>3,214,730</u>

Revenue from contracts with customers

(a) Revenue information

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Types of goods or service		
Sales of biopharmaceutical products	4,553,548	2,675,372
Research and development services	698,906	325,484
Licensing revenue	138,953	211,016
Others	782	928
	<hr/>	<hr/>
Total revenue from contracts with customers	5,392,189	3,212,800
	<hr/> <hr/>	<hr/> <hr/>
Timing of revenue recognition		
Transferred at a point in time	4,782,856	2,899,468
Transferred over time	609,333	313,332
	<hr/>	<hr/>
Total revenue from contracts with customers	5,392,189	3,212,800
	<hr/> <hr/>	<hr/> <hr/>

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:

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Revenue recognised that was included in contract liabilities at the beginning of the reporting period:		
Licensing revenue	23,383	182,366
Research and development services	194,499	24,375
	<hr/>	<hr/>
	217,882	206,741
	<hr/> <hr/>	<hr/> <hr/>

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 overtime 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:

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Amounts expected to be recognised as revenue:		
Within one year	687,922	469,966
After one year	1,090,827	726,156
	1,778,749	1,196,122

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

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Interest income	8,146	3,571
Exchange gains	(1,421)	32,919
Government grants	59,814	69,043
Others	2,375	19
Total other income and gains	68,914	105,552

5. PROFIT/(LOSS) BEFORE TAX

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

	<i>Notes</i>	2023 RMB'000	2022 <i>RMB'000</i>
Cost of inventories sold		799,043	504,504
Cost of services provided		677,069	340,117
Depreciation of property, plant and equipment*		135,768	113,828
Depreciation of right-of-use assets*		73,693	64,520
Amortisation of intangible assets*		149,772	99,255
Research and development expenses:			
Current year expenditure		1,118,732	1,394,514
Lease payments not included in the measurement of lease liabilities		8,751	5,594
Auditor's remuneration		5,400	3,350
Employee benefit expense (including directors' and chief executive's remuneration):			
Wages and salaries		1,390,934	1,127,336
Staff welfare expenses		255,547	227,120
Share-based payment expense*		2,587	12,517
Foreign exchange (gains)/losses		1,421	(32,919)
Impairment of financial assets, net:			
Impairment of trade receivables		9,031	1,638
Impairment of other receivables		21,249	199,153
Write-down of inventories to net realisable value		22,817	24,669
Bank interest income	4	(8,146)	(3,571)
Gain on disposal of right-of-use assets		(455)	–
(Gain)/loss on disposal of items of property, plant and equipment		(267)	248

* 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.

6. FINANCE COSTS

An analysis of finance costs is as follows:

	2023 RMB'000	2022 <i>RMB'000</i>
Interest expense on bank and other borrowings	134,175	115,886
Interest expense on lease liabilities	13,348	14,910
Less: Interest capitalised	(36,984)	(25,124)
Total	110,539	105,672

7. INCOME TAX

The provision for Chinese Mainland current income tax is based on the statutory rate of 25% (2022: 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 Henlius USA incorporated in the United State and Henlius Industrial incorporated in Hong Kong in the year of 2023, is based on the statutory rates of 29.84% and 8.25%, respectively (2022: 29.84%, 8.25% respectively).

	2023 RMB'000	2022 <i>RMB'000</i>
Current – Mainland China	23,559	1,372
Total tax charged for the year	23,559	1,372

8. DIVIDENDS

No dividends have been paid or declared by the Company during the reporting period.

9. EARNINGS/(LOSS) PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic earnings/(loss) per share amounts is based on the profit/(loss) attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 543,299,247 (2022: 542,021,455) in issue during the year.

The calculation of the diluted earnings/(loss) per share amounts is based on the profit/(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 earnings/(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/(loss) per share are based on:

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Earnings/(loss)		
Profit/(loss) attributable to ordinary equity holders of the parent, used in the basic earnings/(loss) per share calculation	<u>546,019</u>	<u>(695,259)</u>
	Number of shares	
	2023	2022
Shares		
Weighted average number of ordinary shares in issue during the year used in the basic earnings/(loss) per share calculation	543,299,247	542,021,455
Effect of dilution – weighted average number of ordinary shares:		
Restricted shares under share award scheme	<u>73,857</u>	<u>–</u>
Weighted average number of ordinary shares in issue during the year in the diluted earnings/(loss) per share calculation	<u>543,373,104</u>	<u>542,021,455</u>

During the year ended 31 December 2022, 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

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Trade receivables	663,957	462,607
Impairment	<u>(16,129)</u>	<u>(7,098)</u>
Net carrying amount	<u>647,828</u>	<u>455,509</u>

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.

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

	2023 RMB'000	2022 <i>RMB'000</i>
Within 3 months	635,950	373,226
3 to 6 months	11,878	114
6 to 12 months	–	20,877
1 to 2 years	–	61,292
Total	647,828	455,509

11. PREPAYMENTS, DEPOSITS AND OTHER RECEIVABLES

	<i>Notes</i>	2023 RMB'000	2022 <i>RMB'000</i>
Prepayments		44,086	54,543
Value added tax to be deducted and certified		134,980	52,119
Deposits and other receivables		21,695	31,395
Due from AMTD	<i>(i)</i>	470,015	601,470
		670,776	739,527
Impairment allowance	<i>(i)</i>	(470,015)	(441,284)
Total		200,761	298,243

Note:

- (i) On 25 September 2019, the Company entered into an investment management agreement (the “**IMA**”) with AMTD Global Markets Limited (“**AMTD**”, now renamed as orientiert XYZ Securities Limited). Pursuant to the IMA, the Company deposited a total principal amount of USD117,000,000 into its investment portfolio account with AMTD (the “**AMTD Account**”) and engaged AMTD to provide investment management services.

The Company recovered in total of USD30,640,000 from AMTD during the years ended 31 December 2020, 2021 and 2022. As at 31 December 2022, the outstanding balances in the AMTD Account amounted to USD86,360,000. During the year ended 31 December 2023, the Company further recovered an amount of USD20,000,000 from AMTD. As at 31 December 2023, the outstanding balances of the investment principal in AMTD Account amounted to USD66,360,000 (equivalent to RMB470,015,000).

Based on the analysis by the Company’s management and with the assistance of the Company’s external legal counsel, it is clarified that when the IMA was terminated on 25 September 2021, the Company had the legal rights to recover all the outstanding investment amounts from AMTD. Therefore, the outstanding investment amounts with AMTD is accounted for as an amount due from AMTD. The previous year balances of financial assets at fair value through profit or loss have been reclassified to amounts due from AMTD. During the year of 2023, the Company has taken legal actions to recover the outstanding investment amount from AMTD.

The Company assessed the expected credit losses based on all the facts and available information, including historical correspondence with AMTD and relevant analysis from the external legal counsel of the Company, etc. As at 31 December 2022, a total expected credit loss amounting to USD63,360,000 (equivalent to RMB441,284,000) was provided in connection with the amount due from AMTD which was reclassified from the total fair value losses on the financial assets at fair value through profit or loss recognised in the previous year. During the year ended 31 December 2023, an additional expected credit loss amounting to USD3,000,000 (equivalent to RMB21,249,000) was further recognised. As at 31 December 2023, the total cumulative expected credit losses amounted to USD66,360,000 (equivalent to RMB470,015,000) was fully provided in connection with the amount due from AMTD.

12. TRADE PAYABLES

	2023 RMB'000	2022 <i>RMB'000</i>
Trade payables	544,815	713,552

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:

	2023 RMB'000	2022 <i>RMB'000</i>
Within 1 year	542,286	713,104
1 to 2 years	2,507	448
2 to 3 years	22	–
Total	544,815	713,552

13. EVENTS AFTER THE REPORTING PERIOD

As at the date of approval of these financial statements, there have been no significant events after the end of the reporting period.

14. COMPARATIVE AMOUNTS

As further explained in note 11 to the financial information, certain amounts have been reclassified which include i) in the consolidated statement of financial position as at 31 December 2022, the financial assets at fair value through profit or loss amounting to RMB160,186,000 as at 31 December 2022 were reclassified to prepayments, deposits and other receivables, representing an amount due from AMTD amounting to RMB601,470,000, net of impairment allowance for the expected credit loss in connection with due from AMTD amounting to RMB441,284,000; ii) in the consolidated statement of profit and loss for the year ended 31 December 2022, a loss on fair value adjustment of financial assets at fair value through profit or loss of RMB199,153,000 recorded in other expenses were reclassified to impairment losses on financial assets; and iii) in the consolidated statement of cashflow for the year ended 31 December 2022, “Changes in restricted cash for investments” amounting to RMB550,610,000 and “Purchase of investment measured at fair value through profit or loss” amounting to RMB550,610,000 were eliminated.

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 2023 annual report containing all the information required by the Listing Rules will be published on the websites of the Company and the Stock Exchange in due course.

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.

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

Hong Kong, 21 March 2024

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. Jun Zhu as the executive director, Mr. Qiyu Chen, Mr. Yifang Wu, Ms. Xiaohui Guan, Mr. Deyong Wen and Dr. Xingli Wang 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.