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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 2025

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 2025 (the “**Reporting Period**”), prepared under International Financial Reporting Standards (“**IFRS Accounting Standards**”).

FINANCIAL SUMMARY:

1. The Group’s total revenue increased by approximately RMB942.2 million or approximately 16.5% to approximately RMB6,666.6 million for the year ended 31 December 2025, compared to approximately RMB5,724.4 million for the year ended 31 December 2024. Such revenue was mainly from drug sales, research and development (“**R&D**”) services provided to customers, and license income. The total revenue from products was approximately RMB5,774.6 million, representing an increase of approximately 17.0%.
2. For the year ended 31 December 2025, the Group recognized R&D expenditure of approximately RMB2,491.9 million, representing an increase of approximately RMB651.4 million as compared to approximately RMB1,840.5 million for the year ended 31 December 2024. The amount was mainly used to increase investment in innovative R&D projects to accelerate the Group’s innovation and transformation. Among this, the expensed R&D expenses were approximately RMB1,515.5 million, representing an increase of approximately RMB480.4 million as compared to approximately RMB1,035.1 million for the year ended 31 December 2024.
3. The Group’s total profit was approximately RMB827.0 million for the year ended 31 December 2025, representing an increase of approximately RMB6.5 million in profit from a profit of approximately RMB820.5 million for the year ended 31 December 2024, mainly due to the continuous increase in sales volume of core commercialized products, the substantial growth in overseas commercialization profit, and the expansion of R&D clinical activities. Among this, the profit from overseas products (including the gross profit from supplying overseas products and the profit from royalties based on sales) was approximately RMB93.9 million.
4. The Board does not recommend a final dividend for the Reporting Period.

BUSINESS HIGHLIGHTS:

As at the Latest Practicable Date, 10 products (40 indications) of the Group have been successfully approved for marketing in China, the United States, Europe, Canada, Australia, Indonesia, Mexico, Bolivia and other countries/regions, including 7 products approved for marketing in multiple overseas markets, covering approximately 60 countries/regions, benefiting over 1,000,000 patients around the world.

1 Forward-looking internationalization strategy to accelerate deepening of global markets:

HANSIZHUANG was approved for marketing in the EU (European trade name: Hetronifly®) and other countries, becoming the first anti-PD-1 monoclonal antibody approved in the EU for small-cell lung cancer

In January 2025, an additional indication of HANSIZHUANG was approved in Indonesia and Thailand for the treatment of squamous non-small cell lung cancer (sqNSCLC), respectively.

In February 2025, HANSIZHUANG (European trade name: Hetronifly®) in combination with carboplatin and etoposide for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) was approved for marketing in the EU.

During the Reporting Period, HANSIZHUANG was approved for marketing in the United Kingdom, Singapore, Malaysia, India and other countries for the treatment of extensive-stage small cell lung cancer (ES-SCLC).

As at the Latest Practicable Date, HANSIZHUANG has been approved for marketing in over 40 countries and regions and has been granted Orphan-drug Designations by drug regulatory authorities in the United States, the EU, Switzerland, the Republic of Korea and Mexico, respectively. It has also been included in the national reimbursement drug lists of seven EU member states.

Two products of HLX14 (denosumab injection) were approved in the United States and Europe (trade names in the United States and Europe: BILDYOS® and BILPREVDA®), respectively

HLX14 has successfully become the first “China-developed” denosumab to enter overseas markets. In the second half of 2025, the United States Food and Drug Administration (FDA), the European Commission (EC) and the UK Medicines and Healthcare products Regulatory Agency (MHRA) approved two products of HLX14, trade names in the United States and Europe: BILDYOS® and BILPREVDA®. BILDYOS® is indicated for osteoporosis and all other indications for which the reference products have been approved in the local market, while BILPREVDA® is indicated for cancer-related bone disease and all other indications for which the reference products have been approved in the local market, thereby broadening therapeutic options for an increasing aging population.

HLX11 (pertuzumab injection) was approved for marketing in the United States (US trade name: POHERDY®)

In November 2025, HLX11 was approved for marketing by the United States Food and Drug Administration (FDA) under the US trade name POHERDY®. It is indicated for the treatment of metastatic HER2 + breast cancer, the neo/adjuvant treatment of early-stage/locally advanced HER2 + breast cancer and all other indications for which the reference products have been approved in the local market. HLX11 has thus become the first and only pertuzumab biosimilar approved for marketing in the United States. In February 2026, HLX11 received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), which recommended approval of its marketing authorisation application (MAA).

HANQUYOU was launched in China, the United States and Europe (US trade name: HERCESSI™; European trade name: Zercepac®), and continued to expand its global commercial footprint

During the Reporting Period, HANQUYOU's international expansion continued on a steady trajectory, and new drug applications for different specifications of HANQUYOU were approved in Mexico and other countries/regions. Currently, HANQUYOU is approved for marketing in over 50 countries and regions, including the United States, Europe, Canada, Australia, etc.

Expanding the global commercial footprint through licensing-out

In February 2025, the Company entered into a license agreement with Dr. Reddy's Laboratories SA, pursuant to which the Company agreed to grant a license to commercialise a biosimilar of daratumumab HLX15 (recombinant anti-CD38 fully human monoclonal antibody injection) in the United States and agreed European region.

In April 2025, the Company entered into a license agreement with Alvogen Korea Co., Ltd., pursuant to which the Company agreed to grant a license to commercialise HANSIZHUANG (serplulimab injection) in the Republic of Korea.

In April and December 2025, the Company entered into a license agreement and an amendment agreement with Sandoz AG, respectively, for the commercialization of a biosimilar of ipilimumab HLX13 (recombinant anti-CTLA-4 fully human monoclonal antibody injection) in the United States, agreed European countries (42 European countries), Japan, Australia, and Canada.

In February 2026, the Company entered into a license agreement with Eisai Co., Ltd., pursuant to which the Company agreed to grant a license to commercialise HANSIZHUANG (serplulimab injection) in Japan.

In February 2026, the Company entered into an amendment agreement with Abbott Products Operations AG, pursuant to which the Company agreed to grant a further license to commercialise HANSIZHUANG (serplulimab injection) in the agreed regions covering Asia, the Middle East, Africa and Eastern Europe (42 countries/regions in total), including the Terminated Territories and other agreed countries or regions. In early 2026, the Company had separately reached termination arrangements with PT Kalbe Genexine Biologics and Fosun Industrial Co., Limited in connection with the commercialization rights of HANSIZHUANG (serplulimab injection) in the agreed Southeast Asian countries (excluding Indonesia), Middle Eastern and North African countries, Hong Kong and Macau regions of China.

2 Orientation toward clinical value and injecting impetus toward the pipeline:

The Group's early-stage R&D is centered around patient needs and guided by clinical value. Leveraging a new drug discovery platform driven by deep data-driven 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. During the Reporting Period, the Group also actively expanded its product pipeline through licensing-in. In June 2025, the Company entered into a license agreement with FBD Biologics Limited, pursuant to which the Company was granted the exclusive rights to develop, manufacture, and commercialize SIRP α -Fc fusion protein (the Company's product code: HLX701) within Chinese Mainland, Hong Kong and Macau regions, and specific countries in Southeast Asia. In December 2025, the Company entered into a project cooperation agreement with GeneQuantum Healthcare (Suzhou) Co., Ltd. (啟德醫藥科技(蘇州)有限公司), pursuant to which the Company obtained the development and exclusive commercialisation rights for the innovative HER2-targeted antibody-drug conjugate (ADC) GQ1005 (the Company's product code: HLX87) in China and specific overseas countries and regions. In December 2025, the Company entered into a project cooperation agreement with U-mab Biopharma (Lianyungang) Co., Ltd. (優邁生物科技(連雲港)有限公司), pursuant to which the Company was granted the global exclusive rights to develop, manufacture and commercialize a monoclonal antibody targeting interleukin-1 receptor accessory protein (IL-1R3) (the Company's product code: HLX109).

As of the Latest Practicable Date, the Group has built an R&D pipeline encompassing over 50 early-stage innovative assets and approximately 10 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.

- In January 2025, an investigational new drug application (IND) for a phase 1b/2 clinical trial of HLX43 for injection (antibody-drug conjugate targeting PD-L1) in combination with HANSIZHUANG (serplulimab injection) 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 an innovative small molecule HLX99 was approved by the United States Food and Drug Administration (FDA). HLX99 is intended for the treatment of amyotrophic lateral sclerosis (ALS).

- In March 2025, an investigational new drug application (IND) for a phase 2 clinical trial of HLX79 injection (human sialidase fusion protein) in combination with HANLIKANG (rituximab injection) for the treatment of active glomerulonephritis was approved by the NMPA.
- In September 2025, an investigational new drug application (IND) for a phase 1 clinical trial of a biosimilar of pembrolizumab HLX17 (recombinant humanised anti-PD-1 monoclonal antibody injection) in patients with various resected solid tumours was approved by the United States Food and Drug Administration (FDA).
- In September 2025, an investigational new drug application (IND) for a phase 1b/2 clinical trial of HLX43 for injection (antibody-drug conjugate targeting PD-L1) in combination with HLX07 (recombinant humanised anti-EGFR monoclonal antibody injection) for the treatment of advanced/metastatic solid tumours was approved by the NMPA.
- In November 2025, an investigational new drug application (IND) for a phase 1 clinical trial of HLX37 (recombinant humanised anti-PD-L1 and anti-VEGF bispecific antibody injection) in patients with advanced/metastatic solid tumours was approved by the NMPA.
- In December 2025, investigational new drug applications (IND) for phase 2/3 clinical trials of HLX22 (recombinant humanised anti-HER2 monoclonal antibody injection) in combination with HLX87 for injection (antibody-drug conjugate targeting HER2) (1) for first-line treatment of HER2-positive breast cancer (BC); and (2) for neoadjuvant treatment of HER2-positive breast cancer (BC neo) were approved by the NMPA, respectively.
- In December 2025 and March 2026, investigational new drug applications (IND) for a phase 1 clinical trial of nivolumab biosimilar HLX18 (recombinant anti-PD-1 humanized monoclonal antibody injection) for the treatment of multiple solid tumours were approved by the United States Food and Drug Administration (FDA) and the NMPA, respectively.
- In January 2026, an investigational new drug application (IND) for a phase 1b/2 clinical trial of HLX701 (recombinant human SIRP α -IgG4 Fc fusion protein injection) in combination with cetuximab and chemotherapy for the treatment of advanced colorectal cancer was approved by the NMPA.
- In January 2026, an investigational new drug application (IND) for HLX43 for injection (an anti-PD-L1 antibody-drug conjugate) in combination with HLX07 (recombinant anti-EGFR humanised monoclonal antibody injection) and HANSIZHUANG (serplulimab injection) for the treatment of advanced solid tumours was approved by the NMPA.
- In March 2026, an investigational new drug application (IND) for HLX97 (KAT6A/B small molecule Inhibitor) for a phase 1 clinical trial in patients with advanced or metastatic solid tumours was approved by the NMPA.

- In March 2026, an investigational new drug application (IND) for HLX3901 for injection (a tetra-specific antibody targeting dual epitopes of DLL3, CD3 and CD28) for a phase 1 clinical trial in patients with advanced/metastatic solid tumours was approved by the NMPA.
- In March 2026, an investigational new drug application (IND) for HLX316 for injection (B7-H3-targeting sialidase Fc fusion protein) for a phase 1 clinical trial in patients with advanced/metastatic solid tumours was approved by the NMPA.
- In January 2026, an investigational new drug application (IND) for a biosimilar of pertuzumab and trastuzumab HLX319 (pertuzumab and trastuzumab injection (subcutaneous injection)) for a phase 1 clinical trial was submitted to the NMPA and accepted in the same month.
- In March 2026, an investigational new drug application (IND) for HLX48 for injection (an antibody-drug conjugate targeting EGFR and c-MET) for a phase 1 clinical trial in patients with advanced/metastatic solid tumors was submitted to the NMPA and accepted in the same month.

3 Sustained and effective global development of clinical-stage products:

HLX43 for Injection (antibody-drug conjugate targeting PD-L1)

In January 2025, an investigational new drug application (IND) for the phase 1b/2 clinical trial of HLX43 in combination with HANSIZHUANG (serplulimab injection) for the treatment of patients with advanced/metastatic solid tumours was approved by the NMPA, and the first patient for the relevant clinical study was dosed in Chinese Mainland in April 2025.

In January 2025, the first patient was dosed in a phase 2 clinical study of HLX43 in patients with recurrent/metastatic esophageal squamous cell carcinoma (ESCC) in Chinese Mainland. During the Reporting Period, the Company commenced several phase 2 clinical trials of HLX43 for different indications in Chinese Mainland.

In June 2025, the first patient was dosed in an international multi-centre phase 2 clinical study of HLX43 in patients with advanced non-small cell lung cancer (NSCLC) in Chinese Mainland. During the Reporting Period, the first patient in the United States, the first patient in Australia and the first patient in Japan were dosed in such international multi-centre phase 2 clinical study, respectively.

In July and September 2025, an international multi-centre phase 1 clinical study of HLX43 for the treatment of thymic carcinoma (TC) was permitted to commence in the United States and Japan, respectively. The first patient in Japan was dosed in such international multi-centre phase 1 clinical study in March 2026.

In September 2025, an investigational new drug application (IND) for a phase 1b/2 clinical trial of HLX43 in combination with HLX07 (recombinant humanised anti-EGFR monoclonal antibody injection) for the treatment of advanced/metastatic solid tumours was approved by the NMPA. In February 2026, the first patient was dosed in a phase 1b/2 clinical study of HLX43 in combination with HLX07 (recombinant anti-EGFR humanised monoclonal antibody injection) or HANSIZHUANG (serplulimab injection) in patients with advanced or metastatic colorectal cancer in Chinese Mainland.

In October 2025, Orphan-drug Designation of HLX43 for the treatment of thymic epithelial tumours (TETs) was granted by the United States Food and Drug Administration (FDA).

HLX22 (recombinant humanised anti-HER2 monoclonal antibody injection)

In March and May 2025, Orphan-drug Designation of HLX22 for the treatment of gastric cancer (GC) were granted by the United States Food and Drug Administration (FDA) and the European Commission (EC), respectively.

In March, July and October 2025, the first patient in Japan, the first patients in the United States and the first patients in the EU were 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 HER2-positive, locally advanced or metastatic gastroesophageal junction cancer and gastric cancer, respectively. Such international multi-centre phase 3 clinical study is currently being conducted simultaneously in Chinese Mainland, the United States, the EU, Australia, Japan and other countries/regions.

In April 2025, the first patient was dosed in a phase 2 clinical study of HLX22 in combination with trastuzumab deruxtecan for the treatment of HER2-low, HR positive, locally advanced or metastatic breast cancer (BC) in Chinese Mainland.

In December 2025, an investigational new drug application (IND) for a phase 2/3 clinical trials of HLX22 in combination with HLX87 for injection (antibody-drug conjugate targeting HER2) for first-line treatment of HER2-positive breast cancer (BC) has been approved by the NMPA. The first patient was dosed in Chinese Mainland in February 2026.

HANSIZHUANG (serplulimab injection)

In January 2025, the recruitment of all subjects was completed in an international multi-centre 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.

In January 2025, HANSIZHUANG in combination with chemotherapy for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC) was approved for a bridging study in Japan. The first patient in this bridging study in Japan was dosed in June 2025. This bridging study will lay the groundwork for the subsequent new drug application of HANSIZHUANG in Japan.

In June 2025, the recruitment of all subjects was completed in an international multi-centre phase 3 clinical study of HANSIZHUANG in combination with bevacizumab injection and chemotherapy for the first-line treatment of metastatic colorectal cancer (mCRC).

In October 2025, the recruitment and enrollment of all subjects was completed in 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).

In September 2025, a phase 3 clinical trial of HANSIZHUANG in combination with chemotherapy for the neo/adjuvant treatment of gastric cancer met the primary study endpoint. HANSIZHUANG for this indication was officially granted the Breakthrough Therapy Designation by the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) in November 2025. The New Drug Application (NDA) for this indication was accepted by the NMPA in December 2025 and granted the procedure for priority review.

In March 2026, an investigational new drug application (IND) for clinical trial of HLX07 (recombinant anti-EGFR humanised monoclonal antibody injection) in combination with HANSIZHUANG and chemotherapy for the treatment of advanced squamous non-small cell lung cancer (sqNSCLC) was approved by the NMPA.

Other products

In March 2025, the marketing authorisation application (MAA) for a biosimilar of pertuzumab HLX11 (recombinant anti-HER2 domain II humanised monoclonal antibody injection) was accepted by the European Medicines Agency (EMA). In February 2026, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion recommending approval of its marketing authorisation application (MAA).

In April 2025, HLX04-O (recombinant anti-VEGF humanised monoclonal antibody injection) met its primary endpoints in a phase 3 clinical study for the treatment of wet age-related macular degeneration (wAMD) in Chinese patients. The new drug application (NDA) for this product in the treatment of wet age-related macular degeneration (wAMD) was accepted by the NMPA in August 2025.

In May 2025, the first patient was dosed in a phase 1/3 clinical study of a biosimilar of ipilimumab HLX13 (recombinant anti-CTLA-4 fully human monoclonal antibody injection) for the first-line treatment of patients with unresectable advanced hepatocellular carcinoma (HCC) in Chinese Mainland. In September 2025, an investigational new drug application (IND) for a phase 1 clinical trial of this product for the first-line treatment of patients with unresectable advanced hepatocellular carcinoma (HCC) was approved by the United States Food and Drug Administration (FDA). The first patient was dosed in the international multi-centre clinical study in Chinese Mainland in November 2025.

In September 2025, an investigational new drug application (IND) for a phase 1 clinical trial of a biosimilar of pembrolizumab HLX17 (recombinant humanised anti-PD-1 monoclonal antibody injection) in patients with various resected solid tumours was approved by the United States Food and Drug Administration (FDA). The first patient in such international multi-centre clinical study was dosed in Chinese Mainland in September 2025.

In November 2025, an investigational new drug application (IND) for a phase 1 clinical trial of HLX37 (recombinant humanised anti-PD-L1 and anti-VEGF bispecific antibody injection) in patients with advanced/metastatic solid tumours was approved by the National Medical Products Administration (NMPA). The first patient was dosed in such clinical study in Chinese Mainland in December 2025.

In December 2025, the New Drug Application (NDA) for a denosumab biosimilar HLX14 (recombinant anti-RANKL fully human monoclonal antibody injection) has been accepted by the NMPA.

In January 2026, an investigational new drug application (IND) for a phase 1b/2 clinical trial of HLX701 (recombinant human SIRP α -IgG4 Fc fusion protein injection) in combination with cetuximab and chemotherapy for the treatment of advanced colorectal cancer was approved by the NMPA.

In February 2026, an investigational new drug (IND) application for a phase 1 clinical trial of a biosimilar of daratumumab HLX15 (recombinant anti-CD38 fully human monoclonal antibody injection – subcutaneous injection) for the treatment of multiple myeloma were approved by the United States Food and Drug Administration (FDA) and the NMPA, respectively.

4 High-quality supply of products worldwide:

As a strong guarantee for the high-quality supply of products worldwide, the Group's biopharmaceutical industrialization base fully supplied markets in China, the United States, Europe, Latin America, Southeast Asia and India. In June 2025, production lines relating to HLX11 and HLX14 in Songjiang First Plant and Songjiang Second Plant have obtained the EU GMP certificates. During the Reporting Period, such production lines also successfully passed the FDA's pre-approval GMP inspections for HLX11 and HLX14. During the Reporting Period, all construction work for the third stage of the Phase I project of Songjiang Second Plant was completed, and the Phase I project achieved overall final acceptance in August 2025.

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 "**Hong Kong Stock Exchange**") and the Company.

PRODUCT PORTFOLIO AND PIPELINE



- Innovative mAb
- Innovative fusion protein
- Innovative multi-specific antibody
- Innovative ADC
- Small molecule
- Biosimilar mAb

- Bridging study in U.S.
- BLA under FDA review
- Global MRCT
- MAA under EMA review
- Approved in global markets

- (1) Approved in 40+ countries, including China, the UK, Germany, India, Singapore, trade name: Heterofilly® in Europe. Business partners: KCBio/ Fousun Pharma/ Intas/ Lotus/ Abbott/ Eisai.
- (2) Approved in China and multiple Latin American countries. The first biosimilar approved in China. Business partners: Fousun Pharma/ Eurofarma/ Abbott/ Boston Oncology.
- (3) The first rituximab approved for the indication in China.
- (4) Approved in 60 countries, including China, U.S., the UK, Germany, France and Australia, trade name in U.S.: HERCESS™. Trade name in Europe: Zerospac®. Business partners: Azzord/ Ethal/ Eurofarma/ Abbott/ KCBio/ Getz Pharma.
- (5) Business partners: Fousun Wanbang/ Getz Pharma.
- (6) Approved in China and multiple Latin American countries. Business partners: Eurofarma.
- (7) Approved in the U.S. and the EU. Trade name: BILDYOS®, BILPREVDA® in the U.S. and the EU. Marketing applications are under review in China. Business partner: Organon.
- (8) Approved in the U.S. Trade name: POHERDY® in the U.S. Marketing applications are under review in the EU, Canada and China. Business partner: Organon.
- (9) Commercialization in China
- (10) NDA under review in China. Business partner: Essex.
- (11) IND approvals obtained in China/the U.S./Japan/the EU.
- (12) The development and exclusive commercialization rights obtained in China and select ex-China markets.
- (13) Exclusive license obtained in China. Phase 3 MRCT enrolling globally. IND approval obtained in China.
- (14) IND approvals obtained in China/the U.S.
- (15) IND approvals obtained in China/the U.S./Japan/Australia.
- (16) Exclusive license obtained in China.
- (17) Exclusive rights in China (excl. Taiwan), several countries in Southeast Asia, and other selected countries and regions; Phase 1b/2a conducting in countries such as China and the U.S.
- (18) Business partner: Shanghai Jingzuo.
- (19) IND approvals obtained in China/the U.S. Business partner: Dr. Reddy's, etc.
- (20) Business partner: Sanzoo, etc.

HANSZHUANG, 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. The Group has successfully realised the “Closed-loop Internationalisation 1.0” and is accelerating toward the “Globalisation 2.0 Era”. During the Reporting Period, while consolidating its traditional strongholds in the United States and Europe, the Group deepened its presence in emerging regions with high growth potential such as Southeast Asia and Latin America. It continues to build global localization operation capabilities spanning clinical operations, drug regulatory registration, and other functions, enabling efficient global product launches and sustaining the upward trajectory of international profitability.

As of 19 March 2026, being the latest practicable date (the “**Latest Practicable Date**”) for the publication of this announcement, 10 products (40 indications) of the Group have been successfully approved for marketing in China, the United States, Europe, Canada, Australia, Indonesia, Mexico, Bolivia and other countries/regions, including 7 products approved for marketing in multiple overseas markets, covering approximately 60 countries/regions, benefiting over 1,000,000 patients around the world. From the beginning of 2025 to date, the Group’s “Go Global” initiatives have yielded fruitful results. In February 2025, HANSIZHUANG in combination with chemotherapy was approved for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) in the European Union (the “EU”), becoming the Group’s second product approved in the EU for marketing, which has proven the recognition of international mainstream markets on the Group’s innovative products. In August and September 2025, the United States Food and Drug Administration (FDA) and the European Commission (EC) approved two products of HLX14, trade names in the United States and Europe: BILDYOS® and BILPREVDA®. The approved indications cover all indications for which the reference products have been approved in the local market. In November 2025, HLX11 (US trade name: POHERDY®) was approved for marketing in the United States for the neo/adjuvant treatment of HER2-positive early-stage breast cancer and the treatment of metastatic breast cancer, thus becoming the first and only approved pertuzumab biosimilar in the United States. In January 2026, the Biologics License Application (BLA) for HANBEITAI was accepted by the United States Food and Drug Administration (FDA), further demonstrating the Company’s outstanding capabilities in international registration and quality management.

(I) Accelerating deep international reach through world-class operations

Guided by its globalization strategy, the Group forged several new partnerships with internationally renowned companies during the Reporting Period, further expanding its global footprint. Meanwhile, the well-trained and mature global drug regulatory registration team collaborates closely with global clinical-operations and medical teams to advance the development process of pipeline products both at home and abroad. During the Reporting Period, the Group achieved 27 investigational new drug application (IND) approvals and 28 new drug application (NDA) approvals spanning approximately 66 countries/regions, including China, the United States, Europe, Japan and Canada. As at the Latest Practicable Date, the in-house clinical-operations teams in China, the United States, and Australia, etc. were orderly advancing clinical studies in nearly 30 countries/regions.

1. Expanding the global commercial footprint through licensing-out

During the Reporting Period, the Group entered into several new agreements with leading international partners and continued to advance the commercial roll-out of existing overseas collaborations.

- In February 2025, the Company entered into a license agreement with Dr. Reddy's Laboratories SA, pursuant to which the Company agreed to grant a license to commercialise a biosimilar of daratumumab HLX15 (recombinant anti-CD38 fully human monoclonal antibody injection) in the United States and agreed European region.
- In April 2025, the Company entered into a license agreement with Alvogen Korea Co., Ltd., pursuant to which the Company agreed to grant a license to commercialise HANSIZHUANG (serplulimab injection) in the Republic of Korea.
- In April and December 2025, the Company entered into a license agreement and an amendment agreement with Sandoz AG, respectively, for the commercialization of a biosimilar of ipilimumab HLX13 (recombinant anti-CTLA-4 fully human monoclonal antibody injection) in the United States, agreed European countries (42 European countries), Japan, Australia and Canada.
- In February 2026, the Company entered into a license agreement with Eisai Co., Ltd., pursuant to which the Company agreed to grant a license to commercialise HANSIZHUANG (serplulimab injection) in Japan.
- In February 2026, the Company entered into an amendment agreement with Abbott Products Operations AG, pursuant to which the Company agreed to grant a further license to commercialise HANSIZHUANG (serplulimab injection) in the agreed regions covering Asia, the Middle East, Africa and Eastern Europe (42 countries/regions in total), including the Terminated Territories (as defined below) and other agreed countries or regions. In early 2026, the Company had separately reached termination arrangements with PT Kalbe Genexine Biologics and Fosun Industrial Co., Limited in connection with the commercialization rights of HANSIZHUANG (serplulimab injection) in the agreed Southeast Asian countries (excluding Indonesia), Middle Eastern and North African countries, Hong Kong and Macau regions of China (the "**Terminated Territories**").

Meanwhile, based on the actual progress of the projects, the Group reached termination agreements with FARMA DE COLOMBIA S.A.S and Cipla Limited in August 2025 and February 2026, respectively, regarding the previous commercialization collaborations for HANLIKANG and HANQUYOU in Colombia, Peru, Australia, New Zealand and other markets. The Group will continue to explore collaboration opportunities for these products in international markets to further optimize the regional partnership layout of the Group's products.

2. Globalisation strategy delivers strong results as overseas launches accelerate

HANSIZHUANG was approved for marketing in the EU (European trade name: Hetronifly®) and other countries, becoming the first anti-PD-1 monoclonal antibody approved in the EU for small-cell lung cancer

With its excellent efficacy and data quality, HANSIZHUANG has been widely acknowledged in the international market. As its license-out areas comprehensively cover over 100 countries and regions across the United States, Europe, Asia and emerging markets, the international commercialisation has been carried out in an orderly manner. During the Reporting Period, HANSIZHUANG has accelerated its commercialisation in international markets:

- In January 2025, an additional indication of HANSIZHUANG was approved in Indonesia and Thailand for the treatment of squamous non-small cell lung cancer (sqNSCLC), respectively.
- In February 2025, HANSIZHUANG (European trade name: Hetronifly®) in combination with carboplatin and etoposide for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) was approved for marketing in the EU.
- During the Reporting Period, HANSIZHUANG was approved for marketing in the United Kingdom, Singapore, Malaysia, India and other countries for the treatment of extensive-stage small cell lung cancer (ES-SCLC).

As at the Latest Practicable Date, HANSIZHUANG has been approved for marketing in over 40 countries and regions and has been granted Orphan-drug Designations by drug regulatory authorities in the United States, the EU, Switzerland, the Republic of Korea and Mexico, respectively. It has also been included in the national reimbursement drug lists of seven EU member states.

Two products of HLX14 (denosumab injection) were approved in the United States and Europe (trade names in the United States and Europe: BILDYOS® and BILPREVDA®), respectively

HLX14 has successfully become the first “China-developed” denosumab to enter overseas markets. In the second half of 2025, the United States Food and Drug Administration (FDA), the European Commission (EC) and the UK Medicines and Healthcare products Regulatory Agency (MHRA) approved two products of HLX14, trade names in the United States and Europe: BILDYOS® and BILPREVDA®. BILDYOS® is indicated for osteoporosis and all other indications for which the reference products have been approved in the local market, while BILPREVDA® is indicated for cancer-related bone disease and all other indications for which the reference products have been approved in the local market, thereby broadening therapeutic options for an increasing aging population.

HLX11 (pertuzumab injection) was approved for marketing in the United States (US trade name: POHERDY®)

In November 2025, HLX11 was approved for marketing by the United States Food and Drug Administration (FDA) under the US trade name POHERDY®. It is indicated for the treatment of metastatic HER2 + breast cancer, the neo/adjuvant treatment of early-stage or locally advanced HER2 + breast cancer and all other indications for which the reference products have been approved in the local market. HLX11 has thus become the first and only approved pertuzumab biosimilar in the United States. In February 2026, HLX11 received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), which recommended approval of its marketing authorisation application (MAA). In early 2026, the Company, together with Organon, its global partner of POHERDY®, reached settlement with the originator of pertuzumab. The product is licensed to be launched on a country-by-country basis in the licensed territory as of the agreed-upon launch dates.

HANQUYOU was launched in China, the United States and Europe (US trade name: HERCESSI™; European trade name: Zercepac®), and continued to expand its global commercial footprint

During the Reporting Period, HANQUYOU's international expansion continued on a steady trajectory, and new drug applications for different specifications of HANQUYOU were approved in Mexico and other countries/regions. With its high international quality standards, HANQUYOU has been approved for marketing in over 50 countries and regions (including the United States, Europe, Canada, Australia, etc.). Furthermore, the Group 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 HANQUYOU's market share in Europe, the United States, Canada, and other regions, as well as many emerging markets at the country level, covering over approximately 100 countries/regions around the world.

Core products such as HANBEITAI also landed on the international stage

During the Reporting Period, HANBEITAI was approved for marketing in Mexico and the Dominican Republic. In January 2026, the Biologics License Application (BLA) for HANBEITAI was accepted by the United States Food and Drug Administration (FDA). The Group will also work closely with partners such as Abbott, Eurofarma, Boston Oncology, LLC and Getz Pharma to continuously promote the launch of HANLIKANG, HANDAYUAN and HANBEITAI in the international market.

3. *High-quality supply of products worldwide*

As at the end of the Reporting Period, the Group's industrialisation base for biologics is fully supporting the worldwide supply of all approved products.

- The Xuhui Facility of the Group has achieved routine commercial shipments to global markets, now covering China, Europe, Latin America, Southeast Asia, India and beyond. During the Reporting Period, the Xuhui Facility underwent a pre-marketing GMP inspection by the Ministry of Food and Drug Safety (MFDS) of Korea in relation to the marketing of HANSIZHUANG in the Republic of Korea. In addition, during the Reporting Period, the Facility 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).
- Songjiang First Plant of the Group in Songjiang District, Shanghai has obtained the Chinese, US and EU GMP certificates. In June 2025, the Group was awarded the Certificate of GMP Compliance of a Manufacturer (EU GMP Certificate) by the Federal Agency for Medicines and Health Products of Belgium, confirming that the HLX11 and HLX14-related production lines at Songjiang First Plant meet EU GMP standards. During the Reporting Period, such production lines also successfully passed pre-approval GMP inspections by the United States Food and Drug Administration (FDA) for HLX11 and HLX14. During the Reporting Period, the Plant completed the first commercial shipment of HLX14 to Europe, thereby creating conditions for its commercial launch in Europe. During the Reporting Period, Songjiang First Plant underwent pre-approval GMP inspections by the Shanghai Medical Products Administration for HLX11 and HLX04-O as well as the pre-marketing GMP inspection by the Ministry of Food and Drug Safety (MFDS) of Korea in relation to the marketing of HANSIZHUANG in the Republic of Korea. In addition, during the Reporting Period, the Facility 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 totals 36,000L. The installation, commissioning and verification of equipment in two main production buildings including production lines of drug substances and drug products and the Prefilled Syringes System (PFS) have been completed, while the commissioning and verification work of the remaining production lines will also be implemented in order according to production requirements. During the Reporting Period, all construction work for the third stage of the Phase I project of Songjiang Second Plant was completed, and the Phase I project achieved overall final acceptance in August 2025. In June 2025, the Group was awarded the Certificate of GMP Compliance of a Manufacturer (EU GMP Certificate) by the Federal Agency for Medicines and Health Products of Belgium, confirming that the HLX14-related production lines at Songjiang Second Plant meet EU GMP standards. Such production lines also successfully passed the pre-approval GMP inspection by the United States Food and Drug Administration (FDA) for HLX14.

(II) Driving innovation: from early R&D to global clinical development

1. Orientation toward clinical value and injecting impetus toward the pipeline

The Group’s early-stage R&D is centered around patient needs and guided by clinical value. Leveraging a new drug discovery platform driven by deep data-driven 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. By deeply integrating artificial intelligence (AI) with biological data, the Group’s HAI Club platform accelerates the identification of novel drug targets, leading to demonstrably higher drug discovery efficiency. By effectively harnessing the synergy across its multi-faceted early-stage R&D technology platforms, the Group has effectively accelerated the development of innovative drug candidates. This approach has established a robust technical foundation and pipeline reserve, enabling the Group to continuously address unmet clinical needs.

During the Reporting Period, the Group also actively expanded its product pipeline through licensing-in. In June 2025, the Company entered into a license agreement with FBD Biologics Limited, pursuant to which the Company was granted the exclusive rights to develop, manufacture, and commercialize SIRP α -Fc fusion protein (the Company's product code: HLX701) within Chinese Mainland, Hong Kong and Macau regions, and specific countries in Southeast Asia. In December 2025, the Company entered into a project cooperation agreement with GeneQuantum Healthcare (Suzhou) Co., Ltd. (啟德醫藥科技(蘇州)有限公司), pursuant to which the Company obtained the development and exclusive commercialisation rights for the innovative HER2-targeted antibody-drug conjugate (ADC) GQ1005 (the Company's product code: HLX87) in China and specific overseas countries and regions. In December 2025, the Company entered into a project cooperation agreement with U-mab Biopharma (Lianyungang) Co., Ltd. (優邁生物科技(連雲港)有限公司), pursuant to which the Company was granted the global exclusive rights to develop, manufacture and commercialize a monoclonal antibody targeting interleukin-1 receptor accessory protein (IL-1R3) (the Company's product code: HLX109).

As of the Latest Practicable Date, the Group has built an R&D pipeline encompassing over 50 early-stage innovative assets and approximately 10 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.

The Group has also actively promoted the conversion of assets from the early-stage to the clinical stage. This effort resulted in successful investigational new drug applications (IND) approvals and the initiation of clinical trials, from January 2025 to date, for the PD-L1-targeted ADC + PD-1 project, the human sialidase fusion protein + CD20, PD-1, PD-L1 \times VEGF and HER2+HER2 ADC programmes.

- In January 2025, an investigational new drug application (IND) for a phase 1b/2 clinical trial of HLX43 for injection (antibody-drug conjugate targeting PD-L1) in combination with HANSIZHUANG (serplulimab injection) for the treatment of patients with advanced/metastatic solid tumours was approved by the National Medical Products Administration (the "NMPA").
- In February 2025, an investigational new drug application (IND) for an innovative small molecule HLX99 was approved by the United States Food and Drug Administration (FDA). HLX99 is intended for the treatment of amyotrophic lateral sclerosis (ALS).
- In March 2025, an investigational new drug application (IND) for a phase 2 clinical trial of HLX79 injection (human sialidase fusion protein) in combination with HANLIKANG (rituximab injection) for the treatment of active glomerulonephritis was approved by the NMPA.

- In September 2025, an investigational new drug application (IND) for a phase 1 clinical trial of a biosimilar of pembrolizumab HLX17 (recombinant humanised anti-PD-1 monoclonal antibody injection) in patients with various resected solid tumours was approved by the United States Food and Drug Administration (FDA).
- In September 2025, an investigational new drug application (IND) for a phase 1b/2 clinical trial of HLX43 for injection (antibody-drug conjugate targeting PD-L1) in combination with HLX07 (recombinant humanised anti-EGFR monoclonal antibody injection) for the treatment of advanced/metastatic solid tumours was approved by the NMPA.
- In November 2025, an investigational new drug application (IND) for a phase 1 clinical trial of HLX37 (recombinant humanised anti-PD-L1 and anti-VEGF bispecific antibody injection) in patients with advanced/metastatic solid tumours was approved by the NMPA.
- In December 2025, investigational new drug applications (IND) for phase 2/3 clinical trials of HLX22 (recombinant humanised anti-HER2 monoclonal antibody injection) in combination with HLX87 for injection (antibody-drug conjugate targeting HER2) for first-line treatment of HER2-positive breast cancer (BC) and for neoadjuvant treatment for HER2-positive breast cancer (BC neo) were approved by the NMPA, respectively.
- In December 2025 and March 2026, investigational new drug applications (IND) for a phase 1 clinical trial of nivolumab biosimilar HLX18 (recombinant anti-PD-1 humanized monoclonal antibody injection) for the treatment of multiple solid tumours were approved by the United States Food and Drug Administration (FDA) and the NMPA, respectively.
- In January 2026, an investigational new drug application (IND) for a phase 1b/2 clinical trial of HLX701 (recombinant human SIRP α -IgG4 Fc fusion protein injection) in combination with cetuximab and chemotherapy for the treatment of advanced colorectal cancer was approved by the NMPA.
- In January 2026, an investigational new drug application (IND) for HLX43 for injection (an anti-PD-L1 antibody-drug conjugate) in combination with HLX07 (recombinant anti-EGFR humanised monoclonal antibody injection) and HANSIZHUANG (serplulimab injection) for the treatment of advanced solid tumours was approved by the NMPA.
- In March 2026, an investigational new drug application (IND) for HLX97 (KAT6A/B small molecule Inhibitor) for a phase 1 clinical trial in patients with advanced or metastatic solid tumours was approved by the NMPA.

- In March 2026, an investigational new drug application (IND) for HLX3901 for injection (a tetra-specific antibody targeting dual epitopes of DLL3, CD3 and CD28) for a phase 1 clinical trial in patients with advanced/metastatic solid tumours was approved by the NMPA.
- In March 2026, an investigational new drug application (IND) for HLX316 for injection (B7-H3-targeting sialidase Fc fusion protein) for a phase 1 clinical trial in patients with advanced/metastatic solid tumours was approved by the NMPA.
- In January 2026, an investigational new drug application (IND) for a biosimilar of pertuzumab and trastuzumab HLX319 (pertuzumab and trastuzumab injection (subcutaneous injection)) for a phase 1 clinical trial was submitted to the NMPA and accepted in the same month.
- In March 2026, an investigational new drug application (IND) for HLX48 for injection (an antibody-drug conjugate targeting EGFR and c-MET) for a phase 1 clinical trial in patients with advanced/metastatic solid tumors was submitted to the NMPA and accepted in the same month.

2. Sustained and effective global development of clinical-stage products

Addressing unmet clinical needs, the Group strategically planned and advanced the global clinical development of its pipeline products. During the Reporting Period, the progress was further promoted in clinical trials for innovative products, including HLX43 (PD-L1 ADC), HLX22 (HER2), HANSIZHUANG (PD-1), HLX79 (human sialidase fusion protein), HLX04-O (VEGF), HLX37 (PD-L1×VEGF), and HLX87 (HER2 ADC), for a range of indications, such as solid tumours, esophageal squamous cell carcinoma (ESCC), non-small cell lung cancer (NSCLC), thymic carcinoma (TC), gastric cancer (GC), breast cancer (BC), small cell lung cancer (SCLC), glomerulonephritis, wet age-related macular degeneration (wAMD), hepatocellular carcinoma (HCC), and metastatic colorectal cancer (mCRC). As at the Latest Practicable Date, the Group is actively conducting more than 30 clinical trials in numerous countries/regions worldwide.

HLX43 for Injection (antibody-drug conjugate targeting PD-L1)

- In January 2025, an investigational new drug application (IND) for the phase 1b/2 clinical trial of HLX43 in combination with HANSIZHUANG (serplulimab injection) for the treatment of patients with advanced/metastatic solid tumours was approved by the NMPA, and the first patient for the relevant clinical study was dosed in Chinese Mainland in April 2025.
- In January 2025, the first patient was dosed in a phase 2 clinical study of HLX43 in patients with recurrent/metastatic esophageal squamous cell carcinoma (ESCC) in Chinese Mainland. During the Reporting Period, the Company commenced several phase 2 clinical trials of HLX43 for different indications in Chinese Mainland.

- In June 2025, the first patient in Chinese Mainland was dosed in an international multi-centre phase 2 clinical study of HLX43 in patients with advanced non-small cell lung cancer (NSCLC). During the Reporting Period, the first patient in the United States, the first patient in Australia and the first patient in Japan were dosed in such international multi-centre phase 2 clinical study, respectively.
- In July and September 2025, an international multi-centre phase 1 clinical study of HLX43 for the treatment of thymic carcinoma (TC) was permitted to commence in the United States and Japan, respectively. The first patient in Japan was dosed in such international multi-centre phase 1 clinical study in March 2026.
- In September 2025, an investigational new drug application (IND) for a phase 1b/2 clinical trial of HLX43 in combination with HLX07 (recombinant humanised anti-EGFR monoclonal antibody injection) for the treatment of advanced/metastatic solid tumours was approved by the NMPA. In February 2026, the first patient was dosed in a phase 1b/2 clinical study of HLX43 in combination with HLX07 (recombinant anti-EGFR humanised monoclonal antibody injection) or HANSIZHUANG (serplulimab injection) in patients with advanced or metastatic colorectal cancer in Chinese Mainland.
- In October 2025, Orphan-drug Designation of HLX43 for the treatment of thymic epithelial tumours (TETs) was granted by the United States Food and Drug Administration (FDA).

During the Reporting Period, the results from the phase 1 clinical trial of HLX43 were released at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting and the 2025 World Conference on Lung Cancer (WCLC), demonstrating good safety and encouraging preliminary efficacy in several solid tumours especially in patients with non-small cell lung cancer (NSCLC). The findings identified HLX43 as a biomarker-independent antibody-drug conjugate (ADC) with immuno-oncology (IO) activity, enabling broad patient coverage. Notably, in patients with NSCLC who had progressed after standard therapy (median number of lines of treatment ≥ 3), HLX43 continued to show a promising response rate and good safety characteristics. Investigator-assessed objective response rate (ORR) was 37.0%, and disease control rate (DCR) was 87.0%. In addition, the results from the phase 2 clinical trial of HLX43 in recurrent/metastatic cervical cancer (CC) were first presented in the Proffered Paper Session at the 2025 European Society for Medical Oncology (ESMO) Asia Congress. The data demonstrated that in patients with recurrent/advanced cervical cancer (CC) who had previously failed, intolerant to, or contraindicated for standard first-line therapy, HLX43 showed good safety characteristics and exhibited compelling preliminary efficacy. Investigator-assessed ORR was 41.4% in total population and reached 70% in 3.0 mg/kg dose group. The results of a phase 2 clinical trial of HLX43 in recurrent/metastatic esophageal squamous cell carcinoma (ESCC) were first presented at the 2026 American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium. The data demonstrated that in patients with recurrent/advanced ESCC who had failed or were intolerable to standard first-line therapy, HLX43 showed good safety profiles and exhibited promising preliminary efficacy. Investigator-assessed ORR was 30.3% in total population and reached 61.5% in 3.0 mg/kg dose group.

HLX22 (recombinant humanised anti-HER2 monoclonal antibody injection)

- In March and May 2025, Orphan-drug Designation of HLX22 for the treatment of gastric cancer (GC) were granted by the United States Food and Drug Administration (FDA) and the European Commission (EC), respectively.
- In March, July and October 2025, the first patient in Japan, the first patient in the United States and the first patient in the EU were 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 HER2-positive, locally advanced or metastatic gastroesophageal junction cancer and gastric cancer, respectively. Such international multi-centre phase 3 clinical study is currently being conducted simultaneously in Chinese Mainland, the United States, the EU, Australia, Japan and other countries/regions.
- In April 2025, the first patient was dosed in a phase 2 clinical study of HLX22 in combination with trastuzumab deruxtecan for the treatment of HER2-low, HR positive, locally advanced or metastatic breast cancer (BC) in Chinese Mainland.
- In December 2025, an investigational new drug application (IND) for a phase 2/3 clinical trials of HLX22 in combination with HLX87 for injection (antibody-drug conjugate targeting HER2) for first-line treatment of HER2-positive breast cancer (BC) has been approved by the NMPA. The first patient in Chinese Mainland was dosed in February 2026.

During the Reporting Period, updated results from a phase 2 clinical study evaluating HLX22 in combination with trastuzumab and chemotherapy as the first-line treatment of HER2-positive gastric cancer were presented at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting. The median follow-up for the HLX22 + trastuzumab + chemotherapy group and the placebo + trastuzumab + chemotherapy group was 28.5 months and 28.7 months, respectively. According to Independent Radiology Review Committee (IRRC) assessments, the progression-free survival (PFS) for the two groups was NR (95% CI: 16.2, NE) versus 8.3 (95% CI: 5.7, 21.4). The HLX22 group showed significant benefit compared to the control group (HR 0.2 95% CI 0.09, 0.54). Safety profiles were comparable between the two groups. These updated findings further confirm the remarkable clinical benefits achieved with HLX22 in combination with trastuzumab and chemotherapy for patients with HER2-positive gastric/gastroesophageal junction cancer (G/GEJC), along with a manageable safety profile.

HANSIZHUANG (serplulimab injection)

- In January 2025, the recruitment of all subjects was completed in an international multi – centre 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.
- In January 2025, HANSIZHUANG in combination with chemotherapy for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC) was approved for a bridging study in Japan. The first patient in this bridging study in Japan was dosed in June 2025. This bridging study will lay the groundwork for the subsequent new drug application of HANSIZHUANG in Japan.
- In June 2025, the recruitment of all subjects was completed in an international multi-centre phase 3 clinical study of HANSIZHUANG in combination with bevacizumab injection and chemotherapy for the first-line treatment of metastatic colorectal cancer (mCRC).
- In September 2025, a phase 3 clinical trial of HANSIZHUANG in combination with chemotherapy for the neo/adjuvant treatment of gastric cancer met the primary study endpoint. HANSIZHUANG for this indication was officially granted the Breakthrough Therapy Designation by the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) in November 2025. The New Drug Application (NDA) for this indication was accepted by the NMPA in December 2025 and granted the procedure for priority review.
- In October 2025, the recruitment and enrollment of all subjects were completed in 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).
- In March 2026, an investigational new drug application (IND) for clinical trial of HLX07 (recombinant anti-EGFR humanised monoclonal antibody injection) in combination with HANSIZHUANG and chemotherapy for the treatment of advanced squamous non-small cell lung cancer (sqNSCLC) was approved by the NMPA.

During the Reporting Period, over ten new study results regarding HANSIZHUANG were presented in various forms at different conferences. In particular, the phase 2 data from the phase 2/3 clinical trial of HANSIZHUANG in combination with bevacizumab and chemotherapy for the first-line treatment of metastatic colorectal cancer (mCRC) were presented at the 2025 American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO GI). As of the data cutoff date (30 June 2024), with a median follow-up of 31.0 months, the HANSIZHUANG in combination with bevacizumab and chemotherapy group (Group A) showed sustained improvements in PFS (16.6 vs. 10.7 months, HR 0.66, 95% CI 0.37-1.19) and DOR (17.7 vs. 11.3 months, HR 0.45, 95% CI 0.20-0.98) compared to the placebo in combination with bevacizumab and chemotherapy group (Group B). The addition of serplulimab to bevacizumab and XELOX for the first-line treatment of mCRC patients (including MSS patients) demonstrated survival benefits with manageable safety. This regimen has the potential to become the first-line treatment option for metastatic colorectal cancer (mCRC). During the Reporting Period, two additional latest study results regarding HANSIZHUANG in the field of gastric cancer were selected for the 16th International Gastric Cancer Congress (IGCC 2025). Specifically, the latest results of the phase 2 study of HANSIZHUANG in neoadjuvant chemoradiation therapy for adenocarcinoma of the gastroesophageal junction were presented in an oral report format. At the 2026 American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO GI), the results of two neoadjuvant studies of HANSIZHUANG in the field of MSS/pMMR locally advanced colon/rectal cancer were officially released in the form of posters, further highlighting the therapeutic potential of HANSIZHUANG in the field of gastrointestinal cancers.

Other products

- In March 2025, the marketing authorisation application (MAA) for a biosimilar of pertuzumab HLX11 (recombinant anti-HER2 domain II humanised monoclonal antibody injection) was accepted by the European Medicines Agency (EMA). In February 2026, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion recommending approval of its marketing authorisation application (MAA).
- In March 2025, an investigational new drug application (IND) for a phase 2 clinical trial of HLX79 injection (human sialidase fusion protein) in combination with HANLIKANG (rituximab injection) for the treatment of active glomerulonephritis was approved by the NMPA. The first patient in Chinese Mainland has been dosed in the clinical study in August 2025.
- In April 2025, HLX04-O (recombinant anti-VEGF humanised monoclonal antibody injection) met its primary endpoints in a phase 3 clinical study for the treatment of wet age-related macular degeneration (wAMD) in Chinese patients. The new drug application (NDA) for this product in the treatment of wet age-related macular degeneration (wAMD) was accepted by the NMPA in August 2025.

- In May 2025, the first patient was dosed in a phase 1/3 clinical study of a biosimilar of ipilimumab HLX13 (recombinant anti-CTLA-4 fully human monoclonal antibody injection) for the first-line treatment of patients with unresectable advanced hepatocellular carcinoma (HCC) in Chinese Mainland. In September 2025, an investigational new drug application (IND) for a phase 1 clinical trial of this product for the first-line treatment of patients with unresectable advanced hepatocellular carcinoma (HCC) was approved by the United States Food and Drug Administration (FDA). The first patient was dosed in the international multi-centre clinical study in Chinese Mainland in November 2025.
- In September 2025, an investigational new drug application (IND) for a phase 1 clinical trial of a biosimilar of pembrolizumab HLX17 (recombinant humanised anti-PD-1 monoclonal antibody injection) in patients with various resected solid tumours was approved by the United States Food and Drug Administration (FDA). The first patient in such international multi-centre clinical study was dosed in Chinese Mainland in September 2025.
- In November 2025, an investigational new drug application (IND) for a phase 1 clinical trial of HLX37 (recombinant humanised anti-PD-L1 and anti-VEGF bispecific antibody injection) in patients with advanced/metastatic solid tumours was approved by the National Medical Products Administration (NMPA). The first patient was dosed in such clinical study in Chinese Mainland in December 2025.
- In December 2025, the New Drug Application (NDA) for a denosumab biosimilar HLX14 (recombinant anti-RANKL fully human monoclonal antibody injection) has been accepted by the NMPA.
- In January 2026, an investigational new drug application (IND) for a phase 1b/2 clinical trial of HLX701 (recombinant human SIRP α -IgG4 Fc fusion protein injection) in combination with cetuximab and chemotherapy for the treatment of advanced colorectal cancer was approved by the NMPA.
- In February 2026, investigational new drug (IND) applications for a phase 1 clinical trial of a biosimilar of daratumumab HLX15 (recombinant anti-CD38 fully human monoclonal antibody injection – subcutaneous injection) for the treatment of multiple myeloma were approved by the United States Food and Drug Administration (FDA) and the NMPA, respectively.

The clinical and pre-clinical application results of the Group's products from the beginning of 2025 up to the Latest Practicable Date:

Product name (targets)	Indications	Progress as of the Latest Practicable Date
Continuous and efficient advancement of clinical research product		
Global development progress of HLX43 for injection (antibody-drug conjugate targeting PD-L1)		
HLX43 (PD-L1 ADC)	Advanced non-small cell lung cancer (NSCLC)	<p>In June 2025, the first patient was dosed in an international multi-centre phase 2 clinical study in Chinese Mainland</p> <p>In June 2025, the international multi-centre phase 2 clinical study was permitted to commence in Australia</p> <p>In July 2025, the international multi-centre phase 2 clinical study was permitted to commence in Japan</p> <p>In August 2025, the first patient in the United States was dosed in an international multi-centre phase 2 clinical study</p> <p>In September 2025, the first patient in Australia was dosed in an international multi-centre phase 2 clinical study</p> <p>In November 2025, the first patient in Japan was dosed in an international multi-centre phase 2 clinical study</p>
HLX43 (PD-L1 ADC)	Solid tumour (including thymic carcinoma (TC))	<p>In July 2025, the international multi-centre phase 1 clinical study for the treatment of thymic carcinoma (TC) was permitted to commence in the United States</p> <p>In September 2025, the international multi-centre phase 1 clinical study for the treatment of thymic carcinoma (TC) was permitted to commence in the Japan</p> <p>In March 2026, the first patient in Japan was dosed in an international multi-centre phase 1 clinical study</p>
HLX43 (PD-L1 ADC)	Solid tumour (including esophageal squamous cell carcinoma (ESCC))	<p>In January 2025, the first patient was dosed in a phase 2 clinical study for the treatment of recurrent/metastatic esophageal squamous cell carcinoma in Chinese Mainland</p> <p>During the Reporting Period, the Company has initiated several phase 2 clinical studies for different indications in Chinese Mainland</p>

Product name (targets)	Indications	Progress as of the Latest Practicable Date
HLX43 (PD-L1 ADC)	Thymic epithelial tumours (TETs)	In October 2025, Orphan-Drug Designation (ODD) was granted by the FDA
HLX43 in combination with HANSIZHUANG (PD-L1 ADC+PD-1)	Solid tumour	In January 2025, an investigational new drug application (IND) for the phase 1b/2 clinical trial was approved by the NMPA In April 2025, the first patient was dosed in a phase 1b/2 clinical study in Chinese Mainland
HLX43 in combination with HLX07 (PD-L1 ADC+EGFR)	Solid tumour (including metastatic colorectal cancer (mCRC))	In September 2025, an investigational new drug application (IND) for the phase 1b/2 clinical trial was approved by the NMPA In February 2026, the first patient was dosed in a phase 1b/2 clinical study of HLX43 in combination with HLX07 or HANSIZHUANG in patients with advanced or metastatic colorectal cancer in Chinese Mainland
Global development progress of HLX22 (recombinant humanised anti-HER2 monoclonal antibody injection)		
HLX22 (HER2)	Gastric cancer (GC)	In March 2025, Orphan-drug Designation (ODD) was granted by the FDA In May 2025, Orphan-Drug Designation (ODD) was granted by the European Commission (EC)
HLX22 (HER2) in combination with trastuzumab	Gastroesophageal junction cancer and gastric cancer (GEJC/GC)	In March 2025, the first patient in Japan was dosed in an international multi-centre phase 3 clinical trial In April 2025, the international multi-centre phase 3 clinical study was permitted to commence in EU countries (Germany) In July 2025, the first patient in the United States was dosed in an international multi-centre phase 3 clinical trial In October 2025, the first patient in EU countries (Spain) was dosed in an international multi-centre phase 3 clinical trial
HLX22 (HER2) in combination with trastuzumab deruxtecan	Breast cancer (BC)	In April 2025, the first patient was dosed in a phase 2 clinical study in Chinese Mainland

Product name (targets)	Indications	Progress as of the Latest Practicable Date
HLX22 in combination with HLX87 (HER2+HER2 ADC)	Breast cancer (BC)	In December 2025, an investigational new drug application (IND) for the phase 2/3 clinical trial for first-line treatment of HER2-positive breast cancer (BC) was approved by the NMPA In February 2026, the first patient was dosed in a phase 2/3 clinical study in Chinese Mainland
Global development progress of HANSIZHUANG (serplulimab injection)		
HANSIZHUANG in combination with chemotherapy (PD-1)	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
HANSIZHUANG in combination with chemotherapy (PD-1)	Extensive-stage small cell lung cancer (ES – SCLC)	In January 2025, the bridging study was permitted to commence in Japan In June 2025, the first patient in the bridging study in Japan was dosed In October 2025, the recruitment of subjects was completed in the bridging study in the United States
HANSIZHUANG in combination with chemotherapy (PD-1)	Neo/adjuvant treatment for Gastric cancer (GC)	In September 2025, a phase 3 clinical study met the primary study endpoint In November 2025, it was officially granted the Breakthrough Therapy Designation by the Center for Drug Evaluation (CDE) of the NMPA In December 2025, the new drug application (NDA) was accepted by the NMPA and granted the procedure for priority review
HANSIZHUANG in combination with bevacizumab and chemotherapy (PD-1+VEGF)	Metastatic colorectal cancer (mCRC)	In June 2025, the recruitment of subjects was completed in an international multi-centre phase 3 clinical study
HLX07 in combination with HANSIZHUANG and chemotherapy (EGFR+PD-1)	Advanced squamous non-small cell lung cancer (sqNSCLC)	In March 2026, an investigational new drug application (IND) for the phase 2/3 clinical trial was approved by the NMPA

Product name (targets)	Indications	Progress as of the Latest Practicable Date
Global development progress of other products		
HLX11 (HER2)	Breast cancer (BC)	<p>In March 2025, the marketing authorisation application (MAA) was accepted by the EMA</p> <p>In February 2026, the marketing authorisation application (MAA) received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA)</p>
HLX79 in combination with HANLIKANG (Human sialidase fusion protein + CD20)	Active glomerulonephritis	<p>In March 2025, an investigational new drug application (IND) for the phase 2 clinical trial was approved by the NMPA</p> <p>In August 2025, the first patient was dosed in a phase 2 clinical study in Chinese Mainland</p>
HLX04-O (VEGF)	Wet age-related macular degeneration (wAMD)	<p>In April 2025, a phase 3 clinical study in Chinese Mainland met the primary study endpoint</p> <p>In August 2025, the new drug application (NDA) was accepted by the NMPA</p>
HLX13 (CTLA-4)	Hepatocellular carcinoma (HCC)	<p>In May 2025, the first patient was dosed in a phase 1/3 clinical study in Chinese Mainland</p> <p>In September 2025, an investigational new drug application (IND) for the phase 1 clinical trial was approved by the United States Food and Drug Administration (FDA)</p> <p>In November 2025, the first patient was dosed in an international multi-centre phase 1 clinical study in Chinese Mainland</p>
HLX17 (PD-1)	Various resected solid tumours	<p>In September 2025, an investigational new drug application (IND) for the phase 1 clinical trial was approved by the United States Food and Drug Administration (FDA)</p> <p>In September 2025, the first patient was dosed in an international multi-centre phase 1 clinical study in Chinese Mainland</p>

Product name (targets)	Indications	Progress as of the Latest Practicable Date
HLX37 (PD-L1 × VEGF)	Solid tumour	In November 2025, an investigational new drug application (IND) for the phase 1 clinical trial was approved by the NMPA In December 2025, the first patient was dosed in a phase 1 clinical study in Chinese Mainland
HLX14 (RANKL)	Osteoporosis (OP) etc.	In December 2025, the new drug application (NDA) was accepted by the NMPA
HLX701 (CD47) in combination with cetuximab and chemotherapy	Colorectal cancer (CRC)	In January 2026, an investigational new drug application (IND) for the phase 1b/2 clinical trial was approved by the NMPA
HLX15 (CD38)	Multiple myeloma (MM)	In February 2026, an investigational new drug application (IND) for the phase 1 clinical trial was approved by the NMPA In February 2026, an investigational new drug application (IND) for the phase 1 clinical trial was approved by the United States Food and Drug Administration (FDA)
Efficient advancement of IND filings for pre-clinical development projects		
HLX43 in combination with HANSIZHUANG (PD-L1 ADC+PD-1)	Solid tumour	In January 2025, an investigational new drug application (IND) for the phase 1b/2 clinical trial was approved by the NMPA (Already in clinical phase in Chinese Mainland)
HLX99 (Polypharmacology)	Amyotrophic lateral sclerosis (ALS)	In February 2025, an investigational new drug application (IND) was approved by the United States Food and Drug Administration (FDA)
HLX79 in combination with HANLIKANG (Human sialidase fusion protein + CD20)	Active glomerulonephritis	In March 2025, an investigational new drug application (IND) for the phase 2 clinical trial was approved by the NMPA (Already in clinical phase in Chinese Mainland)
HLX17 (PD-1)	Various resected solid tumours	In September 2025, an investigational new drug application (IND) for the phase 1 clinical trial was approved by the United States Food and Drug Administration (FDA) (Already in clinical phase in Chinese Mainland)

Product name (targets)	Indications	Progress as of the Latest Practicable Date
HLX43 in combination with HLX07 (PD-L1 ADC+EGFR)	Solid tumour	In September 2025, an investigational new drug application (IND) for the phase 2 clinical trial was approved by the NMPA (Already in clinical phase in Chinese Mainland)
HLX37 (PD-L1×VEGF)	Solid tumour	In November 2025, an investigational new drug application (IND) for the phase 1 clinical trial was approved by the NMPA (Already in clinical phase in Chinese Mainland)
HLX22 in combination with HLX87 (HER2+HER2 ADC)	Breast cancer (BC)	In December 2025, an investigational new drug application (IND) for the phase 2/3 clinical trial was approved by the NMPA (Already in clinical phase in Chinese Mainland)
HLX22 in combination with HLX87 (HER2+HER2 ADC)	Neoadjuvant treatment for breast cancer (BC neo)	In December 2025, an investigational new drug application (IND) for the phase 2/3 clinical trial was approved by the NMPA
HLX18 (PD-1)	Solid tumour	In December 2025, an investigational new drug application (IND) for the phase 1 clinical trial was approved by the United States Food and Drug Administration (FDA) In March 2026, an investigational new drug application (IND) for the phase 1 clinical trial was approved by the NMPA
HLX701 (CD47) in combination with cetuximab and chemotherapy	Colorectal cancer (CRC)	In January 2026, an investigational new drug application (IND) for the phase 1b/2 clinical trial was approved by the NMPA
HLX43 in combination with HLX07 and HANSIZHUANG (PD-L1 ADC + EGFR + PD-1)	Solid tumour	In January 2026, an investigational new drug application (IND) was approved by the NMPA
HLX97	Solid tumour	In March 2026, an investigational new drug application (IND) for the phase 1 clinical trial was approved by the NMPA

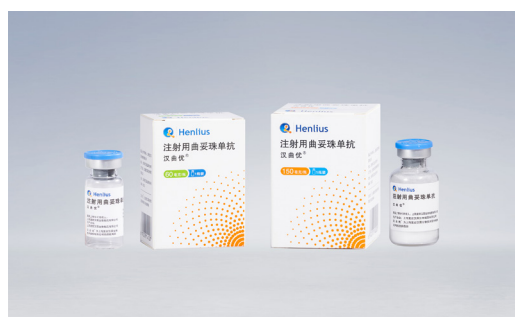
Product name (targets)	Indications	Progress as of the Latest Practicable Date
HLX3901 (DLL3×DLL3×CD3×CD28)	Solid tumour	In March 2026, an investigational new drug application (IND) for the phase 1 clinical trial was approved by the NMPA
HLX316 (B7-H3)	Solid tumour	In March 2026, an investigational new drug application (IND) for the phase 1 clinical trial was approved by the NMPA
HLX319 (HER2+HER2)	Breast cancer (BC)	In January 2026, an investigational new drug application (IND) for the phase 1 clinical trial was submitted to the NMPA and was accepted
HLX48 (EGFR×cMetADC)	Solid tumour	In March 2026, an investigational new drug application (IND) for the phase 1 clinical trial was submitted to the NMPA and was accepted

(III) Sustainable commercialisation fulfillment capabilities

During the Reporting Period, the Group continued to strengthen its commercialisation system, and leveraged on product differentiation and synergistic promotion mechanisms etc. to deepen sustainable competitive advantages. As at the end of the Reporting Period, the Group's commercialisation team was over 1,600 people, promoting the commercialisation of seven products, including HANQUYOU and HANSIZHUANG, in an orderly manner in Chinese Mainland.

- HANQUYOU (trastuzumab for injection, a therapeutic product for breast cancer and gastric cancer), a product with the largest market share in China's intravenous trastuzumab market, sequential treatment with HANNAIJIA (neratinib maleate) for the extended adjuvant treatment of breast cancer, and together with FUTUONING (Fovinaciclib Citrate Capsules), it further consolidates the Group's leading position in the field of breast cancer treatment.***

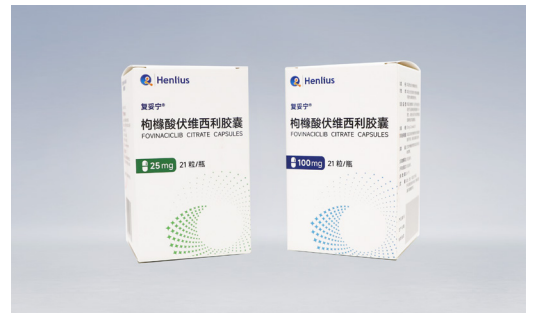
HANQUYOU is the core product of the Group in the field of anti-tumour therapy, and was independently developed by the Group in accordance with the relevant regulations on biosimilar drugs of Chinese Mainland, the EU, and the United States. In Chinese Mainland, HANQUYOU has continued to penetrate the 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. 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 market recognition of HANQUYOU.



HANNAIJIA is an oral small-molecule pan-HER tyrosine kinase inhibitor (TKI) for the extended adjuvant therapy of HER2-positive early breast cancer in adult patients after adjuvant therapy containing trastuzumab. HANNAIJIA and HANQUYOU can achieve sequential synergy, with the potential to further reduce the 5-year and 10-year postoperative recurrence risks in patients with HER2-positive early-stage breast cancer, bringing survival benefits to more patients with HER2-positive early-stage breast cancer. During the Reporting Period, HANNAIJIA has completed the tendering process on the procurement platform and has been included in the medical insurance procurement platform in all provinces in Chinese Mainland, with its market share gradually increasing. Meanwhile, the Group actively promoted education on sequential treatment with neratinib, an extended adjuvant therapy, aiming to cure more patients with HER2-positive early-stage breast cancer.



In December 2025, the Company entered into a cooperation agreement with Jinzhou Avanc Pharmaceutical Company Limited* (锦州奥鸿药业有限责任公司), pursuant to which the Company was granted the exclusive right to commercialize FUTUONING (Fovinaciclib Citrate Capsules) within Chinese Mainland. FUTUONING can synergize with other existing breast cancer pipeline products of the Company. FUTUONING is an innovative CDK4/6 small



molecule inhibitor approved in Chinese Mainland for (1) use in combination with Fulvestrant for the treatment of adult patients with hormone receptor (HR) positive and human epidermal growth factor receptor-2 (HER2) negative recurrent or metastatic breast cancer, who have experienced disease progression after prior endocrine therapy; and (2) use in combination with an aromatase inhibitor as initial endocrine therapy for the treatment of adult patients with hormone receptor (HR) positive and human epidermal growth factor receptor-2 (HER2) negative locally advanced or metastatic breast cancer. In December 2025, FUTUONING was newly included in Category B of the National Drug List for Basic Medical Insurance, Maternity Insurance and Work-Related Injury Insurance (2025) and is poised to benefit more patients with HR-positive and HER2-negative breast cancer.

2. HANSIZHUANG (serplulimab injection) possesses significant differentiated advantages in the field of small cell lung cancer

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,

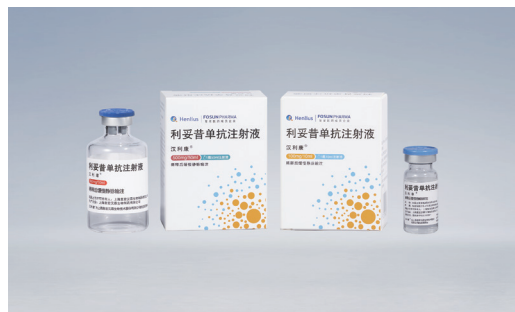
including the Guidelines of CSCO for Small-Cell Lung Cancer (《CSCO 小細胞肺癌診療指南》), Guidelines of CSCO for Non-small Cell Lung Cancer (《CSCO 非小細胞肺癌診療指南》), Guidelines of CSCO for Esophageal Cancer (《CSCO 食管癌診療指南》), Guidelines of CSCO for Immune Checkpoint Inhibitor Clinical Practice (《CSCO 免疫檢查點抑制劑臨床應用指南》), and Chinese Guidelines for the Radiotherapy of Esophageal Cancer (《中國食管癌放射治療指南》).



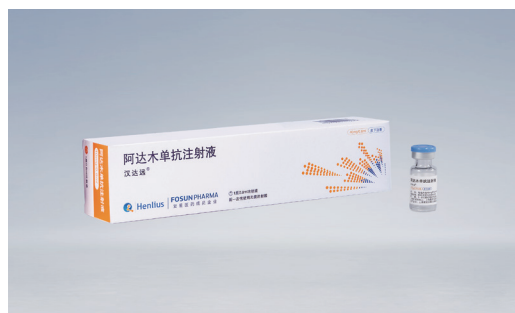
HANSIZHUANG has been approved in Chinese Mainland for the first-line treatment in combination with chemotherapy for squamous non-small cell lung cancer (sqNSCLC), extensive-stage small cell lung cancer (ES-SCLC), esophageal squamous cell carcinoma (ESCC), and non-squamous non-small cell lung cancer (nsNSCLC). 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. HANSIZHUANG in combination with chemotherapy for the neo/ adjuvant treatment of gastric cancer was officially granted the Breakthrough Therapy Designation by the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) in November 2025. The New Drug Application (NDA) for this new indication was accepted by the NMPA in December 2025 and granted the procedure for priority review, positioning it to potentially become the world's first anti-PD-1 monoclonal antibody approved for perioperative treatment of gastric cancer.

3. ***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***

HANLIKANG is 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. 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**”), a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd. (“**Fosun Pharma**”), the controlling shareholder of the Company.



HANDAYUAN is the third product of the Group marketed in Chinese Mainland. 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**”), a subsidiary of Fosun Pharma, the controlling shareholder of the Company. HANDAYUAN covers all eight indications of originator adalimumab approved for marketing in Chinese Mainland, including rheumatoid arthritis, ankylosing spondylitis, psoriasis, uveitis, polyarticular juvenile idiopathic arthritis, pediatric plaque psoriasis, Crohn’s disease and pediatric Crohn’s disease.



HANBEITAI is the fourth biosimilar product of the Group, which was approved for marketing and realised commercial sales, covering all indications of the originator bevacizumab approved for marketing in Chinese Mainland, including metastatic colorectal cancer, advanced, metastatic or recurrent non-small cell lung cancer, recurrent glioblastoma, hepatocellular carcinoma, 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.



(IV) Social responsibility, environmental policies and performance

The Group's path toward sustainable development is always based on the fundamental mission of serving patient needs. We are committed to enhancing the accessibility and quality of biologic therapies for patients worldwide, while conscientiously honouring our responsibilities to patients, employees, partners, communities and all other stakeholders. Recognizing the long-term value of sustainable development, we have fully integrated environmental, social and governance (ESG) concepts into our operations and systematically focused our efforts on corporate governance, product, talent, environment and the society. In terms of corporate governance, we focus on enhancing the Board's oversight and leadership role on ESG issues, translating our sustainable development strategies into concrete actions, and continuously improving our management systems including compliant operations and responsible marketing. In terms of products, we adhere to the principle of "quality first" throughout the entire lifecycle of research, development and manufacturing, while enhancing the accessibility and affordability of our therapies by leveraging medical insurance access and global market expansion. In terms of talent, we foster a diverse and inclusive organizational culture, consolidate professional excellence based on the global recruitment and training system, and share the fruits of development through equity incentive schemes and other long-term mechanisms. The Group has been awarded "HR Asia Best Companies to Work for in Asia" for four consecutive years. In terms of environment, we remain committed to green operations, predict climate-related risks and opportunities with reference to the Task Force on Climate-related Financial Disclosures (TCFD) recommendations, set and track environmental targets, and implement a series of energy-saving and emission-reduction measures. In terms of social contribution, we actively give back to society, pay attention to the health and well-being of patients and the public, continuously carry out public welfare projects, and collaborate with our industry partners to foster a more dynamic pharmaceutical ecosystem.

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 2026

In 2026, the Group will continue to be guided by clinical needs, persist in deepening product innovation, and further consolidate its internationalised capability of "integrating research, production and marketing". By 2030, the Company expects more than 20 products being approved for marketing worldwide, of which over 15 products are expected to be approved for marketing in Europe and the United States.

(I) High-quality internationalised operations and innovation capabilities, with a focus on deepening the global market

1. Continue to facilitate the footprint of pipeline products worldwide

In 2026, the Group will continuously promote the marketing approval process of more products in the global market with experiences gained along the way.

- HANSIZHUANG in combination with chemotherapy for the neo/adjuvant treatment of gastric cancer is expected to be approved in Chinese Mainland in the first half of 2026.
- HANSIZHUANG in combination with chemotherapy for the treatment of new indications, including non-small cell lung cancer (sqNSCLC), esophageal squamous cell carcinoma (ESCC) and non-squamous non-small cell lung cancer (nsqNSCLC), is expected to be approved in the EU in 2026.
- The Biologics License Application (BLA) for HANSIZHUANG in combination with chemotherapy for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC) is planned to be submitted to the United States Food and Drug Administration (FDA) in 2026. In addition, the Biologics License Application (BLA) for HANSIZHUANG in combination with chemotherapy and concurrent radiotherapy for the treatment of limited-stage small cell lung cancer (LS-SCLC) is also planned to be submitted in Chinese Mainland in 2026.
- HLX11 (pertuzumab) is expected to be approved for marketing in Chinese Mainland, the EU and other countries in the first half of 2026.
- HLX04-O (recombinant anti-VEGF humanised monoclonal antibody injection) is expected to be approved for marketing in Chinese Mainland in 2026.
- In 2026, 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 Chinese Mainland, the United States, the EU, Argentina, Mexico, Brazil, and other countries and regions.

Meanwhile, the Group will, as always, promote the business cooperation and local market establishment of its self-developed products in international markets, deepen its global out-licensing strategy to expand the international influence and accelerate the global value realization. The Group will also continuously work closely with international partners, leverage forward-looking market insights and refined access strategies to enhance its global commercialization capabilities, promote to integrate products into the local market deeply to benefit more overseas patients.

2. Continue to expand the product pipeline based on patients' needs through innovative iteration

Several of the Group's key innovative assets are expected to achieve breakthrough clinical progress in 2026. Among others, several global registration pivotal clinical studies for the treatment of lung cancer and several proof-of-concept studies for solid tumours relating to HLX43 for injection (antibody-drug conjugate targeting PD-L1) will initiate in 2026. Clinical data of such product in fields of esophageal squamous cell carcinoma, non-small cell lung cancer, nasopharyngeal carcinoma, cervical cancer and other fields are expected to be published at major academic conferences in 2026. Several clinical studies of the combination therapy regimens relating to HLX43 for injection (antibody-drug conjugate targeting PD-L1) will also be carried out successively.

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 of early research and development results. In 2026, Investigational New Drug (IND) applications are planned to be submitted for several products, such as HLX48 (EGFR × cMet ADC), HLX49 (HER2 × HER2 ADC), and HLX105 (PD-1 × IL2v) for the treatment of various solid tumours, HLX403 (CDH17 ADC) for the treatment of gastrointestinal cancer, HLX3902 (STEAP1 × CD3 × CD28) for the treatment of prostate cancer, and HLX109 (IL-1R3) for the treatment of autoimmune diseases further enriching the Group's product pipeline.

In addition, the Group will also focus on high-value and differentiated high-quality assets through diversified means such as in-licensing and co-development. Leveraging our established capability of "integrating research, production and marketing", we will drive in-depth integration of acquired assets and our existing technological capabilities to develop a globally competitive portfolio, thus promoting our long-term sustainable development.

3. Maintain international high-quality manufacturing standards to support a stable global market supply of products

In line with the product R&D and global commercialisation process, the Group has proactively planned the construction of production bases and the expansion of production capacity to provide strong support for the commercial sales of its products. The Xuhui Facility will continue to implement a series of refined management and process optimization measures to ensure stable and efficient international commercial production. The Facility is expected to undergo a pre-approval GMP inspection by the United States Food and Drug Administration (FDA) for HANBEITAI in the United States in 2026. Songjiang First Plant will continue to improve its international standard quality system and is expected to undergo pre-marketing GMP inspections for HLX14 in Chinese Mainland in 2026. In 2026, the supply scope of Songjiang First Plant is expected to expand to include the supply of more products to Chinese Mainland, North America, Europe, and Latin America. Songjiang Second Plant will expedite the preparatory work for the market supply of HLX14 in Canada.

(II) Leverage first-mover advantages to achieve sustainable development in the domestic market

As one of the leading domestic biopharma companies, 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 Shanghai Henlius Pharmaceutical Trading Co., Ltd., a wholly-owned subsidiary of the Company, 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 2026, while continuing to expand into lower-tier markets to steadily increase the market share of HANQUYOU, the Group will accelerate the commercialisation of HANNAIJIA, including securing market access in core hospitals and promoting comprehensive treatment coverage for all eligible patients within the intensified adjuvant target population, so as to further consolidate the Group's leading position in the treatment of HER2-positive breast cancer. Meanwhile, for HR+/HER2-advanced breast cancer, the inclusion of FUTUONING into the newly updated National Reimbursement Drug List has come into effect in 2026, which is expected to significantly enhance its accessibility and affordability. The Group will accelerate the commercial promotion of FUTUONING and proactively facilitate hospital access to ensure that more breast cancer patients benefit from innovative therapies as soon as possible.
- HANSIZHUANG (European trade name: Hetronifly[®]) was officially approved for marketing in the EU in early 2025 based on the excellent clinical research data and international quality, becoming the first monoclonal antibody drug targeting PD-1 approved for the treatment of extensive-stage small cell lung cancer (ES-SCLC) in the EU. In 2026, 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, deploy a dedicated gastric cancer sales force in line with the approval pace of new indications for HANSIZHUANG Chinese Mainland, 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 2026, HANBEITAI will continue to focus on the dual-channel market while actively pursuing hospital access opportunities in non-dual-channel regions with a view to further increasing 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 2026, the Group will maintain close cooperation with Fosun Yaohong and Fosun Wanbang, thereby continuously carrying out commercial sales of products.

III. FINANCIAL REVIEW

During the Reporting Period, adhering to the “patient-oriented” concept, the Group leveraged its integrated capabilities spanning R&D, production, registration, and commercialization to steadily advance the development of innovative products and expand its international footprint, thereby enabling more innovative solutions to benefit patients worldwide. During the Reporting Period, the Group further solidified its profitability and continued to drive breakthroughs in overseas revenue. By pursuing a dual-track R&D strategy, it established a diversified and platform-based innovation technology matrix. Collaborating with international capital markets and industry partners, the Group unlocked global value and steadily advanced its globalization efforts.

As an international and innovative biopharmaceutical company, the Group will remain focused on addressing unmet clinical needs, strengthening its end-to-end closed-loop system, and actively exploring greater growth potential through product synergies and international expansion. The Group will enhance its global innovation and operational capabilities, establish a replicable and sustainable global growth model, and enter the “Globalization 2.0” phase as characterized by systemic capacity building and innovation-driven development.

(I) Revenue

During the Reporting Period, the Group realised an operating income of approximately RMB6,666.6 million, representing an increase of 16.5% 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 sales revenue of approximately RMB2,809.1 million, representing an increase of approximately RMB116.7 million or 4.3% as compared to the same period in the last year. Zercepac[®] and HERCESSI[™] recorded overseas sales revenue of approximately RMB155.4 million.

HANSIZHUANG (serplulimab injection) was the first self-developed and approved bio-innovative 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 RMB1,439.8 million, representing a steady increase of approximately RMB130.9 million or 10.0% as compared to the same period in the last year. Zerpidio[®] and Hetronify[®] recorded sales revenue of approximately RMB52.8 million.

HANBEITAI (bevacizumab injection) is the fourth biosimilar product of the Group approved for marketing in Chinese Mainland and commercialised by the Group's in-house team, and commenced commercialization in the domestic market from January 2023. During the Reporting Period, HANBEITAI recorded sales revenue of approximately RMB356.4 million, representing an increase of approximately RMB159.3 million or 80.8% as compared to the same period in the last year.

In respect of HANLIKANG (rituximab injection), 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 RMB589.8 million, and licensing income of approximately RMB21.9 million under the aforementioned profit-sharing arrangement with its partners.

In respect of HANDAYUAN (adalimumab injection), according to the cooperation agreement with Fosun Pharma, Fosun Pharma would reimburse all the expenses related to the clinical trials of HANDAYUAN incurred by the Group after the relevant cooperation agreement was signed, and the Group was responsible for the production of HANDAYUAN in China and the supply of HANDAYUAN to Fosun Pharma after the commercialisation of HANDAYUAN, and shall share the profits from the sales of HANDAYUAN in China. During the Reporting Period, HANDAYUAN recorded sales revenue of approximately RMB58.5 million and licensing revenue of approximately RMB0.7 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 RMB301.2 million.

FUTUONING (Fovinaciclib Citrate Capsules) is an innovative small-molecule CDK4/6 inhibitor, and its commercial promotion in China is the responsibility of the Group. FUTUONING started shipment in September 2025. During the Reporting Period, FUTUONING recorded sales revenue of approximately RMB1.9 million.

HLX14 (Denosumab injection, with its trade names BILDYOS® and BILPREVDA® in the United States and Europe) has successfully become the first China-developed denosumab to enter overseas markets. In the second half of 2025, United States Food and Drug Administration (FDA), the European Commission (EC) and the UK Medicines and Healthcare products Regulatory Agency (MHRA) approved two products of HLX14. The approved indications cover all indications for which the reference products have been approved in the local market. During the Reporting Period, HLX14 recorded sales revenue of approximately RMB9.8 million.

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

By establishing a diversified and high-quality product pipeline, the Group is advancing a whole-industry-chain approach and a R&D-driven development model to accelerate the global accessibility of innovative and affordable therapies. The Group will intensify its presence in both global mainstream markets and emerging countries, while continuously deepening cooperation with international regulatory bodies and industry partners to further enhance its global influence and commercial transformation capabilities. 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[®]), granting Accord exclusive commercialisation rights in special territories as agreed therein. In July 2020, the marketing authorisation application of Zercepac[®] submitted by a wholly-owned subsidiary of Accord was approved. Since then, Zercepac[®] has been the first “Chinese” monoclonal antibody biosimilar drug approved for sale in the EU. The Group recognised revenue from licensing and R&D services of approximately RMB36.5 million for the 12 months ended 31 December 2025.

In September 2019, the Group entered into a co-development and commercialisation agreement with PT Kalbe Genexine Biologics in relation to HANSIZHUANG (serplulimab injection). With the continuous advancement of R&D services, the Group has recognised revenue from R&D services of approximately RMB9.2 million for the 12 months ended 31 December 2025.

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 RMB19.3 million for the 12 months ended 31 December 2025.

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 fully 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 licensing and R&D services of approximately RMB306.4 million for the 12 months ended 31 December 2025.

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 injection) independently developed by the Group in the United States. The Group has recognised revenue from R&D services of approximately RMB128.8 million for the 12 months ended 31 December 2025.

In October 2023, the Group entered into a license agreement with Intas Pharmaceuticals Limited (“**Intas**”) in relation to HANSIZHUANG (serplulimab injection), granting Intas exclusive developing and commercial rights in special territories as agreed therein. The Group has recognized licensing revenue of approximately RMB22.8 million for the 12 months ended 31 December 2025.

In December 2024, the Group entered into an agreement with ABBOTT, granting it a license to commercialize five products in 69 countries and regions, including Asia and Latin America, within the agreed-upon territories. The Group has recognised revenue from licensing of approximately RMB41.3 million for the 12 months ended 31 December 2025.

In April and December 2025, the Group entered into a license agreement and an amendment agreement with Sandoz AG, respectively, granting Sandoz AG the exclusive right to commercialize HLX13 (recombinant anti-CTLA-4 fully human monoclonal antibody injection) in the United States, agreed-upon European regions (42 European countries), Japan, Australia, and Canada. The Group recognised revenue from licensing and R&D services of approximately RMB171.5 million for the 12 months ended 31 December 2025.

In April and December 2025, the Group entered into a licensing agreement and an amendment agreement with Alvogen Korea Co., Ltd., granting it the exclusive right to commercialize HANSIZHUANG (serplulimab injection) in South Korea. The Group has recognised revenue from licensing of approximately RMB39.5 million for the 12 months ended 31 December 2025.

3) Revenue from other R&D service businesses

The Group recognised revenue from CMC Technical Services of approximately RMB73.0 million for the 12 months ended 31 December 2025.

(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 2025, the Group recorded cost of sales of approximately RMB1,681.9 million, representing an increase of approximately RMB142.1 million as compared with that for the 12 months ended 31 December 2024 due to the increase of the sales volume of the key commercial product markets.

(III) Gross profit

For the 12 months ended 31 December 2025, the Group recorded a gross profit of approximately RMB4,984.7 million, representing an increase of approximately RMB800.0 million as compared with that for the 12 months ended 31 December 2024, mainly due to the growth in revenue from the Group's joint development and technology transfer/commercialisation licensing, as well as 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); and (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 RMB130.6 million.

	Year ended 31 December	
	2025	2024
	<i>RMB'000</i>	<i>RMB'000</i>
Government grants	99,958	77,785
Interest income	18,787	21,703
Exchange gains	–	8,136
Gains on reclassification adjustments for disposal of a subsidiary outside Chinese Mainland	10,833	–
Others	999	356
Total	<u>130,577</u>	<u>107,980</u>

(V) R&D expenses

	Year ended 31 December	
	2025	2024
	<i>RMB'000</i>	<i>RMB'000</i>
Expensed R&D expenses		
R&D employee salaries	298,155	315,319
Clinical trials	450,268	294,995
Outsourcing fees	414,543	147,461
Reagents and consumables	95,481	115,297
Depreciation and amortisation	46,278	57,111
Consulting expense	24,891	28,881
Technology expense	88,307	12,541
Utilities expenses	7,758	10,133
Share-based compensation	31,088	–
Others	58,729	53,392
	<hr/>	<hr/>
Total expensed R&D expenses	1,515,498	1,035,130
	<hr/> <hr/>	<hr/> <hr/>
	Year ended 31 December	
	2025	2024
	<i>RMB'000</i>	<i>RMB'000</i>
Capitalised R&D expenses		
Clinical trials	505,478	315,988
R&D employee salaries	164,358	175,315
Reagents and consumables	62,690	85,925
Technology expense	53,467	67,511
Depreciation and amortisation	43,189	51,410
Outsourcing fees	50,754	42,717
Utilities expenses	16,765	29,084
Consulting expense	5,392	3,898
Share-based compensation	11,991	–
Others	62,351	33,525
	<hr/>	<hr/>
Total capitalised R&D expenses	976,435	805,373
	<hr/> <hr/>	<hr/> <hr/>

For the 12 months ended 31 December 2025, the Group recognized R&D expenses of approximately RMB2,491.9 million, representing an increase of approximately RMB651.4 million as compared with approximately RMB1,840.5 million for the 12 months ended 31 December 2024, mainly due to increased investment in innovative R&D projects during the Reporting Period to accelerate the Group's innovation and transformation. Our R&D expenses mainly arose from advancing technology platform innovation, IND application, and clinical trials for new drugs.

(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 2025, the Group recognised administrative expenses of approximately RMB443.1 million, representing an increase of approximately RMB72.3 million as compared with approximately RMB370.8 million for the 12 months ended 31 December 2024. The increase in administrative expenses of the Group was mainly due to: (1) the increased share-based payments to drive the Company's long-term development strategy; and (2) the corresponding increases in third-party consulting fees and depreciation costs to support business development and 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 2025, the Group recognised selling and distribution expenses of approximately RMB2,198.5 million, which were mainly the marketing expenses incurred in continuous sales growth of HANQUYOU, HANSIZHUANG, HANBEITAI and HANNAIJIA and the marketing and selling of FUTUONING.

(VIII) Other expenses

For the 12 months ended 31 December 2025, the Group recognised other expenses of approximately RMB34.0 million, which mainly included semi-finished products, finished products, raw materials, and losses from changes in fair value.

(IX) Income tax expenses

For the 12 months ended 31 December 2025, the Group incurred income tax expense of approximately RMB-15.3 million, mainly due to the impact of recognizing deferred tax assets by certain subsidiaries of the Group.

(X) Profit for the year

In view of the above, the Group recorded an increase of approximately RMB6.5 million in profit from a profit of approximately RMB820.5 million for the year ended 31 December 2024 to a profit of approximately RMB827.0 million for the year ended 31 December 2025.

(XI) Liquidity and capital resources

As of 31 December 2025, cash and bank balances of the Group were approximately RMB772.2 million, mainly denominated in Renminbi (“RMB”), United States Dollars (“USD”), New Taiwan Dollars (“NTD”), Hong Kong Dollars (“HKD”), Euro (“EUR”), and Japanese Yen (“JPY”), compared to cash and bank balances of the Group of approximately RMB773.0 million as at 31 December 2024, representing a decrease of approximately RMB0.8 million.

As of 31 December 2025, the current assets of the Group were approximately RMB3,486.0 million, including cash and bank balances of approximately RMB772.2 million, inventories of approximately RMB612.4 million, trade receivables of approximately RMB1,815.9 million, contract assets of approximately RMB17.4 million, and other receivables of approximately RMB268.1 million.

As of 31 December 2025, the current liabilities of the Group were approximately RMB4,940.8 million, including trade payables of approximately RMB831.0 million, other payables and accruals of approximately RMB1,293.9 million, contract liabilities of approximately RMB518.1 million, tax payable of approximately RMB51.2 million and interest-bearing bank and other borrowings of approximately RMB2,246.6 million.

As at 31 December 2025, the bank balances in foreign exchange were as follows:

	<i>RMB'000</i>
RMB	389,537
HKD	7,030
USD	359,059
EUR	4,602
NTD	1,678
JPY	10,303
	<hr/> <hr/>
	<i>Original amount'000</i>
RMB	389,537
HKD	7,783
USD	51,193
EUR	559
NTD	7,523
JPY	230,000
	<hr/> <hr/>

(XII) Inventories

Inventories of the Group amounted to approximately RMB612.4 million as at 31 December 2025, representing a decrease of approximately RMB115.9 million as compared with approximately RMB728.3 million as at 31 December 2024, mainly due to further improvement in inventory management.

(XIII) Trade receivables

As at 31 December 2024 and 31 December 2025, trade receivables from customer contracts were approximately RMB857.4 million and RMB1,815.9 million, respectively. There were no changes in accounting estimates or key assumptions made in both years.

	As at 31 December	
	2025	2024
	<i>RMB'000</i>	<i>RMB'000</i>
Within 3 months	1,815,602	856,286
3 to 6 months	255	1,144
Total	1,815,857	857,430

(XIV) Interest-bearing bank and other borrowings

As of 31 December 2025, borrowings from bank and other institutions (exclusive of lease liabilities) of the Group were approximately RMB3,437.1 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 2025 and 31 December 2024, of which lease liabilities were recognised in accordance with IFRS 16 – Leases.

	As at 31 December	
	2025	2024
	<i>RMB'000</i>	<i>RMB'000</i>
Within 1 year	2,246,628	2,559,515
In the second year	481,516	348,137
In the third to fifth year (inclusive)	850,100	726,050
Over five years	18,780	14,484
Total	3,597,024	3,648,186

(XVI) Collateral and pledged assets

As at 31 December 2025, the Group's pledged assets in relation to borrowings included property, plant and equipment of approximately RMB1,184.7 million and land use right of approximately RMB184.1 million.

(XVII) Key financial ratios

	31 December 2025	31 December 2024
Current ratio ⁽¹⁾ :	70.6%	49.9%
Quick ratio ⁽²⁾ :	58.2%	35.4%
Gearing ratio ⁽³⁾ :	43.2%	50.5%

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	
	2025	2024
	RMB'000	RMB'000
Construction in progress	115,482	256,114
Plant and machinery	–	14,881
Electronic equipment	–	2,968
Leasehold improvements	976	15,887
	<hr/>	<hr/>
Total	116,458	289,850
	<hr/> <hr/>	<hr/> <hr/>

We had capital commitments for plant and machinery contracted but not provided for of approximately RMB64.5 million as at 31 December 2025. These capital commitments primarily relate to expenditures expected to be incurred for the purchase of machinery, renovation of our existing laboratories and buildings and the R&D expenditure to be capitalised.

(XX) Contingent liabilities

As of 31 December 2025, the Group did not have any material contingent liabilities.

(XXI) Material acquisitions and disposals

As of 31 December 2025, 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 2025.

IV. RISK MANAGEMENT

(I) Foreign exchange risk

As at 31 December 2025, 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 operations of the Group are in the PRC and most of the revenue and expenses are settled in RMB, which is the Group's reporting currency. With the acceleration of the Group's development in overseas markets, it is expected that the sales revenue and licensing revenue denominated in USD and EUR will increase in the future. Fluctuations in exchange rates may affect the Group's cash flows, revenues, earnings and financial position.

(III) Potential risks

1. Market Risk

The biologics market is highly competitive, and the Group's existing commercialised products and products that may be commercialised in the future face competition from pharmaceutical companies around the world in respect of various factors such as indication treatment, drug novelty, drug quality and reputation, breadth of drug portfolio, manufacturing and distribution capacity, drug price, breadth and depth of customer coverage, consumer behaviour and supply chain relationships. The Group's ability to remain competitive depends to a large extent on our ability to innovate, develop and promote new products and technologies that meet market needs in a timely manner to capture market share. 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

The global situation is ever-changing and the 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 follows: HANSIZHUANG, HANLIKANG, HANQUYOU, HANDAYUAN, HANBEITAI, BILDYOS[®]、BILPREVDA[®] and POHERDY[®]. 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 is 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 2025:

Function	Number of employees
R&D and technology	1,014
Manufacturing	907
Commercial Operation	1,576
General and administrative	265
Total	<u><u>3,762</u></u>

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

COMMUNICATION WITH SHAREHOLDERS AND INVESTORS

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

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

FINAL DIVIDEND

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

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

The Company will arrange the time of convening the forthcoming annual general meeting (the “AGM”) as soon as practicable, and the notice of the AGM will be published in a timely manner in accordance with the requirements of the Rules Governing the Listing of Securities on the Stock Exchange (the “**Listing Rules**”) and the articles of association of the Company (the “**Articles of Association**”). Once the date of the AGM is finalised, the Company will publish the period of closure of the register of members of H shares of the Company in 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 2025 annual results and the financial statements for the year ended 31 December 2025 prepared in accordance with the IFRS Accounting Standards.

AUDITOR

The figures in respect of the Group’s consolidated statement of financial position, consolidated statement of profit or loss and other comprehensive income and the related notes thereto for the year ended 31 December 2025 as set out in the preliminary announcement have been agreed by the Company’s external auditors to the amounts set out in the Group’s audited consolidated financial statements for the year. The work performed by the Company’s auditors in this respect did not constitute an assurance engagement and consequently no opinion or assurance conclusion has been expressed by the Company’s auditors on the preliminary announcement.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS*Year ended 31 December 2025*

	<i>Notes</i>	2025 RMB'000	2024 <i>RMB'000</i>
REVENUE	3	6,666,627	5,724,449
Cost of sales		<u>(1,681,920)</u>	<u>(1,539,787)</u>
Gross profit		4,984,707	4,184,662
Other income and gains	4	130,577	107,980
Selling and distribution expenses		(2,198,471)	(1,917,391)
Administrative expenses		(443,136)	(370,799)
Impairment losses on financial assets, net		(9,999)	4,843
Research and development expenses		(1,515,498)	(1,035,130)
Other expenses		(33,965)	(5,397)
Finance costs	6	<u>(102,493)</u>	<u>(122,887)</u>
PROFIT BEFORE TAX	5	811,722	845,881
Income tax expense	7	<u>15,320</u>	<u>(25,411)</u>
PROFIT FOR THE YEAR		<u>827,042</u>	<u>820,470</u>
Attributable to:			
Owners of the parent		827,042	820,470
Non-controlling interests		<u>—</u>	<u>—</u>
		<u>827,042</u>	<u>820,470</u>
EARNINGS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic			
– For profit for the year (RMB)	9	<u>1.52</u>	<u>1.51</u>
Diluted			
– For profit for the year (RMB)	9	<u>1.51</u>	<u>1.51</u>

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

Year ended 31 December 2025

	2025 <i>RMB'000</i>	2024 <i>RMB'000</i>
PROFIT FOR THE YEAR	827,042	820,470
OTHER COMPREHENSIVE (LOSS)/INCOME		
Other comprehensive (loss)/income that may be reclassified to profit or loss in subsequent periods:		
Exchange differences:	(3,315)	850
Reclassification adjustment for liquidation of a subsidiary outside Chinese Mainland	(10,833)	—
OTHER COMPREHENSIVE (LOSS)/INCOME FOR THE YEAR, NET OF TAX	(14,148)	850
TOTAL COMPREHENSIVE (LOSS)/INCOME FOR THE YEAR	812,894	821,320
Attributable to:		
Owners of the parent	812,894	821,320
Non-controlling interests	—	—
	812,894	821,320

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

Year ended 31 December 2025

	<i>Notes</i>	2025 RMB'000	2024 RMB'000
NON-CURRENT ASSETS			
Property, plant and equipment		2,261,918	2,343,354
Intangible assets		6,162,288	5,355,204
Right-of-use assets		319,528	357,103
Other non-current assets		59,811	30,335
Deferred tax assets		71,516	–
Total non-current assets		8,875,061	8,085,996
CURRENT ASSETS			
Inventories		612,412	728,266
Trade receivables	<i>10</i>	1,815,857	857,430
Prepayments, deposits and other receivables	<i>11</i>	268,146	108,938
Contract assets		17,408	43,928
Cash and bank balances		772,209	772,962
Total current assets		3,486,032	2,511,524
CURRENT LIABILITIES			
Trade payables	<i>12</i>	831,012	729,099
Other payables and accruals		1,293,921	1,299,350
Tax payable		51,173	–
Contract liabilities		518,115	444,033
Interest-bearing bank and other borrowings		2,246,628	2,559,514
Total current liabilities		4,940,849	5,031,996
NET CURRENT LIABILITIES		(1,454,817)	(2,520,472)
TOTAL ASSETS LESS CURRENT LIABILITIES		7,420,244	5,565,524
NON-CURRENT LIABILITIES			
Interest-bearing bank and other borrowings		1,350,396	1,088,671
Other long-term payables		188,877	149,266
Contract liabilities		1,643,322	1,075,238
Deferred income		277,180	238,728
Total non-current liabilities		3,459,775	2,551,903
Net assets		3,960,469	3,013,621
EQUITY			
Share capital		543,495	543,495
Reserves		3,416,974	2,470,126
Equity attributable to owners of the parent and total equity		3,960,469	3,013,621

NOTES TO FINANCIAL STATEMENTS

Year ended 31 December 2025

1.1 BASIS OF PREPARATION

These financial statements have been prepared in accordance with 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 RMB1,454,817,000 as at 31 December 2025. 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 2025. 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 amendments to IAS 21 *Lack of Exchangeability* for the first time for the current year's financial statements. The Group has not early adopted any other standard or amendment that has been issued but is not yet effective.

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. As the currencies that the Group had transacted in and the functional currencies of overseas subsidiaries, joint ventures for translation into the Group's presentation currency were exchangeable, the amendments did not have any impact on the Group's financial statements.

In addition, the IASB has issued amendments to Illustrative Examples on IFRS 7, IFRS 18, IAS 1, IAS 8, IAS 36 and IAS 37 Disclosures about Uncertainties in the Financial Statements, which added illustrative examples in the corresponding IFRS Accounting Standards. These examples reflect existing requirements in the corresponding IFRS Accounting Standards to report the effects of uncertainties in the financial statements using climate-related examples. Therefore, the amendments do not have an effective date or transitional provisions.

1.3 ISSUED BUT NOT YET EFFECTIVE IFRS ACCOUNTING STANDARDS

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

IFRS 18	<i>Presentation and Disclosure in Financial Statements²</i>
IFRS 19 and its amendments	<i>Subsidiaries without Public Accountability: Disclosures²</i>
Amendments to IFRS 9 and IFRS 7	<i>Amendments to the Classification and Measurement of Financial Instruments¹</i>
Amendments to IFRS 9 and IFRS 7	<i>Contracts Referencing Nature-dependent Electricity¹</i>
Amendments to IFRS 10 and IAS 28	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture³</i>
Amendments to IAS 21	<i>Lack of Exchangeability²</i>
<i>Annual Improvements to IFRS Accounting Standards – Volume 11</i>	Amendments to IFRS 1, IFRS 7, IFRS 9, IFRS 10 and IAS 7 ¹

¹ Effective for annual periods beginning on or after 1 January 2026

² Effective for annual/reporting periods beginning on or after 1 January 2027

³ 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. IFRS 19 was amended in April 2025 to include IFRS Accounting Standards in the eligibility criteria for applying the standard. The standard was further amended in October 2025 to (i) remove disclosure objectives from IFRS 19; (ii) reduce the disclosure requirements relating to supplier finance arrangements and a specific class of financial liabilities; and (iii) replace disclosure requirements relating to management-defined performance measures with a cross-reference to IFRS 18 for entities that use these measures. Earlier application is permitted. As the Company is a listed company, it is not eligible to elect to apply IFRS 19 and its amendments. Some of the Company's subsidiaries are considering the application of IFRS 19 and its amendments in their specified financial statements.

Amendments to IFRS 9 and IFRS 7 *Amendments to the Classification and Measurement of Financial Instruments* 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 9 and IFRS 7 *Contracts Referencing Nature-dependent Electricity* clarify the application of the "own-use" requirements for in-scope contracts and amend the designation requirements for a hedged item in a cash flow hedging relationship for in-scope contracts. The amendments also include additional disclosures that enable users of financial statements to understand the effects these contracts have on an entity's financial performance and future cash flows. The amendments relating to the own-use exception shall be applied retrospectively. Prior periods are not required to be restated and can only be restated without the use of hindsight. The amendments relating to the hedge accounting shall be applied prospectively to new hedging relationships designated on or after the date of the initial application. Earlier application is permitted. The amendments to IFRS 9 and IFRS 7 shall be applied at the same time. 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 HKICPA. However, the amendments are available for adoption now.

Amendments to IAS 21 *Translation to a Hyperinflationary Presentation Currency* require the translation from a non-hyperinflationary functional currency into a hyperinflationary presentation currency at the closing rate. The amendments also require an entity whose functional currency and presentation currency are the currency of a hyperinflationary economy to restate the comparative amounts of a foreign operation whose functional currency is that of a non-hyperinflationary economy, by applying the general price index, in accordance with paragraph 34 of IAS 29 *Financial Reporting in Hyperinflationary Economies*, to the foreign operation's comparative figures. The amendments introduce certain additional disclosures. Earlier application is permitted. 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. However, the amendments do not address how a lessee distinguishes between a lease modification as defined in HKFRS 16 and an extinguishment of a lease liability in accordance with IFRS 9. 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

	2025 <i>RMB'000</i>	2024 <i>RMB'000</i>
Chinese Mainland	5,781,769	5,046,100
Asia Pacific (excluding Chinese Mainland)	116,011	236,864
North America	465,473	329,124
South America	27,578	10,624
Europe	275,796	101,412
Oceania	–	325
	<hr/>	<hr/>
Total revenue	6,666,627	5,724,449

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

(b) Non-current assets

	2025 <i>RMB'000</i>	2024 <i>RMB'000</i>
Chinese Mainland	8,746,073	7,982,313
Overseas	57,472	103,683
	<hr/>	<hr/>
Total non-current assets	8,803,545	8,085,996

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:

	2025 <i>RMB'000</i>	2024 <i>RMB'000</i>
Customer A	2,469,372	2,055,889

3. REVENUE

An analysis of revenue is as follows:

	2025 <i>RMB'000</i>	2024 <i>RMB'000</i>
<i>Revenue from contracts with customers</i>	6,663,761	5,721,643
<i>Revenue from other sources</i>		
Gross rental income from operating leases	<u>2,866</u>	<u>2,806</u>
Total revenue	<u>6,666,627</u>	<u>5,724,449</u>

Revenue from contracts with customers

(a) Revenue information

	2025 <i>RMB'000</i>	2024 <i>RMB'000</i>
Types of goods or service		
Sales of biopharmaceutical products	5,774,611	4,933,529
Research and development services	619,141	523,473
Licensing revenue	257,766	260,760
Others	<u>12,243</u>	<u>3,881</u>
Total revenue from contracts with customers	<u>6,663,761</u>	<u>5,721,643</u>
Timing of revenue recognition		
Transferred at a point in time	5,973,473	5,220,316
Transferred over time	<u>690,288</u>	<u>501,327</u>
Total revenue from contracts with customers	<u>6,663,761</u>	<u>5,721,643</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:

	2025 <i>RMB'000</i>	2024 <i>RMB'000</i>
Revenue recognised that was included in contract liabilities at the beginning of the reporting period:		
Sales of biopharmaceutical products	136,065	155,203
Licensing revenue	38,149	25,959
Research and development services	<u>265,887</u>	<u>301,322</u>
	<u>440,101</u>	<u>482,484</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:

	2025 RMB'000	2024 RMB'000
Amounts expected to be recognised as revenue:		
Within one year	518,115	444,033
After one year	1,643,322	1,075,238
	2,161,437	1,519,271

The remaining performance obligations expected to be recognised after one year mainly relate to the transaction prices allocated to sale of biopharmaceutical products, 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

	2025 RMB'000	2024 RMB'000
Interest income	18,787	21,703
Exchange gains	–	8,136
Government grants	99,958	77,785
Gains on reclassification adjustments for liquidation of a subsidiary outside Chinese Mainland	10,833	–
Others	999	356
Total other income and gains	130,577	107,980

5. PROFIT BEFORE TAX

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

	<i>Notes</i>	2025 RMB'000	2024 <i>RMB'000</i>
Cost of inventories sold		1,183,517	896,929
Cost of services provided		498,403	642,858
Depreciation of property, plant and equipment*		161,062	141,500
Depreciation of right-of-use assets*		74,971	71,944
Amortisation of intangible assets*		193,377	161,355
Research and development expenses:			
Current year expenditure		1,515,498	1,035,130
Lease payments not included in the measurement of lease liabilities		7,422	12,551
Auditor's remuneration		5,000	4,100
Employee benefit expense (including directors' and chief executive's remuneration):			
Wages and salaries		1,267,099	1,392,662
Staff welfare expenses		337,243	283,527
Share-based payment expense*		124,519	–
Foreign exchange (gains)/losses		6,828	(8,136)
Impairment of financial assets, net:			
Impairment of trade receivables		10,478	(5,160)
Impairment of other receivables		(479)	317
Impairment of contract assets		95	129
Write-down of inventories to net realisable value		23,460	5,102
Change in fair value of financial liabilities		2,614	–
Bank interest income	4	(18,787)	(21,703)
Gain on disposal of right-of-use assets		(440)	(911)
Loss on disposal of items of property, plant and equipment		(51)	90
Gain on reclassification adjustments for liquidation of a subsidiary outside Chinese Mainland		(10,833)	–
		<u>(10,833)</u>	<u>–</u>

* 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:

	2025 <i>RMB'000</i>	2024 <i>RMB'000</i>
Interest expense on bank and other borrowings	102,806	128,661
Interest expense on lease liabilities	9,457	11,583
Less: Interest capitalised	<u>(9,770)</u>	<u>(17,357)</u>
Total	<u>102,493</u>	<u>122,887</u>

7. INCOME TAX

The provision for Chinese Mainland current income tax is based on the statutory rate of 25% (2024: 25%) of the assessable profits of the Group as determined in accordance with the PRC Corporate Income Tax Law which was approved and became effective on 1 January 2008, except for certain group entities in Chinese Mainland, which are taxed at a preferential rate of 15%.

Taxes on profits assessable elsewhere have been calculated at the tax rates prevailing in the jurisdictions in which the Group operates. The provision for current income tax of Henlius USA incorporated in the United State and Henlius Industrial incorporated in Hong Kong in the year of 2024, is based on the statutory rates of 29.84% and 8.25%, respectively (2024: 29.84% and 8.25% respectively).

	2025 <i>RMB'000</i>	2024 <i>RMB'000</i>
Current – Chinese Mainland	56,196	25,411
Deferred	<u>(71,516)</u>	<u>–</u>
Total tax charged for the year	<u>(15,320)</u>	<u>25,411</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 (2024: 543,494,853) 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:

	2025 <i>RMB'000</i>	2024 <i>RMB'000</i>
Earnings		
Profit attributable to ordinary equity holders of the parent, used in the basic earnings per share calculation	<u>827,042</u>	<u>820,470</u>
	Number of shares	
	2025	2024
Shares		
Weighted average number of ordinary shares in issue during the year used in the basic earnings per share calculation	543,494,853	543,494,853
Effect of dilution – weighted average number of ordinary shares:		
– Share award scheme	2,282,566	–
– Share option scheme	<u>155,677</u>	<u>–</u>
Weighted average number of ordinary shares in issue during the year in the diluted earnings per share calculation	<u>545,933,096</u>	<u>543,494,853</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

	2025 <i>RMB'000</i>	2024 <i>RMB'000</i>
Trade receivables	1,836,111	867,206
Impairment	<u>(20,254)</u>	<u>(9,776)</u>
Net carrying amount	<u>1,815,857</u>	<u>857,430</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:

	2025 <i>RMB'000</i>	2024 <i>RMB'000</i>
Within 3 months	1,815,602	856,286
3 to 6 months	<u>255</u>	<u>1,144</u>
Total	<u>1,815,857</u>	<u>857,430</u>

11. PREPAYMENTS, DEPOSITS AND OTHER RECEIVABLES

	<i>Notes</i>	2025 RMB'000	2024 <i>RMB'000</i>
Prepayments		181,269	44,278
Value added tax to be deducted and certified		15,841	23,890
Deposits and other receivables		71,036	40,770
Due from AMTD	<i>(i)</i>	466,438	477,029
		734,584	585,967
Impairment allowance	<i>(i)</i>	(466,438)	(477,029)
Total		268,146	108,938

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 2024 and 2025, the outstanding balances of the investment principal in AMTD Account amounted to USD66,361,000 (equivalent to RMB477,029,000 and RMB466,438,000 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 of the amount due from AMTD amounted to USD66,361,000 was provided for amounts due from AMTD as at 31 December 2025 and 2024.

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 2025 and 2024, the loss allowance was assessed to be minimal.

12. TRADE PAYABLES

	2025 <i>RMB'000</i>	2024 <i>RMB'000</i>
Trade payables	<u>831,012</u>	<u>729,099</u>

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:

	2025 <i>RMB'000</i>	2024 <i>RMB'000</i>
Within 1 year	791,462	692,208
1 to 2 years	38,291	36,869
2 to 3 years	1,259	–
Over 3 years	–	22
Total	<u>831,012</u>	<u>729,099</u>

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 2025 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, 20 March 2026

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. Yuqing Chen, Ms. Xiaohui Guan, Dr. Yi Liu and Dr. Xingli Wang as the non-executive directors, and Mr. Tak Young So, Dr. Lik Yuen Chan, Dr. Ruilin Song and Mr. Yihao Zhang as the independent non-executive directors.