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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 2024**

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 2024 (the “**Reporting Period**”), prepared under International Financial Reporting Standards (“**IFRS Accounting Standards**”).

### **FINANCIAL SUMMARY:**

1. The Group’s total revenue increased by approximately RMB329.5 million or approximately 6.1% to approximately RMB5,724.4 million for the year ended 31 December 2024, compared to approximately RMB5,394.9 million for the year ended 31 December 2023. 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 2024, the Group recognized R&D expenditure of approximately RMB1,840.5 million, representing an increase of approximately RMB406.9 million as compared to approximately RMB1,433.6 million for the year ended 31 December 2023. R&D expenses mainly arose from advancing technology platform innovation, IND application, and clinical trials for new drugs to accelerate the Group’s innovation and transformation.
3. The Group’s total profit was approximately RMB820.5 million for the year ended 31 December 2024, representing an increase of approximately RMB274.5 million in profit from a profit of approximately RMB546.0 million for the year ended 31 December 2023, 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<sup>®</sup>, US trade name: HERCESSI<sup>™</sup>), HANNAIJIA (neratinib maleate):**

As at the Latest Practicable Date, HANQUYOU has benefited over 240,000 patients in total in Mainland China.

In April 2024, trastuzumab for injection (US trade name: HERCESSI<sup>™</sup>) was approved by the FDA for treatment of adjuvant breast cancer, metastatic breast cancer and metastatic gastric cancer.

In August 2024, trastuzumab for injection (Canadian trade name: Adheroza) was approved by Health Canada for the treatment of early breast cancer, metastatic breast cancer and metastatic gastric cancer.

From the beginning of 2024 to date, the new drug applications of different specifications of HANQUYOU were also approved in countries/regions, including Brazil, the Philippines, Uzbekistan, and Mexico.

During the Reporting Period, the Company licensed in HANNAIJIA, with a view to achieving sequential treatment with HANQUYOU, to further reduce the 5-year and 10-year postoperative recurrence risks in patients with HER2-positive early breast cancer. As at the Latest Practicable Date, HANNAIJIA has completed the tendering process on the procurement platform and has been included in the medical insurance procurement platform in all provinces in Mainland China.

### **2 HANSIZHUANG (serplulimab injection, European trade name: Hetronifly<sup>®</sup>):**

As at the Latest Practicable Date, HANSIZHUANG has benefited over 100,000 patients in total in Mainland China.

In December 2024, the new drug application (NDA) for new indication of HANSIZHUANG in combination with pemetrexed and carboplatin for the first-line treatment of unresectable locally advanced or metastatic non-squamous non-small cell lung cancer (nsNSCLC) with negative epidermal growth factor receptor (EGFR) gene mutation and negative anaplastic lymphoma kinase (ALK) status was approved by the NMPA.

In February 2025, the marketing authorisation application (MAA) for HANSIZHUANG (European trade name: Hetronifly<sup>®</sup>) in combination with carboplatin and etoposide for the first-line treatment for adult patients with extensive-stage small cell lung cancer (ES-SCLC) was approved by the European Commission (EC).

From the beginning of 2024 to date, the new drug applications for HANSIZHUANG across various indications were also approved in countries/regions, including Cambodia, Thailand, and Indonesia.

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

As at the Latest Practicable Date, HANLIKANG has benefited over 300,000 patients in total in Mainland China.

From the beginning of 2024 to date, the new drug applications for HANLIKANG were approved in Peru, Nicaragua, and Bolivia, respectively.

In February 2024, the supplemental new drug applications (sNDA) for four new indications of HANDAYUAN, including polyarticular juvenile idiopathic arthritis, pediatric plaque psoriasis, Crohn's disease and pediatric Crohn's disease were accepted by the NMPA, and were approved in May 2024.

During the Reporting Period, HANBEITAI focused on "dual-channel" market and smoothly progressed towards its established commercialisation goals.

In December 2024, HANBEITAI was approved for marketing in Bolivia.

**4** During the Reporting Period, the equity transfer transaction under the Framework Agreement in relation to the Acquisition of DDL Licensed Company was officially completed. As Henlius Pharmaceutical Trading, the target company of the acquisition, holds a pharmaceutical business license, the Group has since gained the capability to commercialise and sell more in-licensing products, thereby expanding its operational channels and further broadening its business model.

**5 Diversified International Collaborations:**

In November 2024, the Group entered into an amendment agreement with Getz Pharma (Private) Limited and Getz Pharma International FZ-LLC, agreeing to grant an additional license to commercialise HANQUYOU in Pakistan.

In December 2024, the Company entered into an agreement with Abbott Products Operations AG., agreeing to grant a license to commercialise five products across 69 agreed countries and regions in Asia, Latin America, the Caribbean, and the Middle East & North Africa (MENA).

In February 2025, the Company entered into an agreement with Dr. Reddy's Laboratories SA, agreeing to grant a license to develop, manufacture, and commercialise HLX15 (recombinant anti-CD38 human monoclonal antibody injection) in the United States and agreed European regions.

In March 2025, the Group entered into an agreement with Fosun Industrial Co., Limited, agreeing to grant a license to commercialise HANSIZHUANG in Hong Kong and Macau regions.

In January and June 2024, the Company entered into an agreement and a supplementary agreement with Sermonix Pharmaceuticals, Inc., being granted an exclusive license to develop, manufacture, and commercialise HLX78 (lasofoxifene) in the Asian region.

In August 2024, the Company entered into an agreement with Convalife Pharmaceuticals Co., Ltd., being granted an exclusive license to commercialise HANNAIJIA in China, as well as exclusive negotiation and conditional licensing rights in agreed overseas countries and regions.

In December 2024, the Company entered into an agreement with Palleon Pharmaceuticals Inc., agreeing to collaborate on the global development of E-602 (the Company's product code: HLX79) and combination therapies, as well as commercialisation within their respective licensed territories.

During the Reporting Period, the Group established a strategic partnership with SVAX, a Saudi Arabian company. The two parties will establish a joint venture in Saudi Arabia, integrating the Group's leading biopharmaceutical R&D and manufacturing capabilities with SVAX's local registration, market access, and commercialisation expertise. This collaboration aims to accelerate the global registration and commercialisation of multiple products, enhancing access to advanced biologics in the MENAT (Middle East, North Africa, and Türkiye) region to benefit more patients.

## **6 Efficient Advancement on Clinical Study Projects both Domestically and Internationally:**

- Progress of international clinical study projects: HLX22 (recombinant humanised anti-HER2 monoclonal antibody injection)
  - In November 2024, the first patient has been dosed in an international multi-centre phase 3 clinical study of HLX22 in combination with trastuzumab and chemotherapy compared to trastuzumab and chemotherapy with or without pembrolizumab for the first-line treatment of locally advanced or metastatic gastroesophageal junction cancer and gastric cancer in Mainland China. During the Reporting Period, such phase 3 clinical trial was permitted to commence in the United States, Japan and Australia, respectively.
  - In March 2025, Orphan-drug Designation of HLX22 (recombinant humanised anti-HER2 monoclonal antibody injection) for the treatment of gastric cancer (GC) was granted by the FDA.
- Progress of international clinical study projects: HANSIZHUANG (serplulimab injection)
  - In May 2024, the first patient in phase 3 part has been dosed in the international multi-centre phase 2/3 clinical trial of HANSIZHUANG in combination with bevacizumab and chemotherapy for the first-line treatment of metastatic colorectal cancer in Mainland China. In July 2024, the phase 3 part of this clinical trial was permitted to commence in Japan and Indonesia, with the first patients dosed in Indonesia in August 2024 and in Japan in October 2024.
  - In January 2025, the recruitment of subjects was completed in the international multi-centre phase 3 clinical study of HANSIZHUANG or placebo in combination with chemoradiotherapy for the treatment of limited-stage small cell lung cancer (LS-SCLC).

- As at the Latest Practicable Date, over 100 sites have been set for the bridging study in the United States for HANSIZHUANG in combination with chemotherapy for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC), and the recruitment of subjects is ongoing.
- Progress of international clinical study projects: other products
  - In January 2024, the recruitment of subjects was completed in the 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).
  - In April 2024, an international multi-centre phase 3 clinical study of a biosimilar of denosumab HLX14 (recombinant anti-RANKL human monoclonal antibody injection) for the treatment of osteoporosis in postmenopausal women at high risk for fracture met the primary study endpoints. During the Reporting Period, new drug applications for the product were accepted by the European Medicines Agency (EMA), Health Canada and the FDA, respectively.
  - In September 2024, an international multi-centre phase 3 clinical study of a biosimilar to pertuzumab HLX11 (recombinant anti-HER2 domain II humanised monoclonal antibody injection) for neo-adjuvant therapy of HER2-positive, HR-negative early or locally advanced breast cancer met the primary study endpoint. In January 2025, the biologic license application (BLA) for the product was accepted by the FDA.
- Progress of domestic clinical study projects: HLX43 (antibody-drug conjugate targeting PD-L1 with novel DNA topoisomerase I inhibitor)
  - In December 2024, an investigational new drug application (IND) for the phase 1b/2 clinical trial of HLX43 for injection (antibody-drug conjugate targeting PD-L1 with novel DNA topoisomerase I inhibitor) as a monotherapy or in combination for the treatment of advanced/metastatic solid tumours was approved by the NMPA. In January 2025, the first patient has been dosed in a phase 2 clinical study of the product in patients with recurrent/metastatic esophageal squamous cell carcinoma in Mainland China.

- Progress of domestic clinical study projects: HLX22 (recombinant humanised anti-HER2 monoclonal antibody injection)
  - In December 2024, an investigational new drug application (IND) for the phase 2 clinical trial of HLX22 (recombinant humanised anti-HER2 monoclonal antibody injection) in combination with trastuzumab and chemotherapy, or in combination with trastuzumab deruxtecan for the treatment of HER2-expressing solid tumours was approved by the NMPA.
- Progress of domestic clinical study projects: HANSIZHUANG (serplulimab injection)
  - In April 2024, an investigational new drug application (IND) for HLX53 (anti-TIGIT Fc fusion protein) in combination with HANSIZHUANG and HANBEITAI for the first-line treatment of locally advanced or metastatic hepatocellular carcinoma was approved by the NMPA. In August 2024, the first patient has been dosed in phase 2 clinical trial of this combination therapy.
  - In April 2024, the recruitment of subjects was completed in the phase 3 clinical study of HANSIZHUANG in combination with chemotherapy for neo-/adjuvant treatment of gastric cancer in Mainland China.
- Progress of domestic clinical study projects: other products
  - In January 2024, a phase 1 clinical study of a biosimilar of denosumab HLX14 (recombinant anti-RANKL human monoclonal antibody injection) in Chinese healthy male subjects was successfully completed. The study met all of the prespecified endpoints.
  - In March 2024, an investigational new drug application (IND) for HLX6018 (recombinant anti-GARP/TGF- $\beta$ 1 humanised monoclonal antibody injection) was approved by the NMPA for the treatment of idiopathic pulmonary fibrosis. In April 2024, the first subject has been dosed in a phase 1 clinical study of this product in healthy subjects in Mainland China.
  - In March 2024, the first patient has been dosed in a phase 1 clinical study of HLX42 for injection (antibody-drug conjugate targeting EGFR with novel DNA topoisomerase I inhibitor) in patients with advanced/metastatic solid tumours in Mainland China.
  - In May 2024, an investigational new drug application (IND) for HLX78 (lasofoxifene) was approved by the NMPA. In November 2024, the first subject has been dosed in a phase 1 clinical study of this product in Chinese healthy female subjects in Mainland China. In December 2024, the first patient in Mainland China has been dosed in an international multi-centre phase 3 clinical study of this product in combination with abemaciclib versus fulvestrant in combination with abemaciclib for the treatment of locally advanced or metastatic breast cancer.
  - In June 2024, a phase 1 clinical study of a biosimilar of daratumumab HLX15 (recombinant fully anti-CD38 human monoclonal antibody injection) in healthy Chinese male subjects was successfully completed. The study met all of the prespecified endpoints.
  - In December 2024, the new drug application (NDA) for a biosimilar of pertuzumab HLX11 (recombinant anti-HER2 domain II humanised monoclonal antibody injection) was accepted by the NMPA.

## **7 Efficient Advancement on Pre-Clinical Development Projects**

The Group attaches great importance to the pre-clinical project pipeline. During the Reporting Period, the Group obtained approvals for investigational new drug applications (IND) for GARP/TGF- $\beta$ 1 and TIGIT+PD-1+VEGF target projects, and proceeded to clinical study smoothly.

- In September 2024, an investigational new drug application (IND) for HLX17 (recombinant humanised anti-PD-1 monoclonal antibody injection) was approved by the NMPA. HLX17 is intended for the treatment of melanoma, non-small cell lung cancer, esophageal cancer, head and neck squamous cell cancer, colorectal cancer, hepatocellular carcinoma, biliary tract cancer, triple-negative breast cancer, microsatellite instability-high or deficient mismatch repair tumours, gastric cancer, etc.
- In January 2025, an investigational new drug application (IND) for the phase 1b/2 clinical trial of HLX43 for injection (antibody-drug conjugate targeting PD-L1 with novel DNA topoisomerase I inhibitor) in combination with HANSIZHUANG for the treatment of patients with advanced/metastatic solid tumours was approved by the NMPA.
- In February 2025, an investigational new drug application (IND) for innovative small molecular HLX99 was approved by the FDA. HLX99 is intended for the treatment of amyotrophic lateral sclerosis (ALS).

## **8 Orientation toward Clinical Value and Injecting Impetus toward the Pipeline:**

By centring on patients' needs, with the clinical value-oriented early R&D, based on new drug discovery platforms driven by deep data and biocomputing accelerated molecular design technology, the Group continues 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 is planning for the development of the next-generation innovative antibody drugs and antibody-based drugs. In terms of the development of T Cell Engager, the Group has developed highly specific products targeting solid tumours, which can effectively overcome the immunosuppressive tumour microenvironment and activate immune-mediated tumour cell killing. 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 approximately 50 molecules in its pipeline and 14 R&D platforms, covering a wealth of drug forms, such as monoclonal antibody, multi-specific antibody, antibody-drug conjugates (ADC), fusion proteins, small molecule drugs and other forms of drugs.

## **9 Layout of Industrialisation Base for Biologics 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, Xuhui Facility has successfully completed the first commercial shipments of the products, including HANSIZHUANG, HANQUYOU, and HANDAYUAN to multiple overseas regions, and multiple overseas customers audits for such products; During the Reporting Period, Songjiang First Plant completed the first commercial shipment of HANQUYOU (US trade name: HERCESSI™) to the United States; During the Reporting Period, the construction of Songjiang Second Plant Phase I facility was completed.

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



- Innovative mAb
- Innovative fusion protein
- Biosimilar mAb
- Innovative ADC
- Small molecule
- Innovative multi-specific antibody
- Bridging study in U.S.
- BLA under FDA review
- Global MRCT
- MAA under EMA review
- Approved in global markets

- (1) Approved in China, the EU and several SEA countries, trade name: Heltronfly® in the EU. Business partners: KGen/Fosun Pharma/Intas.
- (2) Approved in countries such as China and Peru. The first biosimilar approved in China. Business partners: Fosun Pharma/Farma de Colombia/Eurofarma/Abbott/Boston Oncology.
- (3) The first rituximab approved for the indication in China.
- (4) Approved in 50+ countries, including China, U.S., the UK, Germany, France and Australia, trade name registered in U.S.: HERCESSI™, trade name registered in Europe: Zercept®. Business partners: Accord/ Cipla/ Jacobson/ Elea/ Eurofarma/ Abbott/ KGen/ Getz.
- (5) Business partners: Fosun Wanbang/Getz Pharma.
- (6) Business partner: Eurofarma.
- (7) Exclusive license obtained in China.
- (8) Marketing applications under review in China, the EU and the U.S. Business partner: Organon.
- (9) Marketing applications under review in China and the U.S. Business partner: Organon.
- (10) IND approvals obtained in China/Australia/the U.S./Singapore/EU countries, etc. Business partner: Essex.
- (11) IND approvals obtained in China/the U.S./Japan.
- (12) Exclusive license obtained in China. Phase 3 MRCT enrolling globally. IND approval obtained in China.
- (13) IND approvals obtained in China/the U.S.
- (14) Exclusive license obtained in China.
- (15) IND approvals obtained in China/the U.S.
- (16) IND approvals obtained in China/the U.S. and granted FDA Fast Track Designation.
- (17) Business partner: Shanghai Jingze.
- (18) Business partner: Dr. Reddy's, etc.
- (19) Exclusive license obtained in China. Phase 1/2 conducting in the U.S.

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

## 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 achieved remarkable success in the international market by leveraging its robust integrated platform of R&D, production and commercialisation, and successfully realised the “Closed-loop Internationalisation 1.0”. During the Reporting Period, the sustained growth in sales of our core products and the significant cost control achievements through refined management measures have laid a solid foundation for the Group’s enhanced profitability. Meanwhile, the orderly progress of global clinical development and drug registrations of pipeline products, the steady progress in international production capacity construction, and the deepening of the “Go Global” strategy have driven the positive cycle and high-quality growth of the Company’s business.

As of 20 March 2025, being the latest practicable date for the publication of this announcement (the “**Latest Practicable Date**”), 6 products (24 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**” or “**China**”) (“**Mainland China**”)), and 4 products have been successfully approved for marketing in Europe, the United States, Canada, Australia, Indonesia, Bolivia and other counties/regions. From the beginning of 2024 to date, the Group’s “Go Global” initiatives have yielded fruitful results. HANQUYOU was approved for commercialisation in the United States and Canada by the FDA and the Health Canada, respectively, marking a new chapter in North American commercialisation. HANSIZHUANG in combination with chemotherapy was approved in the European Union (the “**EU**”) for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC) in adult patients, becoming the Group’s second product approved in the EU after HANQUYOU, further solidifying international mainstream markets’ recognition of the Group’s products. HANLIKANG was approved in Peru, and HANBEITAI was approved in Bolivia. Additionally, the new drug applications for HLX14 were accepted in the EU, the United States and Canada, respectively, while the new drug application for HLX11 was accepted in the United States, paving the way for more products to shine in international mainstream markets.

#### (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 optimising the commercialisation layout, achieving remarkable results. As at the end of the Reporting Period, the Group’s commercialisation team was over 1,500 people, promoting the commercialisation of six products, including HANQUYOU and HANSIZHUANG, in an orderly manner in Mainland China. Meanwhile, leveraging on the foresighted R&D strategy and commercialisation management system, the Group has made significant strides in overseas markets with multiple products to expand its global footprint, further benefiting patients worldwide.

In addition, the Group formally completed the equity transfer transaction under the Framework Agreement on Acquisition of DDL Licensed Company during the Reporting Period. As Shanghai Henlius Pharmaceutical Trading Co., Ltd. (formerly known as “Shanghai Baodao Hongshun Pharmaceutical Trading Co., Ltd.”) (the “**Henlius Pharmaceutical Trading**”), the target company of the acquisition, holds a pharmaceutical business license, the Group has since gained the capability to commercialise and sold more in-licensing products, thereby expanding its operational channels and further broadening its business model.

***HANQUYOU (trastuzumab for injection, European trade name: Zercepac®, US trade name: HERCESSI™) (a therapeutic product for breast cancer and gastric cancer) became the monoclonal antibody biosimilar drug approved in Mainland China, the United States, and Europe; sequential treatment with HANNAIJIA (neratinib maleate) for the extended adjuvant treatment of breast cancer***

HANQUYOU is the core product of the Group in the field of anti-tumour therapy, and was independently developed by the Group in accordance with the relevant regulations on biosimilar drugs of Mainland China, the EU, and the United States. In Mainland China, HANQUYOU has continued to penetrate the domestic market and generate significant sales revenue for the Group leveraging the Group’s efficient market access and sales execution capabilities, as well as the differentiated advantages offered by HANQUYOU’s flexible dose portfolio of 150mg and 60mg. As at the end of the Reporting Period, both dosage strengths of HANQUYOU have completed the tendering process on the procurement platform and have been included in the medical insurance procurement platform in all provinces in Mainland China, and so far, have benefited over 240,000 patients in Mainland China. During the Reporting Period, the Group has also strengthened the treatment ecosystem for patients with HER2-positive breast cancer and gastric cancer, further enhancing the international quality and market recognition of HANQUYOU.



In April 2024, trastuzumab for injection (US trade name: HERCESSI™) was approved by the FDA for the treatment of adjuvant breast cancer, metastatic breast cancer and metastatic gastric cancer. Since then, HANQUYOU has become a monoclonal antibody biosimilar drug approved in Mainland China, Europe, and the United States. In addition, the new drug submission (NDS) for trastuzumab for injection (Canadian trade name: Adheroza) was approved by the Health Canada in August 2024. From the beginning of 2024 to date, the new drug applications of different specifications of HANQUYOU were approved in countries/regions, including Brazil, the Philippines, Uzbekistan, and Mexico.

As at the Last Practicable Date, HANQUYOU has been approved in Europe and Mainland China for over four years. With its high international quality standards, HANQUYOU has been approved for marketing in over 50 countries and regions (including the United States, the United Kingdom, Germany, Spain, France, Italy, Switzerland, Australia, Singapore, Argentina, Brazil, Canada, etc.). Furthermore, the Group successfully collaborated with internationally renowned biomedicine enterprises, including Abbott Operations Uruguay S.R.L. (“**Abbott**”), Accord Healthcare Limited (“**Accord**”), Eurofarma Laboratorios S.A. (“**Eurofarma**”), 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 at country level, covering over 100 countries/regions around the world.

During the Reporting Period, the Company licensed in HANNAIJIA, with a view to achieving sequential treatment with HANQUYOU to further reduce the 5-year and 10-year postoperative recurrence risks in patients with HER2-positive early-stage breast cancer. HANNAIJIA, an oral small-molecule pan-HER tyrosine kinase inhibitor (TKI), was approved by the National Medical Products Administration (the “**NMPA**”) in June 2024 for the extended adjuvant therapy of HER2-positive early breast cancer in adult patients after adjuvant therapy containing trastuzumab. While accelerating the market accessibility of HANNAIJIA, the Group actively promoted education on sequential treatment with neratinib, an extended adjuvant therapy, offering the possibility for curing more patients with early breast cancer. As at the Latest Practicable Date, HANNAIJIA has completed the tendering process on the procurement platform and has been included in the medical insurance procurement platform in all provinces in Mainland China.



***HANSIZHUANG (serplulimab injection, European trade name: Hetronifly®) has significant differentiated advantages in the treatment of small-cell lung cancer, and the marketing authorisation application for new indications of HANSIZHUANG has been approved during the Reporting Period, further expanding its international presence***

HANSIZHUANG is a core innovative PD-1 monoclonal antibody product independently developed by the Group. Several of its key clinical study results have been published in prestigious journals, including the Journal of the American Medical Association (JAMA) (《美國醫學會雜誌》), Nature Medicine (《自然－醫學》), Cancer Cell, and the British Journal of Cancer. Meanwhile, HANSIZHUANG was recommended by numerous guidelines, including the 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 Immune Checkpoint Inhibitor Clinical Practice (《CSCO免疫檢查點抑制劑臨床應用指南》), and Chinese Guidelines for the Radiotherapy of Esophageal Cancer (《中國食管癌放射治療指南》).



During the Reporting Period, the new drug application (NDA) for new indication of HANSIZHUANG in combination with pemetrexed and carboplatin for the first-line treatment of unresectable locally advanced or metastatic non-squamous non-small cell lung cancer (nsNSCLC) with negative epidermal growth factor receptor (EGFR) gene mutation and negative anaplastic lymphoma kinase (ALK) status was approved by the NMPA, offering more treatment options for lung cancer patients. As at the Latest Practicable Date, HANSIZHUANG has been approved in Mainland China for the first-line treatment in combination with chemotherapy for squamous non-small cell lung cancer (sqNSCLC), extensive-stage small cell lung cancer (ES-SCLC), esophageal squamous cell carcinoma (ESCC), and non-squamous non-small cell lung cancer (nsNSCLC). 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 Latest Practicable Date, HANSIZHUANG has benefited over 100,000 cancer patients.

With its excellent efficacy and data quality, HANSIZHUANG has been widely acknowledged in the international market. As its licenses-out areas covering the United States, Europe, Southeast Asia, the Middle East and North Africa, India, and emerging countries and regions, the international commercialisation has been carried out in an orderly manner. After being approved for marketing in Indonesia in 2023, HANSIZHUANG has accelerated its commercialisation in international markets.

- In April 2024, HANSIZHUANG was approved for marketing in Cambodia for the treatment of extensive-stage small cell lung cancer (ES-SCLC).
- In July 2024, HANSIZHUANG was approved for marketing in Thailand for the treatment of extensive-stage small cell lung cancer (ES-SCLC).
- In January 2025, HANSIZHUANG was approved for an additional indication in Indonesia and Thailand for the treatment of squamous non-small cell lung cancer (sqNSCLC), respectively.
- In February 2025, HANSIZHUANG (European trade name: Hetronifly<sup>®</sup>) in combination with carboplatin and etoposide for the first-line treatment for adult patients with extensive-stage small cell lung cancer (ES-SCLC) was approved for marketing in the EU, further expanding its international presence and solidifying its recognition in mainstream markets.

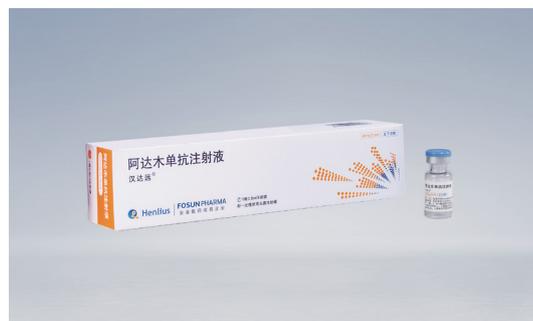
As at the Latest Practicable Date, HANSIZHUANG has been approved for marketing in over 30 countries and regions and has been granted Orphan-drug Designation by regulatory authorities in the United States, the EU and Switzerland, respectively. In January 2024, HANSIZHUANG received the Innovation Passport Designation from the UK's Innovative Licensing and Access Pathway Steering Group, including the Medicines and Healthcare products Regulatory Agency (MHRA), for the treatment of extensive-stage small cell lung cancer (ES-SCLC).

***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***

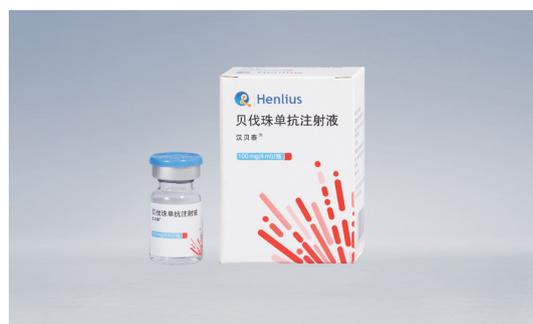
As the first monoclonal antibody drug approved for marketing under the Guidelines for the R&D and Evaluation of Biosimilars (Trial) (《生物類似藥研發與評價技術指導原則(試行)》) in China in 2019, HANLIKANG has benefited over 300,000 patients in total in Mainland China. The domestic commercial sale of HANLIKANG is undertaken by Fosun Yaohong (Jiangsu) Pharmaceutical Technology Co., Ltd.\* (復星曜泓(江蘇)醫藥科技有限公司) (“**Fosun Yaohong**”, formerly known as Jiangsu Fosun Pharmaceutical Sales Co., Ltd.\* (江蘇復星醫藥銷售有限公司)), a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd. (“**Fosun Pharma**”), the controlling shareholder of the Company. In the international market, the Company actively collaborates with its partners, including Abbott, Boston Oncology, LLC, Eurofarma, and FARMA DE COLOMBIA S.A.S to continuously advance the global presence of HANLIKANG. During the Reporting Period, HANLIKANG was approved for marketing in Peru, Nicaragua, and Bolivia, becoming the third self-developed and manufactured product of the Group to be approved for overseas marketing after HANQUYOU and HANSIZHUANG.



HANDAYUAN is the third product of the Group marketed in Mainland China. Its domestic commercial sale is undertaken by Fosun Wanbang (Jiangsu) Pharmaceutical Group Co., Ltd.\* (復星萬邦(江蘇)醫藥集團有限公司) (“**Fosun Wanbang**”, formerly known as Jiangsu Wanbang (Group) Biopharmaceutical Co., Ltd.\* (江蘇萬邦生化醫藥集團有限責任公司)), the controlling shareholder of the Company. In February 2024, the supplemental new drug applications (sNDA) for four new indications of HANDAYUAN were accepted by the NMPA, and were approved in May 2024. As at the end of the Reporting Period, HANDAYUAN has been approved in Mainland China for all eight indications of originator adalimumab for domestic marketing, including rheumatoid arthritis, ankylosing spondylitis, psoriasis, uveitis, polyarticular juvenile idiopathic arthritis, pediatric plaque psoriasis, Crohn’s disease and pediatric Crohn’s disease.



Additionally, HANBEITAI, the fourth biosimilar product of the Group, which was approved for marketing and realised commercial sales, has 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. During the Reporting Period, HANBEITAI focused on “dual-channel” market and smoothly progressed towards its established commercialisation goals. In December 2024, HANBEITAI was approved for marketing in Bolivia, marking a new breakthrough in its internationalisation.



***Further promote the overseas commercialisation process of products through diverse international cooperation***

In line with its internationalisation strategy, the Group entered into partnerships with renowned international companies as well as continued to promote the commercialisation of existing overseas cooperation during the Reporting Period.

- In November 2024, the Group entered into an amendment agreement with Getz Pharma (Private) Limited and Getz Pharma International FZ-LLC, agreeing to grant the license further to commercialise HANQUYOU in Pakistan.
- In December 2024, the Company entered into an agreement with Abbott Products Operations AG., agreeing to grant a license to commercialise five products in the agreed regions. The license covers 69 countries and regions in Asia, Latin America, the Caribbean, the Middle East and North Africa.
- In February 2025, the Company entered into an agreement with Dr. Reddy's Laboratories SA, agreeing to grant a license to develop, manufacture and commercialise HLX15 (recombinant anti-CD38 human monoclonal antibody injection) in the United States and agreed European region.
- In March 2025, the Group entered into an agreement with Fosun Industrial Co., Limited, agreeing to grant a license to commercialise HANSIZHUANG in Hong Kong and Macau regions.

During the Reporting Period, the Group also actively expanded the research and development of its product pipeline through licensing-in and cooperative development to provide patients with more treatment options.

- In January and June 2024, the Company entered into an agreement and a supplement agreement with Sermonix Pharmaceuticals, Inc., to acquire the exclusive rights of development, manufacture and commercialisation of HLX78 (Lasofexifene) in Asian region.
- In August 2024, the Company entered into an agreement with Convalife Pharmaceuticals Co., Ltd. to in-license the exclusive commercialisation rights of HANNAIJIA in PRC, as well as the exclusive negotiation rights and conditional license rights in agreed overseas countries and regions.
- In December 2024, the Company entered into an agreement with Palleon Pharmaceuticals Inc., in which both parties agree to go into cooperation for the joint development worldwide and commercialisation in respective licensed regions (for the Company, the PRC (including Hong Kong, Macau, and Taiwan); for Palleon, the rest of the world) with respect to the E-602 (code in the Company: HLX79) and combination therapies.

During the Reporting Period, the Group entered into a strategic cooperation with the Saudi Arabian company AL-TIRYAQ AL-KHALAWI Medical Company ("SVAX"). The two sides will establish a joint venture in Saudi Arabia to advance the global registration and commercialisation of several products of the Group and improve access to advanced biologics in the Middle East, North Africa, and Türkiye (MENAT) region for the purpose of benefiting more patients through creating synergy between the Group's leading capabilities in biologics R&D and manufacturing and the SVAX's advantages in local registration, market access, and commercialisation resources.

## **(II) Sustainable global clinical development capability on medical products**

During the Reporting Period, based on clinical needs, the Group has 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, HLX22 (recombinant humanised anti-HER2 monoclonal antibody injection) and related combination therapies, HLX42 for injection (antibody-drug conjugate targeting EGFR with novel DNA topoisomerase I inhibitor), HLX6018 (recombinant anti-GARP/TGF- $\beta$ 1 humanised monoclonal antibody injection), HLX78 (lasofoxifene), HLX43 for injection (antibody-drug conjugate targeting PD-L1 with novel DNA topoisomerase I inhibitor) for the treatment of solid tumours, small cell lung cancer (SCLC), metastatic colorectal cancer (mCRC), gastric cancer (GC), hepatocellular carcinoma (HCC), breast cancer, and esophageal squamous cell carcinoma (ESCC).

With well-established teams for global drug registration and clinical operation, the Group is committed to promoting the development of pipeline products domestically and internationally. During the Reporting Period, the Group submitted 17 investigational new drug applications (INDs) and 25 new drug applications (NDAs), and received approval for 12 investigational new drug applications (INDs) and 17 new drug applications (NDAs), in China, the United States, the EU and nearly 40 other countries, including Canada, Indonesia and Japan. The Group has formed its clinical operation teams in the United States, Australia, etc. for operation and management of overseas research centres. As of the end of the Reporting Period, the Group had a number of ongoing international multi-centre clinical studies in China, the United States, Japan, Australia, Spain, Germany, Poland, Hungary, Latvia, Indonesia and other countries.

### ***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***

- Progress of HLX22 (recombinant humanised anti-HER2 monoclonal antibody injection)
  - In November 2024, the first patient has been dosed in an international multi-centre phase 3 clinical study of HLX22 in combination with trastuzumab and chemotherapy compared to trastuzumab and chemotherapy with or without pembrolizumab for the first-line treatment of locally advanced or metastatic gastroesophageal junction cancer and gastric cancer in Mainland China. During the Reporting Period, such phase 3 clinical trial was permitted to commence in the United States, Japan and Australia, respectively.
  - In March 2025, Orphan-drug Designation of HLX22 (recombinant humanised anti-HER2 monoclonal antibody injection) for the treatment of gastric cancer (GC) was granted by the FDA.

- Progress of HANSIZHUANG (serplulimab injection)
  - In May 2024, the first patient in phase 3 part has been dosed in an international multi-centre phase 2/3 clinical trial of HANSIZHUANG in combination with bevacizumab and chemotherapy for the first-line treatment of metastatic colorectal cancer in Mainland China. In July 2024, the phase 3 part of this clinical trial was permitted to commence in Japan and Indonesia, respectively. The first patient in this part has been dosed in Indonesia and Japan in August 2024 and October 2024, respectively.
  - In January 2025, the recruitment of subjects was completed in an international multicentre phase 3 clinical study comparing HANSIZHUANG or placebo in combination with chemotherapy and concurrent radiotherapy for the treatment of limited-stage small cell lung cancer (LS-SCLC) patients.
  - As at the Latest Practicable Date, over 100 sites have been set for the bridging study in the United States for HANSIZHUANG in combination with chemotherapy for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC), and the recruitment of subjects is ongoing.
- Progress of other products
  - In January 2024, the recruitment of subjects was completed 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).
  - In April 2024, an international multi-centre phase 3 clinical study of a biosimilar of denosumab HLX14 (recombinant anti-RANKL human monoclonal antibody injection) for the treatment of osteoporosis in postmenopausal women at high risk for fracture met the primary study endpoints. During the Reporting Period, new drug applications for the product were accepted by the European Medicines Agency (EMA), Health Canada and the FDA, respectively.
  - In September 2024, an international multi-centre phase 3 clinical study of a biosimilar of pertuzumab HLX11 (recombinant anti-HER2 domain II humanised monoclonal antibody injection) for the neoadjuvant therapy of HER2-positive, HR-negative early or locally advanced breast cancer met the primary study endpoint. In January 2025, the biologic license application (BLA) for the product has been accepted by the FDA.

### ***Progress of domestic clinical study projects***

- Progress of HLX43 (antibody-drug conjugate targeting PD-L1 with novel DNA topoisomerase I inhibitor)
  - In December 2024, an investigational new drug application (IND) for the phase 1b/2 clinical trial of HLX43 for injection (antibody-drug conjugate targeting PD-L1 with novel DNA topoisomerase I inhibitor) as a monotherapy or in combination for the treatment of advanced/metastatic solid tumours was approved by the NMPA. In January 2025, the first patient has been dosed in a phase 2 clinical study of the product for the treatment of recurrent/metastatic esophageal squamous cell carcinoma in Mainland China.
  
- Progress of HLX22 (recombinant humanised anti-HER2 monoclonal antibody injection)
  - In December 2024, an investigational new drug application (IND) for the phase 2 clinical trial of HLX22 (recombinant humanised anti-HER2 monoclonal antibody injection) in combination with trastuzumab and chemotherapy or with trastuzumab deruxtecan for treatment of HER2 expressing solid tumours was approved by the NMPA.
  
- Progress of HANSIZHUANG (serplulimab injection)
  - In April 2024, an investigational new drug application (IND) for HLX53 (anti-TIGIT Fc fusion protein) in combination with HANSIZHUANG and HANBEITAI for the first-line treatment of locally advanced or metastatic hepatocellular carcinoma was approved by the NMPA. The first patient has been dosed in phase 2 clinical trial of this combination therapy in August 2024.
  
  - In April 2024, the recruitment of subjects was completed in the phase 3 clinical study of HANSIZHUANG in combination with chemotherapy for neo-/adjuvant treatment of gastric cancer in Mainland China.

- Progress of other products
  - In January 2024, a phase 1 clinical study of a biosimilar of denosumab HLX14 (recombinant anti-RANKL human monoclonal antibody injection) in Chinese healthy male subjects was successfully completed. The study met all of the pre-specified endpoints.
  - In March 2024, an investigational new drug application (IND) for HLX6018 (recombinant anti-GARP/TGF- $\beta$ 1 humanised monoclonal antibody injection) was approved by the NMPA for the treatment of idiopathic pulmonary fibrosis. In April 2024, the first subject has been dosed in a phase 1 clinical study in healthy subjects of this product in Mainland China.
  - In March 2024, the first patient has been dosed in a phase 1 clinical study of HLX42 for injection (antibody-drug conjugate targeting EGFR with novel DNA topoisomerase I inhibitor) for the treatment of advanced/metastatic solid tumours in Mainland China.
  - In May 2024, an investigational new drug application (IND) for HLX78 (lasofoxifene) was approved by the NMPA. In November 2024, the first subject has been dosed in a phase 1 clinical study of this product in Chinese healthy female subjects in Mainland China. In December 2024, the first patient in Mainland China has been dosed in an international multi-centre phase 3 clinical study of the combination of this product and abemaciclib compared to the combination of fulvestrant and abemaciclib for the treatment of locally advanced or metastatic breast cancer.
  - In June 2024, a phase 1 clinical study of a biosimilar of daratumumab HLX15 (recombinant anti-CD38 fully human monoclonal antibody injection) in healthy Chinese male subjects was successfully completed. The study met all of the pre-specified endpoints.
  - In December 2024, the new drug application (NDA) for a biosimilar of pertuzumab HLX11 (recombinant anti-HER2 domain II humanised monoclonal antibody injection) was accepted by the NMPA.

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

The Group attached great importance to the pre-clinical project pipeline. During the Reporting Period, we made progress in and obtained approvals of investigational new drug application (IND) for GARP/TGF- $\beta$ 1 and TIGIT+PD-1+VEGF target projects, and proceeded to clinical study smoothly.

- In September 2024, an investigational new drug application (IND) for HLX17 (recombinant humanised anti-PD-1 monoclonal antibody injection) was approved by the NMPA. HLX17 is intended for the treatment of melanoma, non-small cell lung cancer, esophageal cancer, head and neck squamous cell cancer, colorectal cancer, hepatocellular carcinoma, biliary tract cancer, triple-negative breast cancer, microsatellite instability-high or deficient mismatch repair tumours, gastric cancer, etc.
- In January 2025, an investigational new drug application (IND) for the phase 1b/2 clinical trial of HLX43 for injection (antibody-drug conjugate targeting PD-L1 with novel DNA topoisomerase I inhibitor) in combination with HANSIZHUANG for the treatment of patients with advanced/metastatic solid tumours was approved by the NMPA.
- In February 2025, an investigational new drug application (IND) for innovative small molecular HLX99 was approved by the FDA. HLX99 is intended for the treatment of amyotrophic lateral sclerosis (ALS).

The clinical and pre-clinical application results of the Group's products from the beginning of 2024 up to the Latest Practicable Date:

Product name (targets)	Indications	Progress as of the Latest Practicable Date
<b>Efficient advancement on international clinical projects</b>		
<b>HLX22 (HER2) in combination with trastuzumab</b>	Gastroesophageal junction cancer and gastric cancer	<p>In May 2024, an investigational new drug application for the phase 3 clinical trial was approved by the FDA</p> <p>In October 2024, the phase 3 clinical trial was permitted to commence in Japan</p> <p>In November 2024, the first patient has been dosed in an international multi-centre phase 3 clinical study</p> <p>In December 2024, the phase 3 clinical trial was permitted to commence in Australia</p>
<b>HLX22 (HER2)</b>	Gastric cancer (GC)	In March 2025, Orphan-drug Designation was granted by the FDA
<b>HANSIZHUANG in combination with bevacizumab and chemotherapy (PD-1+VEGF)</b>	Metastatic colorectal cancer (mCRC)	<p>In May 2024, the first patient in phase 3 part has been dosed in the international multi-centre phase 2/3 clinical trial</p> <p>In July 2024, the phase 3 part in the international multi-centre phase 2/3 clinical trial was permitted to commence in Japan and Indonesia respectively</p> <p>The international multi-centre phase 3 clinical trial is ongoing in Mainland China, Japan and Indonesia</p>

Product name (targets)	Indications	Progress as of the Latest Practicable Date
<b>HANSIZHUANG in combination with chemotherapy (PD-1)</b>	Limited-stage small cell lung cancer (LS-SCLC)	In January 2025, the recruitment of subjects was completed in an international multi-centre phase 3 clinical study
<b>HANSIZHUANG in combination with chemotherapy (PD-1)</b>	Extensive-stage small cell lung cancer (ES-SCLC)	As at the Latest Practicable Date, over 100 sites have been set for the bridging study in the United States, and the recruitment of subjects is ongoing.
<b>HLX04-O (VEGF)</b>	Wet age-related macular degeneration (wAMD)	In January 2024, the recruitment of subjects was completed in an international multi-centre phase 3 clinical study
<b>HLX14 (RANKL)</b>	Osteoporosis (OP) etc.	<p>In April 2024, an international multi-centre phase 3 clinical study met the primary study endpoints</p> <p>In May 2024, the marketing authorisation application (MAA) was validated by the European Medicines Agency (EMA)</p> <p>In September 2024, the new drug submission (NDS) was accepted by Health Canada</p> <p>In October 2024, the biologic license application (BLA) was accepted by the FDA</p>
<b>HLX11 (HER2)</b>	Breast cancer (BC)	<p>In September 2024, an international multi-centre phase 3 clinical study met the primary study endpoint</p> <p>In January 2025, the biologic license application (BLA) was accepted by the FDA</p>

Product name (targets)	Indications	Progress as of the Latest Practicable Date
<b>Smooth progress of domestic clinical projects</b>		
<b>HLX43 (PD-L1 ADC)</b>	Solid tumour (including esophageal squamous cell carcinoma (ESCC))	<p>In December 2024, an investigational new drug application for the phase 1b/2 clinical trial was approved by the NMPA</p> <p>In January 2025, the first patient has been dosed in a phase 2 clinical study for the treatment of recurrent/metastatic esophageal squamous cell carcinoma</p>
<b>HLX22 (HER2) in combination with trastuzumab and chemotherapy or combined with trastuzumab deruxtecan</b>	Solid tumour	<p>In December 2024, an investigational new drug application for the phase 2 clinical trial was approved by the NMPA</p>
<b>HLX53 in combination with HANSIZHUANG and HANBEITAI (TIGIT+PD-1+VEGF)</b>	Hepatocellular carcinoma (HCC)	<p>In April 2024, an investigational new drug application was approved by the NMPA</p> <p>In August 2024, the first patient has been dosed in a phase 2 clinical study</p>
<b>HANSIZHUANG in combination with chemotherapy (PD-1)</b>	Neo-/adjuvant for Gastric cancer	<p>In April 2024, the recruitment of subjects in a phase 3 clinical study was completed</p>
<b>HLX14 (RANKL)</b>	Osteoporosis (OP) etc.	<p>In January 2024, a phase 1 clinical study in Chinese healthy male subjects was completed</p>
<b>HLX6018 (GARP/TGF-β1)</b>	Idiopathic pulmonary fibrosis (IPF)	<p>In March 2024, an investigational new drug application was approved by the NMPA</p> <p>In April 2024, the first subject has been dosed in a phase 1 clinical study</p>
<b>HLX42 (EGFR ADC)</b>	Solid tumour	<p>In March 2024, the first patient has been dosed in a phase 1 clinical study</p>

<b>Product name (targets)</b>	<b>Indications</b>	<b>Progress as of the Latest Practicable Date</b>
<b>HLX78 (SERM)</b>	Breast cancer (BC)	<p>In May 2024, an investigational new drug application was approved by the NMPA</p> <p>In November 2024, the first subject has been dosed in a phase 1 clinical study</p> <p>In December 2024, the first patient in Mainland China has been dosed in an international multi-centre phase 3 clinical study</p>
<b>HLX15 (CD38)</b>	Multiple myeloma (MM)	In June 2024, phase 1 clinical study in healthy male subjects was completed
<b>HLX11 (HER2)</b>	Breast cancer (BC)	In December 2024, the new drug application (NDA) was accepted by the NMPA
<b>Efficient advancement of IND filings for pre-clinical development projects</b>		
<b>HLX6018 (GARP/TGF-β1)</b>	Idiopathic pulmonary fibrosis (IPF)	<p>In March 2024, an investigational new drug application was approved by the NMPA</p> <p>(Already in clinical phase in Mainland China)</p>
<b>HLX53 in combination with HANSIZHUANG and HANBEITAI (TIGIT+PD-1+VEGF)</b>	Hepatocellular carcinoma (HCC)	<p>In April 2024, an investigational new drug application was approved by the NMPA</p> <p>(Already in clinical phase in Mainland China)</p>
<b>HLX17 (PD-1)</b>	Melanoma, non-small cell lung cancer, esophageal cancer, head and neck squamous cell cancer, colorectal cancer, hepatocellular carcinoma, biliary tract cancer, triple-negative breast cancer, microsatellite instability-high or deficient mismatch repair tumours, gastric cancer, etc.	In September 2024, an investigational new drug application was approved by the NMPA

Product name (targets)	Indications	Progress as of the Latest Practicable Date
<b>HLX43 in combination with HANSIZHUANG (PD-L1 ADC+PD-1)</b>	Solid tumour	In January 2025, an investigational new drug application for the phase 1b/2 clinical trial was approved by the NMPA
<b>HLX99 (Polypharmacology)</b>	Amyotrophic lateral sclerosis (ALS)	In February 2025, an investigational new drug application was approved by the FDA

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

The Group's early R&D is focused on patients' needs and clinical value. Based on new drug discovery platforms driven by deep data and biocomputing accelerated molecular design technology, the Group continues 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 is planning for the development of the next-generation innovative antibody drugs and antibody-based drugs. In terms of the development of T cell engager, the Group developed highly specific products targeting solid tumours, which can efficiently break through the immune microenvironment of solid tumours, and activate the autoimmunity to kill the tumour cells. 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 approximately 50 molecules in its pipeline and 14 R&D platforms, covering a wealth of drug forms, such as monoclonal antibody, multi-specific antibody, antibody-drug conjugates (ADC), fusion proteins, small molecule drugs and other forms of drugs.

### **(IV) Layout of industrialisation base for biologics 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 global supply of products approved for marketing.

- Xuhui Facility, the Group's first biopharmaceutical production base in Shanghai Caohejing Hi-Tech Park has been granted with the Chinese, EU, Brazilian and Indonesian GMP certificates and has regularised its supply in global markets. During the Reporting Period, the Xuhui Facility has successfully completed the first batch of commercial shipment to multiple overseas regions and multiple overseas customers audits for the products of HANSIZHUANG, HANQUYOU, HANDAYUAN, etc.

- 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. Songjiang First Plant has obtained the Chinese and US GMP certificates, and completed the first batch of commercial shipment of HANQUYOU (US trade name: HERCESSI™) to the United States during the Reporting Period. In early 2025, the Plant has successfully passed the ISO 14001 environmental management system certification and ISO 45001 occupational health and safety management system certification, and obtained the accreditation marks of International Accreditation Forum (IAF) and Deutsche Akkreditierungsstelle GmbH (DakKS).
- 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 construction of the overall facility buildings for the first stage of this project has been completed during the Reporting Period. The installation and commissioning of equipment in two main production buildings including production lines of some drug substances and drug products, the Prefilled Syringes System (PFS), and the pilot production line of antibody drug conjugates (ADC) and the equipment verification work have been completed, while the verification work of the remaining production lines will also be implemented in order according to production requirements.

#### **(V) Social responsibility, environmental policies and performance**

The Group regards the concept of “Patient-oriented” as the starting point of its development, and 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. Based on a deep understanding of sustainable development, 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 improved its compliance management systems, strengthened the ESG performance capabilities of the Board of Directors, and promoted the implementation of the sustainable development strategy. 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 accessibility of products with medical security and product layout globalisation. We continuously achieved cost reduction and efficiency improvement through the process optimisation to enhance the affordability of medicines. In terms of talent, the Group attached great importance to talent development, and built an open and inclusive corporate culture. Through the global talent introduction program and career development system, the Group has built an international and professional team, and has been awarded the “Best Corporate Employer in Asia” for three consecutive years. In terms of environment, the Group has actively fulfilled its commitment to green development, systematically promoted TCFD climate risk management, continued to monitor the progress of its environmental targets, and has put multiple environmental management measures into practice. On the social front, the Group took the initiative to shoulder social responsibilities, paid attention to the well-being of patients and the public, continuously carried out medical public welfare projects, and jointed hands with partners to build a new ecosystem in the pharmaceutical industry.

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 2025**

In 2025, the Group will continue to focus on clinical needs and devote itself to oncology, auto-immune diseases and other key fields, and continuously deepen product innovation, market expansion and international cooperation so as to further consolidate its international capability of "R&D, production and sales integration". Meanwhile, the Group will actively explore the application of innovative AI platforms in the research and development, accelerate the process of digital transformation, and be committed to making steady progress at a larger, international, and more profitable Biopharma stage, to create more value for global patients.

### **(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. At the same time, relying on the qualifications of Henlius Pharmaceutical Trading and its Good Supply Practice (GSP) certification in China, the Group will also explore more business cooperation possibilities, further expand the commercialised product pipeline and enrich the overall business format of the Group and promote the quality and growth of the commercialisation sector.

- The Group has accumulated strong commercial capabilities in the field of breast cancer treatment. In 2025, while expanding the potential of the lower-tier markets and stabilizing the overall market share of HANQUYOU, the Group will make every effort to promote the commercialisation process of HANNAIJIA. The Group will make full use of the market coverage capabilities and customer resources of the commercialisation team of HANQUYOU to more quickly and widely increase the awareness and treatment rate of intensive adjuvant therapy for HER2-positive early breast cancer, and ensure that the target groups of the intensive adjuvant therapy receive treatment. We aim to build HANNAIJIA into a benchmark brand of neratinib, benefiting more Chinese patients with HER2-positive breast cancer, thus further consolidating the Group's leading position in the treatment of HER2-positive breast cancer.
- HANSIZHUANG (European trade name: Hetronifly®) was officially approved for marketing in the European Union in early 2025 based on the excellent clinical research data and international quality, becoming the first and only monoclonal antibody drug targeting PD-1 approved for the treatment of extensive-stage small cell lung cancer (ES-SCLC) in the European Union. In 2025, the Group will continue to uphold the differentiated product strategy, strengthen the competitive advantages of HANSIZHUANG, consolidate its leading position in the treatment of small cell lung cancer, and further expand its market share in the treatment fields including non-small cell lung cancer and esophageal cancer, so that more patients can benefit from it.

- In 2025, HANBEITAI will continue to focus on the dual-channel market with a view to further increase the market share.
- Fosun Yaohong and Fosun Wanbang, subsidiaries of Fosun Pharma, the controlling Shareholder of the Company, are responsible for the domestic commercial sales of HANLIKANG and HANDAYUAN, respectively. In 2025, the Group will maintain close cooperation with Fosun Yaohong and Fosun Wanbang, thereby continuously carrying out commercial sales of products.

While actively expanding the domestic market, the Group will constantly promote the business cooperation of its self-developed products and establish presence 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 work closely with international partners and leverage the commercial capability of partners in their own field to effectively integrate the Group's products into the local market to benefit a wide range of overseas patients and achieve long-term win-win results. In addition, the Group will also continue to actively promote the authorized introduction and cooperative development of external innovative technologies and projects, and rapidly expand the Group's innovative product pipeline through business development.

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

As at the Latest Practicable Date, 6 products of the Group have been successfully approved for marketing in Mainland China, Europe, the United States, Canada, Australia, Indonesia, Bolivia and other countries/regions. In 2025, the Group will continuously promote the marketing approval process of more products in the global market with experiences gained along the way.

- In 2025, HANSIZHUANG in combination with chemotherapy for extensive-stage small cell lung cancer (ES-SCLC) and squamous non-small cell lung cancer (sqNSCLC) indications is expected to be approved for marketing in more countries or regions, accelerating the penetration of the Europe, Southeast Asia, Middle East and other markets.
- The biologic license application (BLA) for pertuzumab biosimilar HLX11 is expected to be approved in the United States in 2025.
- The new drug applications for denosumab biosimilar HLX14 are expected to be approved in the United States, European Union and Canada in 2025 respectively. The new drug application (NDA) of the product is also expected to be submitted in Mainland China in 2025.
- The new drug application (NDA) for HLX04-O for wet age-related macular degeneration (wAMD) indications is expected to be submitted in Mainland China in 2025.
- In 2025, the Group will also proactively cooperate with international partners to facilitate the marketing approval process in terms of HANLIKANG, HANQUYOU, HANDAYUAN, HANBEITAI, HANSIZHUANG, HLX11, HLX14, and HLX04-O in the United States, the EU, Canada, Japan, the United Kingdom, Switzerland, Saudi Arabia, Indonesia, Argentina, 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 integrate international resources and advantages to explore cutting-edge innovative products with significant clinical value. Meanwhile, the Group will actively deploy the in-depth application of artificial intelligence (AI) technology in the product research and development process, and accelerate the transformation and deepening of early research and development results. Moreover, the Group will continue to rapidly empower and expand the pipeline by project cooperation, with a view to meeting the unmet clinical needs as soon as possible. In 2025, the Group will fully promote the investigational new drug application (IND) of multiple innovative products (including antibody-drug conjugates (ADC), small molecule drugs and innovative drugs, and accelerate the progress of innovative products into the clinical research stage, laying a solid foundation for the long-term development of the Group.

### **(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 optimisation measures to ensure the stability and efficiency of international commercial production and promote the marketing application of HANSIZHUANG in the United States as soon as possible. Songjiang First Plant will continuously improve the international standard quality system. In 2025, the relevant production lines in Songjiang First Plant plan to receive the GMP compliance inspection of relevant products before the launch from the drug and health supervision agencies in the Mainland China, the United States and the EU.

Songjiang Second Plant Phase I Project is expected to be overall completed and accepted in 2025, and will expedite the realisation of global supply for the first commercial production line of drug substance and drug product. In 2025, the relevant production lines in Songjiang Second Plant will usher in the GMP compliance inspection of relevant products before the launch in Mainland China, the United States and EU respectively. The Group will spare no effort to build Songjiang Second Plant into a 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 promoted the exploration of extensive portfolio of existing products and improved the integrated platform for biopharmaceutical R&D, production and commercialisation. Meanwhile, it has deeply tapped into the potential of combination treatment by adopting the “combination therapy + internationalisation” strategy to promote a number of international multi-center clinical studies, and amplified its own competitive capabilities, offering high-quality treatment options for patients across the world. During the Reporting Period, the Group’s profitability continued to trend upwards, and the R&D pipeline showed a strong potential for innovation growth. Together with global partners, the Group secured the rapid entry and successful promotion of products to complete the layout of globalisation for overseas markets.

As an international and innovative biopharmaceutical company, the Group will continuously focus on clinical needs and build differentiated, innovative product pipelines, while accelerating international market expansion and establishing multi-level global clinical product development and operation capabilities to offer affordable high-quality biopharmaceuticals that can benefit more patients. The Group will accelerate the advancement of the layout of globalisation, covering the mainstream biopharmaceutical market and emerging markets, and strive to expand and deepen strategic cooperation.

During the Reporting Period, the Group realised an operating income of approximately RMB5,724.4 million, representing an increase of 6.1% 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 RMB2,692.4 million, representing an increase of approximately RMB48.0 million or 1.8% as compared to the same period in the last year. Zercepac<sup>®</sup> and HERCESSI<sup>™</sup> recorded overseas sales revenue of approximately RMB117.6 million.

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 RMB1,308.9 million, representing a stable increase of approximately RMB189.1 million or approximately 16.9% as compared to the same period in the last year. Zerpidio<sup>®</sup> and its overseas products recorded sales revenue of approximately RMB3.7 million.

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 RMB197.1 million.

In respect of HANLIKANG (rituximab), according to the cooperation agreement with Fosun Pharma, Fosun Pharma would reimburse all the expenses related to the clinical trials of HANLIKANG incurred by the Group after the relevant cooperation agreement was signed, and the Group was responsible for the production of HANLIKANG in China and the supply of HANLIKANG to Fosun Pharma after the commercialisation of HANLIKANG, and shall share the profits from the sales of HANLIKANG in China. During the Reporting Period, the Group recorded sales revenue of approximately RMB528.5 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 RMB40.1 million under the aforementioned profit-sharing arrangement with its partners.

HANNAIJIA (Neratinib Maleate) is another important product of the Group for breast cancer treatment, which is expected to form a sequential therapy with the existing product HANQUYOU in the pipeline, further reducing the 5-year and 10-year postoperative recurrence risks in patients with HER2-positive early breast cancer. HANNAIJIA started shipment in September 2024. During the Reporting Period, HANNAIJIA recorded sales revenue of approximately RMB45.3 million.

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

The Group has been conforming to global standards in respect of product R&D, partner selection and quality management and unwaveringly implementing the internationalisation strategy to provide high-quality treatment options to patients around the world. The Group will further consolidate the globalisation capability model and create a more international portfolio of innovative pipelines to achieve newer, faster and more comprehensive internationalisation. 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 and commercial authorisation, etc.

In June 2018, the Group entered into a license agreement with Accord in relation to HANQUYOU (European trade name: Zercepac<sup>®</sup>), granting Accord exclusive commercialisation rights in special territories as agreed therein. In July 2020, the marketing authorisation application of Zercepac<sup>®</sup> submitted by a wholly-owned subsidiary of Accord was approved. Since then, Zercepac<sup>®</sup> has been the first “Chinese” monoclonal antibody biosimilar drug approved for sale in the EU. The Group recognised licensing revenue of approximately RMB5.6 million for the 12 months ended 31 December 2024.

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 RMB2.0 million for the 12 months ended 31 December 2024.

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 RMB36.5 million for the 12 months ended 31 December 2024.

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 RMB290.0 million for the 12 months ended 31 December 2024.

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 right 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 RMB142.3 million for the 12 months ended 31 December 2024.

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 RMB233.2 million for the 12 months ended 31 December 2024.

### **3) Revenue from other R&D service businesses**

The Group recognised revenue from CMC Technical Services of approximately RMB52.7 million for the 12 months ended 31 December 2024.

## **(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 2024, the Group recorded cost of sales of approximately RMB1,539.8 million, representing an increase of approximately RMB63.7 million as compared with that for the 12 months ended 31 December 2023 due to the increase of the sales volume of the key commercial product markets.

### (III) Gross profit

For the 12 months ended 31 December 2024, the Group recorded a gross profit of approximately RMB4,184.7 million, representing an increase of approximately RMB265.9 million as compared with that for the 12 months ended 31 December 2023, 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 RMB108.0 million.

	Year ended 31 December	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Government grants	77,785	59,814
Interest income	21,703	8,146
Exchange gains/(losses)	8,136	(1,421)
Others	356	2,375
<b>Total</b>	<b>107,980</b>	<b>68,914</b>

### (V) R&D expenses

	Year ended 31 December	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
<b>Expensed R&amp;D expenses</b>		
R&D employee salaries	315,319	333,275
Clinical trials	294,995	299,424
Outsourcing fees	147,461	120,180
Reagents and consumables	115,297	128,878
Depreciation and amortisation	57,111	65,661
Consulting expense	28,881	25,676
Technology expense	12,541	62,020
Utilities expenses	10,133	11,640
Share-based compensation	–	161
Others	53,392	71,817
<b>Total expensed R&amp;D expenses</b>	<b>1,035,130</b>	<b>1,118,732</b>

	<b>Year ended 31 December</b>	
	<b>2024</b>	<b>2023</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
<b>Capitalised R&amp;D expenses</b>		
Clinical trials	<b>315,988</b>	84,333
R&D employee salaries	<b>175,315</b>	125,791
Reagents and consumables	<b>85,925</b>	29,849
Technology expense	<b>67,511</b>	–
Depreciation and amortisation	<b>51,410</b>	21,217
Outsourcing fees	<b>42,717</b>	27,852
Utilities expenses	<b>29,084</b>	4,668
Consulting expense	<b>3,898</b>	677
Share-based compensation	–	38
Others	<b>33,525</b>	20,486
	<hr/>	<hr/>
<b>Total capitalised R&amp;D expenses</b>	<b><u>805,373</u></b>	<b><u>314,911</u></b>

For the 12 months ended 31 December 2024, the Group recognized R&D expenses of approximately RMB1,840.5 million, representing an increase of approximately RMB406.9 million as compared with approximately RMB1,433.6 million for the 12 months ended 31 December 2023, mainly due to (1) the development expenditures under the contracts were included in the cost of R&D service after certain projects were licensed out in the previous period, thereby reducing the Group's own R&D expenses; and (2) during the Reporting Period, the Group adhered to a scientific and efficient R&D strategy, focused on unmet clinical needs, and optimized pipeline resource allocation. Our R&D expenses mainly arose from 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, consulting fees, depreciation and amortisation, etc.

For the 12 months ended 31 December 2024, the Group recognised administrative expenses of approximately RMB370.8 million, representing a decrease of approximately RMB13.0 million as compared with approximately RMB383.8 million for the 12 months ended 31 December 2023. The decrease in administrative expenses of the Group was mainly due to: (1) the decrease in administrative staff costs as the Group implemented its cost reduction and efficiency enhancement strategy; and (2) the corresponding decrease in third-party consulting fees and depreciation costs to improve operational efficiency.

## **(VII) Selling and distribution expenses**

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

For the 12 months ended 31 December 2024, the Group recognised selling and distribution expenses of approximately RMB1,917.4 million, which were mainly the marketing expenses incurred in continuous sales growth of HANQUYOU, HANSIZHUANG, HANBEITAI, and the marketing and selling of HANNAIJIA. Among which, the marketing expenses ratio of HANQUYOU in the domestic market remained stable.

## **(VIII) Other expenses**

For the 12 months ended 31 December 2024, the Group recognised other expenses of approximately RMB5.4 million, which mainly included provision for loss on devaluation of inventories of semi-finished products, finished products, and raw materials.

## **(IX) Income tax expense**

For the 12 months ended 31 December 2024, the Group incurred income tax expense of approximately RMB25.4 million.

## **(X) Profit for the year**

In view of the above, the Group recorded an increase of approximately RMB274.5 million in profit from a profit of approximately RMB546.0 million for the year ended 31 December 2023 to a profit of approximately RMB820.5 million for the year ended 31 December 2024.

## **(XI) Liquidity and capital resources**

As of 31 December 2024, cash and bank balances of the Group were approximately RMB773.0 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 RMB987.7 million as of 31 December 2023, representing a decrease of approximately RMB214.7 million.

As of 31 December 2024, the current assets of the Group were approximately RMB2,511.5 million, including cash and bank balances of approximately RMB773.0 million, inventories of approximately RMB728.3 million, trade receivables of approximately RMB857.4 million, contract assets of approximately RMB43.9 million, and other receivables of approximately RMB108.9 million.

As of 31 December 2024, the current liabilities of the Group were approximately RMB5,032.0 million, including trade payables of approximately RMB729.1 million, other payables and accruals of approximately RMB1,299.4 million, contract liabilities of RMB444.0 million, and interest-bearing bank and other borrowings of approximately RMB2,559.5 million.

As at 31 December 2024, the bank balances in foreign exchange were as follows:

	<i>RMB'000</i>
RMB	466,791
HKD	2,803
USD	299,954
EUR	669
NTD	2,745
	<u><u>                    </u></u>
	<i>Original amount'000</i>
RMB	466,791
HKD	3,026
USD	41,692
EUR	35
NTD	12,314
	<u><u>                    </u></u>

## (XII) Inventories

Inventories of the Group amounted to approximately RMB728.3 million as at 31 December 2024, representing a decrease of approximately RMB29.1 million as compared with approximately RMB757.4 million as at 31 December 2023, mainly due to further improvement in inventory management.

## (XIII) Trade receivables

As at 31 December 2023 and 31 December 2024, trade receivables from customer contracts were approximately RMB647.8 million and RMB857.4 million, respectively. There were no changes in accounting estimates or key assumptions made in both years.

	<b>As at 31 December</b>	
	<b>2024</b>	<b>2023</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
Within 3 months	<b>856,286</b>	635,950
3 to 6 months	<b>1,144</b>	11,878
	<u>                    </u>	<u>                    </u>
<b>Total</b>	<b><u><u>857,430</u></u></b>	<b><u><u>647,828</u></u></b>

#### (XIV) Interest-bearing bank and other borrowings

As of 31 December 2024, borrowings from bank and other institutions (exclusive of lease liabilities) of the Group were approximately RMB3,445.8 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 2024 and 31 December 2023, of which lease liabilities were recognised in accordance with IFRS 16 – Leases.

	As at 31 December	
	2024	2023
	RMB'000	RMB'000
Within one year	2,559,515	2,800,377
In the second year	348,137	213,288
In the third to fifth year (inclusive)	726,050	899,218
Over five years	14,484	180,168
<b>Total</b>	<b>3,648,186</b>	<b>4,093,051</b>

#### (XVI) Collateral and pledged assets

As at 31 December 2024, the Group's pledged assets in relation to borrowings included property, plant and equipment of approximately RMB1,115.6 million and land use right of approximately RMB188.4 million.

#### (XVII) Key financial ratios

	31 December 2024	31 December 2023
Current ratio <sup>(1)</sup> :	49.9%	52.8%
Quick ratio <sup>(2)</sup> :	35.4%	37.9%
Gearing ratio <sup>(3)</sup> :	50.5%	59.5%

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 investments

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	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Construction in progress	256,114	472,846
Plant and machinery	14,881	52,046
Electronic equipment	2,968	11,574
Leasehold improvements	15,887	35,589
<b>Total</b>	<b>289,850</b>	<b>572,055</b>

We had capital commitments for plant and machinery contracted but not provided for of approximately RMB83.3 million as at 31 December 2024. 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 2024, the Group did not have any material contingent liabilities.

### (XXI) Material acquisitions and disposals

As at 31 December 2024, 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 2024.

## **IV. RISK MANAGEMENT**

### **(I) Foreign exchange risk**

As at 31 December 2024, 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. Meanwhile, after the advancement and implementation of the relevant centralised procurement policies in the PRC, the resulting impact on the Group's relevant products is uncertain. The Group will continue to track the subsequent policy developments.

#### **2. Business and Operational Risk**

Global situation is ever-changing and global biologics market is also 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 Group has independently developed products and successfully made them available on the market as below: 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 2024:

<b>Function</b>	<b>Number of employees</b>
R&D and technology	953
Manufacturing	848
Commercial Operation	1,452
General and administrative	262
<b>Total</b>	<b><u><u>3,515</u></u></b>

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](mailto: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 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 (including sale of treasury shares).

## **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.

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

## **COMPLIANCE WITH CODE FOR SECURITIES TRANSACTIONS**

The Company has adopted the Model Code for Securities Transactions by Directors of Listed Issuers (the "Model Code") as set out in Appendix 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 2024 annual results and the financial statements for the year ended 31 December 2024 prepared in accordance with the IFRS Accounting Standards.

## CONSOLIDATED STATEMENT OF PROFIT OR LOSS

Year ended 31 December 2024

	Notes	2024 RMB'000	2023 RMB'000
<b>REVENUE</b>	3	<b>5,724,449</b>	5,394,909
Cost of sales		<u>(1,539,787)</u>	<u>(1,476,112)</u>
<b>Gross profit</b>		<b>4,184,662</b>	3,918,797
Other income and gains	4	<b>107,980</b>	68,914
Selling and distribution expenses		<b>(1,917,391)</b>	(1,754,241)
Administrative expenses		<b>(370,799)</b>	(383,840)
Impairment losses on financial assets, net		<b>4,843</b>	(30,280)
Research and development expenses		<b>(1,035,130)</b>	(1,118,732)
Other expenses		<b>(5,397)</b>	(20,501)
Finance costs	6	<u><b>(122,887)</b></u>	<u>(110,539)</u>
<b>PROFIT BEFORE TAX</b>	5	<b>845,881</b>	569,578
Income tax expense	7	<u><b>(25,411)</b></u>	<u>(23,559)</u>
<b>PROFIT FOR THE YEAR</b>		<u><b>820,470</b></u>	<u>546,019</u>
<b>Attributable to:</b>			
Owners of the parent		<b>820,470</b>	546,019
Non-controlling interests		<u>—</u>	<u>—</u>
		<u><b>820,470</b></u>	<u>546,019</u>
<b>EARNINGS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT</b>			
Basic			
– For profit for the year (RMB)	9	<u><b>1.51</b></u>	<u>1.01</u>
Diluted			
– For profit for the year (RMB)	9	<u><b>1.51</b></u>	<u>1.00</u>

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

Year ended 31 December 2024

	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
<b>PROFIT FOR THE YEAR</b>	<b>820,470</b>	546,019
<b>OTHER COMPREHENSIVE INCOME</b>		
Other comprehensive income that may be reclassified to profit or loss in subsequent periods:		
Exchange differences:		
Exchange differences on translation of foreign operations	<u>850</u>	<u>17</u>
<b>OTHER COMPREHENSIVE INCOME FOR THE YEAR, NET OF TAX</b>	<b>850</b>	17
<b>TOTAL COMPREHENSIVE INCOME FOR THE YEAR</b>	<b>821,320</b>	546,036
<b>Attributable to:</b>		
Owners of the parent	<b>821,320</b>	546,036
Non-controlling interests	<u>—</u>	<u>—</u>
	<b>821,320</b>	546,036

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

Year ended 31 December 2024

	<i>Notes</i>	<b>2024</b> <b>RMB'000</b>	2023 RMB'000
<b>NON-CURRENT ASSETS</b>			
Property, plant and equipment		2,343,354	2,237,768
Intangible assets		5,355,204	4,510,729
Right-of-use assets		357,103	414,886
Other non-current assets		<u>30,335</u>	<u>64,156</u>
<b>Total non-current assets</b>		<u><b>8,085,996</b></u>	<u>7,227,539</u>
<b>CURRENT ASSETS</b>			
Inventories		728,266	757,359
Trade receivables	10	857,430	647,828
Prepayments, deposits and other receivables	11	108,938	200,761
Contract assets		43,928	82,419
Cash and bank balances		<u>772,962</u>	<u>987,665</u>
<b>Total current assets</b>		<u><b>2,511,524</b></u>	<u>2,676,032</u>
<b>CURRENT LIABILITIES</b>			
Trade payables	12	729,099	544,815
Other payables and accruals		1,299,350	1,255,363
Contract liabilities		444,033	466,878
Interest-bearing bank and other borrowings		<u>2,559,514</u>	<u>2,800,377</u>
<b>Total current liabilities</b>		<u><b>5,031,996</b></u>	<u>5,067,433</u>
<b>NET CURRENT LIABILITIES</b>		<u><b>(2,520,472)</b></u>	<u>(2,391,401)</u>
<b>TOTAL ASSETS LESS CURRENT LIABILITIES</b>		<u><b>5,565,524</b></u>	<u>4,836,138</u>
<b>NON-CURRENT LIABILITIES</b>			
Interest-bearing bank and other borrowings		1,088,671	1,292,674
Other long-term payables		149,266	172,071
Contract liabilities		1,075,238	949,044
Deferred income		<u>238,728</u>	<u>230,048</u>
<b>Total non-current liabilities</b>		<u><b>2,551,903</b></u>	<u>2,643,837</u>
<b>Net assets</b>		<u><b>3,013,621</b></u>	<u>2,192,301</u>
<b>EQUITY</b>			
Share capital		543,495	543,495
Reserves		<u>2,470,126</u>	<u>1,648,806</u>
<b>Equity attributable to owners of the parent and total equity</b>		<u><b>3,013,621</b></u>	<u>2,192,301</u>

# NOTES TO FINANCIAL STATEMENTS

Year ended 31 December 2024

## 1.1 BASIS OF PREPARATION

These financial statements have been prepared in accordance with International Financial Reporting Standards (“**IFRS Accounting Standards**”), 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 RMB2,520,472,000 as at 31 December 2024. 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 2024. 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 revised IFRS Accounting Standards for the first time for the current year's financial statements.

Amendments to IFRS 16	<i>Lease Liability in a Sale and Leaseback</i>
Amendments to IAS 1	<i>Classification of Liabilities as Current or Non-current</i> (the "2020 Amendments")
Amendments to IAS 1	<i>Non-current Liabilities with Covenants</i> (the "2022 Amendments")
Amendments to IAS 7 and IFRS 7	<i>Supplier Finance Arrangements</i>

The nature and the impact of the revised IFRS Accounting Standards are described below:

- (a) 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. Since the Group has no sale and leaseback transactions with variable lease payments that do not depend on an index or a rate occurring from the date of initial application of IFRS 16, the amendments did not have any impact on the financial position or performance of the Group.
- (b) 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 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 Group has reassessed the terms and conditions of its liabilities as at 1 January 2023 and 2024 and concluded that the classification of its liabilities as current or non-current remained unchanged upon initial application of the amendments. Accordingly, the amendments did not have any impact on the financial position or performance of the Group.

- (c) 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.

## 1.3 ISSUED BUT NOT YET EFFECTIVE INTERNATIONAL FINANCIAL REPORTING STANDARDS

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

IFRS 18	<i>Presentation and Disclosure in Financial Statements<sup>3</sup></i>
IFRS 19	<i>Subsidiaries without Public Accountability: Disclosures<sup>3</sup></i>
Amendments to IFRS 9 and IFRS 7	<i>Amendments to the Classification and Measurement of Financial Instruments<sup>2</sup></i>
Amendments to IFRS 10 and IAS 28	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture<sup>4</sup></i>
Amendments to IAS 21	<i>Lack of Exchangeability<sup>1</sup></i>
<i>Annual Improvements to IFRS Accounting Standards – Volume 11</i>	Amendments to IFRS 1, IFRS 7, IFRS 9, IFRS 10 and IAS 7 <sup>2</sup>

<sup>1</sup> Effective for annual periods beginning on or after 1 January 2025

<sup>2</sup> Effective for annual periods beginning on or after 1 January 2026

<sup>3</sup> Effective for annual/reporting periods beginning on or after 1 January 2027

<sup>4</sup> No mandatory effective date yet determined but available for adoption

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

IFRS 18 replaces IAS 1 Presentation of Financial Statements. While a number of sections have been brought forward from IAS 1 with limited changes, IFRS 18 introduces new requirements for presentation within the statement of profit or loss, including specified totals and subtotals. Entities are required to classify all income and expenses within the statement of profit or loss into one of the five categories: operating, investing, financing, income taxes and discontinued operations and to present two new defined subtotals. It also requires disclosures about management-defined performance measures in a single note and introduces enhanced requirements on the grouping (aggregation and disaggregation) and the location of information in both the primary financial statements and the notes. Some requirements previously included in IAS 1 are moved to IAS 8 *Accounting Policies, Changes in Accounting Estimates and Errors*, which is renamed as IAS 8 *Basis of Preparation of Financial Statements*. As a consequence of the issuance of IFRS 18, limited, but widely applicable, amendments are made to IAS 7 *Statement of Cash Flows*, IAS 33 *Earnings per Share* and IAS 34 *Interim Financial Reporting*. In addition, there are minor consequential amendments to other IFRS Accounting Standards. IFRS 18 and the consequential amendments to other IFRS Accounting Standards are effective for annual periods beginning on or after 1 January 2027 with earlier application permitted. Retrospective application is required. The Group is currently analysing the new requirements and assessing the impact of IFRS 18 on the presentation and disclosure of the Group's financial statements.

IFRS 19 allows eligible entities to elect to apply reduced disclosure requirements while still applying the recognition, measurement and presentation requirements in other IFRS Accounting Standards. To be eligible, at the end of the reporting period, an entity must be a subsidiary as defined in IFRS 10 *Consolidated Financial Statements*, cannot have public accountability and must have a parent (ultimate or intermediate) that prepares consolidated financial statements available for public use which comply with IFRS Accounting Standards. Earlier application is permitted. As the Company is a listed company, it is not eligible to elect to apply IFRS 19. Some of the Company's subsidiaries are considering the application of IFRS 19 in their specified financial statements.

Amendments to IFRS 9 and IFRS 7 clarify the date on which a financial asset or financial liability is derecognised and introduce an accounting policy option to derecognise a financial liability that is settled through an electronic payment system before the settlement date if specified criteria are met. The amendments clarify how to assess the contractual cash flow characteristics of financial assets with environmental, social and governance and other similar contingent features. Moreover, the amendments clarify the requirements for classifying financial assets with non-recourse features and contractually linked instruments. The amendments also include additional disclosures for investments in equity instruments designated at fair value through other comprehensive income and financial instruments with contingent features. The amendments shall be applied retrospectively with an adjustment to opening retained profits (or other component of equity) at the initial application date. Prior periods are not required to be restated and can only be restated without the use of hindsight. Earlier application of either all the amendments at the same time or only the amendments related to the classification of financial assets is permitted. The amendments are not expected to have any significant impact on the Group's financial statements.

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 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.

*Annual Improvements to IFRS Accounting Standards – Volume 11* set out amendments to IFRS 1, IFRS 7 (and the accompanying *Guidance on implementing IFRS 7*), IFRS 9, IFRS 10 and IAS 7. Details of the amendments that are expected to be applicable to the Group are as follows:

- **IFRS 7 *Financial Instruments: Disclosures*:** The amendments have updated certain wording in paragraph B38 of IFRS 7 and paragraphs IG1, IG14 and IG20B of the *Guidance on implementing IFRS 7* for the purpose of simplification or achieving consistency with other paragraphs in the standard and/or with the concepts and terminology used in other standards. In addition, the amendments clarify that the *Guidance on implementing IFRS 7* does not necessarily illustrate all the requirements in the referenced paragraphs of IFRS 7 nor does it create additional requirements. Earlier application is permitted. The amendments are not expected to have any significant impact on the Group’s financial statements.
- **IFRS 9 *Financial Instruments*:** The amendments clarify that when a lessee has determined that a lease liability has been extinguished in accordance with IFRS 9, the lessee is required to apply paragraph 3.3.3 of IFRS 9 and recognise any resulting gain or loss in profit or loss. In addition, the amendments have updated certain wording in paragraph 5.1.3 of IFRS 9 and Appendix A of IFRS 9 to remove potential confusion. Earlier application is permitted. The amendments are not expected to have any significant impact on the Group’s financial statements.
- **IFRS 10 *Consolidated Financial Statements*:** The amendments clarify that the relationship described in paragraph B74 of IFRS 10 is just one example of various relationships that might exist between the investor and other parties acting as de facto agents of the investor, which removes the inconsistency with the requirement in paragraph B73 of IFRS 10. Earlier application is permitted. The amendments are not expected to have any significant impact on the Group’s financial statements.
- **IAS 7 *Statement of Cash Flows*:** The amendments replace the term “cost method” with “at cost” in paragraph 37 of IAS 7 following the prior deletion of the definition of “cost method”. Earlier application is permitted. The amendments are not expected to have any 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*

	2024 <i>RMB’000</i>	2023 <i>RMB’000</i>
Mainland China	5,046,100	4,810,621
Asia Pacific (excluding Mainland China)	236,864	193,988
North America	329,124	314,789
South America	10,624	19,144
Europe	101,412	56,367
Oceania	325	–
	<hr/>	<hr/>
Total revenue	<b>5,724,449</b>	<b>5,394,909</b>
	<hr/> <hr/>	<hr/> <hr/>

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

(b) *Non-current assets*

	<b>2024</b> <b>RMB'000</b>	2023 <i>RMB'000</i>
Mainland China	<b>7,982,313</b>	7,087,635
Overseas	<b>103,683</b>	139,904
Total non-current assets	<b>8,085,996</b>	7,227,539

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:

	<b>2024</b> <b>RMB'000</b>
Customer A	<b>2,055,889</b>
	2023 <i>RMB'000</i>
Customer A	1,932,173
Customer B	552,068
	2,484,241

**3. REVENUE**

An analysis of revenue is as follows:

	<b>2024</b> <b>RMB'000</b>	2023 <i>RMB'000</i>
<i>Revenue from contracts with customers</i>	<b>5,721,643</b>	5,392,189
<i>Revenue from other sources</i>		
Gross rental income from operating leases	<b>2,806</b>	2,720
Total revenue	<b>5,724,449</b>	5,394,909

## Revenue from contracts with customers

### (a) Revenue information

	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
<b>Types of goods or service</b>		
Sales of biopharmaceutical products	4,933,529	4,553,548
Research and development services	523,473	698,906
Licensing revenue	260,760	138,953
Others	3,881	782
	<u>5,721,643</u>	<u>5,392,189</u>
<b>Timing of revenue recognition</b>		
Transferred at a point in time	5,220,316	4,782,856
Transferred over time	501,327	609,333
	<u>5,721,643</u>	<u>5,392,189</u>

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:

	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
<b>Revenue recognised that was included in contract liabilities at the beginning of the reporting period:</b>		
Sales of biopharmaceutical products	155,203	–
Licensing revenue	25,959	23,383
Research and development services	301,322	194,499
	<u>482,484</u>	<u>217,882</u>

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:

	<b>2024</b>	2023
	<b><i>RMB'000</i></b>	<i>RMB'000</i>
Amounts expected to be recognised as revenue:		
Within one year	<b>444,033</b>	687,922
After one year	<b>1,075,238</b>	1,090,827
	<b><u>1,519,271</u></b>	<u>1,778,749</u>

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 sale of biopharmaceutical products is expected to be recognised in which the risk of the biopharmaceutical products is transferred. 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**

	<b>2024</b>	2023
	<b><i>RMB'000</i></b>	<i>RMB'000</i>
Interest income	<b>21,703</b>	8,146
Exchange gains/(losses)	<b>8,136</b>	(1,421)
Government grants	<b>77,785</b>	59,814
Others	<b>356</b>	2,375
Total other income and gains	<b><u>107,980</u></b>	<u>68,914</u>

#### **5. PROFIT BEFORE TAX**

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

	<b>2024</b>	2023
	<b><i>RMB'000</i></b>	<i>RMB'000</i>
	<i>Notes</i>	
Cost of inventories sold	<b>896,929</b>	799,043
Cost of services provided	<b>642,858</b>	677,069
Depreciation of property, plant and equipment*	<b>141,500</b>	135,768
Depreciation of right-of-use assets*	<b>71,944</b>	73,693
Amortisation of intangible assets*	<b>161,355</b>	149,772

	<i>Notes</i>	<b>2024</b> <b><i>RMB'000</i></b>	2023 <i>RMB'000</i>
Research and development expenses:			
Current year expenditure		<b>1,035,130</b>	1,118,732
Lease payments not included in the measurement of lease liabilities		<b>12,551</b>	8,751
Auditor's remuneration		<b>4,100</b>	5,400
Employee benefit expense (including directors' and chief executive's remuneration:			
Wages and salaries		<b>1,392,662</b>	1,390,934
Staff welfare expenses		<b>283,527</b>	255,547
Share-based payment expense*		–	2,587
Foreign exchange (gains)/losses	4	<b>(8,136)</b>	1,421
Impairment of financial assets, net:			
Impairment of trade receivables		<b>(5,160)</b>	9,031
Impairment of other receivables		<b>317</b>	21,249
Impairment of contract assets		<b>129</b>	–
Write-down of inventories to net realisable value		<b>5,102</b>	22,817
Bank interest income	4	<b>(21,703)</b>	(8,146)
Gain on disposal of right-of-use assets		<b>(911)</b>	(455)
Loss/(gain) on disposal of items of property, plant and equipment		<b>90</b>	(267)
		<b><u>          </u></b>	<b><u>          </u></b>

\* 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:

	<b>2024</b> <b><i>RMB'000</i></b>	2023 <i>RMB'000</i>
Interest expense on bank and other borrowings	<b>128,661</b>	134,175
Interest expense on lease liabilities	<b>11,583</b>	13,348
Less: Interest capitalised	<b>(17,357)</b>	(36,984)
	<b><u>          </u></b>	<b><u>          </u></b>
Total	<b><u>122,887</u></b>	<b><u>110,539</u></b>

## 7. INCOME TAX

The provision for Mainland China current income tax is based on the statutory rate of 25% (2023: 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 Mainland China, 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 2024, is based on the statutory rates of 29.84% and 8.25%, respectively (2023: 29.84% and 8.25% respectively).

	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
Current – Mainland China	<u>25,411</u>	<u>23,559</u>
Total tax charged for the year	<u><u>25,411</u></u>	<u><u>23,559</u></u>

## 8. DIVIDENDS

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

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

The calculation of the basic earnings per share amounts is based on the profit attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 543,494,853 (2023: 543,299,247) in issue during the year.

The calculation of the diluted earnings per share amounts is based on the profit 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 per share calculation, and the weighted average number of conversion of all dilutive potential ordinary shares into ordinary shares.

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

	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
<b>Earnings</b>		
Profit attributable to ordinary equity holders of the parent, used in the basic earnings per share calculation	<u><u>820,470</u></u>	<u><u>546,019</u></u>
	<b>Number of shares</b>	
	2024	2023
<b>Shares</b>		
Weighted average number of ordinary shares in issue during the year used in the basic earnings per share calculation	543,494,853	543,299,247
Effect of dilution – weighted average number of ordinary shares:		
Restricted shares under share award scheme	<u>–</u>	<u>73,857</u>
Weighted average number of ordinary shares in issue during the year in the diluted earnings per share calculation	<u><u>543,494,853</u></u>	<u><u>543,373,104</u></u>

All the shares under the share award scheme had been vested in 2023. Therefore, there was no effect of dilution in 2024.

## 10. TRADE RECEIVABLES

	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
Trade receivables	867,206	663,957
Impairment	<u>(9,776)</u>	<u>(16,129)</u>
Net carrying amount	<u><b>857,430</b></u>	<u><b>647,828</b></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:

	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
Within 3 months	856,286	635,950
3 to 6 months	<u>1,144</u>	<u>11,878</u>
Total	<u><b>857,430</b></u>	<u><b>647,828</b></u>

## 11. PREPAYMENTS, DEPOSITS AND OTHER RECEIVABLES

	Notes	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
Prepayments		44,278	44,086
Value added tax to be deducted and certified		23,890	134,980
Deposits and other receivables		40,770	21,695
Due from AMTD	(i)	<u>477,029</u>	<u>470,015</u>
Impairment allowance	(i)	<u>585,967</u> <u>(477,029)</u>	670,776 <u>(470,015)</u>
Total		<u><b>108,938</b></u>	<u><b>200,761</b></u>

*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 oOo Securities (HK) Group 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 and 2024, the outstanding balances of the investment principal in AMTD Account amounted to USD66,361,000 (equivalent to RMB470,015,000 and RMB477,029,000 respectively).

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. Since 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. Impairment amounted to USD66,361,000 was provided for amounts due from AMTD as at 31 December 2024 and 2023.

The deposits and other receivables included in the above balances relate to receivables for which there was no recent history of default and past due amounts. As at 31 December 2024 and 2023, the loss allowance was assessed to be minimal.

## 12. TRADE PAYABLES

	<b>2024</b> <b>RMB'000</b>	2023 <i>RMB'000</i>
Trade payables	<b>729,099</b>	544,815

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:

	<b>2024</b> <b>RMB'000</b>	2023 <i>RMB'000</i>
Within 1 year	<b>692,208</b>	542,286
1 to 2 years	<b>36,869</b>	2,507
2 to 3 years	–	22
Over 3 years	<b>22</b>	–
Total	<b>729,099</b>	544,815

## 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.

## **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 2024 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 value for all its shareholders.

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

Hong Kong, 24 March 2025

*As at the date of this announcement, the board of directors of the Company comprises Mr. Wenjie Zhang as the chairman and non-executive director, Dr. 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.*