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)

INTERIM RESULTS ANNOUNCEMENT FOR THE SIX MONTHS ENDED 30 JUNE 2025

The board of directors (the "**Board**") of Shanghai Henlius Biotech, Inc. (the "**Company**" or "**Henlius**") is pleased to announce the unaudited consolidated financial results of the Company and its subsidiaries (collectively referred to as the "**Group**" or "**we**") for the six months ended 30 June 2025 (the "**Reporting Period**"), prepared under International Financial Reporting Standards ("**IFRSs**").

FINANCIAL SUMMARY:

1. The Group's total revenue increased by approximately RMB73.4 million or approximately 2.7% to approximately RMB2,819.5 million for the six months ended 30 June 2025, compared to approximately RMB2,746.1 million for the six months ended 30 June 2024. Such revenue was mainly from drug sales, research and development ("**R&D**") services provided to customers, and license income.

2. For the six months ended 30 June 2025, the Group recognised R&D expenditure of approximately RMB995.4 million, representing an increase of approximately RMB169.8 million as compared to approximately RMB825.6 million for the six months ended 30 June 2024. Such expenditure was primarily used to increase investment in innovative research projects, accelerating our innovation transformation.

3. The Group's total profit was approximately RMB390.1 million for the six months ended 30 June 2025, representing an increase of approximately RMB3.8 million in profit from a profit of approximately RMB386.3 million for the six months ended 30 June 2024.

4. For the six months ended 30 June 2025, the Group's revenue from sales of overseas products (including revenue from supply of overseas products and royalty income based on sales) was approximately RMB40.6 million. Profit from overseas products (including gross profit from overseas product supply and profit from royalty based on sales) achieved a breakthrough of more than 2 times as compared with the same period of last year, which was mainly due to the fact that the Group adhered to the internationalisation strategy and increased the sales volume in the United States market, which contributed to the continuous improvement of international profitability.

BUSINESS HIGHLIGHTS:

As at the Latest Practicable Date, 6 products (25 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 4 products approved for marketing in multiple overseas markets. Such 6 products reached nearly 60 countries/regions, benefiting over 850,000 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 for adult patients with extensive-stage small cell lung cancer (ES-SCLC) was approved for marketing in the EU.

During May to June 2025, 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 30 countries and regions and has been granted Orphan-drug Designations by drug regulatory authorities in the United States, the EU, Switzerland and the Republic of Korea, respectively.

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 develop, manufacture and commercialise a biosimilar of daratumumab HLX15 (recombinant anti-CD38 human monoclonal antibody injection) in the United States and agreed European region.

In March 2025, the Group entered into a product exclusive license and supply agreement with Fosun Industrial Co., Limited, pursuant to which the Group agreed to grant an exclusive license to commercialise HANSIZHUANG (serplulimab injection) in Hong Kong and Macau regions of China.

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 develop and commercialise HANSIZHUANG (serplulimab injection) in the Republic of Korea.

In April 2025, the Company entered into a license agreement with Sandoz AG, pursuant to which the Company agreed to grant a license to develop, manufacture, and commercialize 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.

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

The Group's early-stage R&D is centered around patients 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 SIRPα-Fc fusion protein within Mainland China, Hong Kong and Macau regions of China, and specific countries in Southeast Asia. In August 2025, the Company entered into a strategic collaboration with GeneQuantum Healthcare (Suzhou) Co., Ltd., pursuant to which, the Company obtained the development and exclusive commercialisation rights for the innovative HER2-targeted antibody-drug conjugate (ADC) GQ1005 in China and specific overseas countries and regions.

As of the Latest Practicable Date, the Group has a total of approximately 50 molecules in its pipeline and over 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 for the treatment of patients with advanced/metastatic solid tumours was approved by the NMPA.

- In February 2025, an investigational new drug application (IND) for innovative small 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 July 2025, an investigational new drug application (IND) for a phase 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 patients with advanced/metastatic solid tumours was submitted to the NMPA and was accepted in the same month.

- In August 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 submitted to the United States Food and Drug Administration (FDA) and was 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 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 Mainland China 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 Mainland China. During the Reporting Period, the Company commenced several phase 2 clinical trials of HLX43 for different indications in Mainland China.

In June and August 2025, the first patient in Mainland China and the United States were dosed in an international multi-centre phase 2 clinical study of HLX43 in patients with advanced non-small cell lung cancer (NSCLC), respectively. Such international multi-centre clinical study was also permitted to commence in Australia and Japan in June and July 2025, respectively.

In July 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.

HLX22 (recombinant humanised anti-HER2 monoclonal antibody injection)

In March and May 2025, Orphan-drug Designations 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 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 Mainland China.

In March and July 2025, the first patients in Japan and the United States 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 was also permitted to commence in an EU country (Germany) in April 2025. The study is currently being conducted simultaneously in Mainland China, the United States, Australia, Japan and other countries/regions.

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).

As at the Latest Practicable Date, over 100 sites have been set for the bridging study in the United States for HANSIZHUANG in combination with chemotherapy for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC), and the recruitment of subjects is progressing steadily.

Other products

In January and March 2025, the new drug applications for a biosimilar of pertuzumab HLX11 (recombinant anti-HER2 domain II humanised monoclonal antibody injection) were accepted by the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA), respectively.

In April 2025, a phase 3 clinical study of HLX04-O (recombinant anti-VEGF humanised monoclonal antibody injection) for the treatment of wet age-related macular degeneration (wAMD) in Chinese patients met the primary study endpoints. 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 human monoclonal antibody injection) for the first-line treatment of patients with unresectable advanced hepatocellular carcinoma (HCC) in Mainland China.

In July 2025, a biosimilar of denosumab HLX14 (recombinant anti-RANKL human monoclonal antibody injection) received positive opinions from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), recommending the approvals of the two marketing authorisation applications (MAAs) for two strengths.

In August 2025, the first patient was dosed in a phase 2 clinical study of HLX79 injection (human sialidase fusion protein) in combination with HANLIKANG (rituximab injection) for the treatment of active glomerulonephritis in Mainland China.

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, 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

In-Market

Serplulimab [1]
PD-1
sqNSCLC, ES-SCLC, ESCC, nsNSCLC

HLX01 (rituximab) [2]
CD20
NHL, CLL, RA [3]

HLX02 (trastuzumab) [4]
HER2
BC, mGC

HLX03 (adalimumab) [5]
TNF-α
RA, AS, Ps, UV, pJIA, pediatric Ps, CD, pediatric CD

HLX04 (bevacizumab) [6]
VEGF
mCRC, NSCLC, GBM, HCC, EOC, FTC or PPC, CC

HLX901 (neratinib) [7]
HER1/HER2/HER4
Extended adjuvant treatment of BC

NDA

HLX04-O [8]
VEGF
Wet AMD

HLX14 [9] (denosumab)
RANKL
Osteoporosis, etc.

HLX11 [10] (pertuzumab)
HER2
BC

Phase 3

Serplulimab [1] **+ Chemo**
PD-1
ES-SCLC 1L

Serplulimab [1] **+ Chemo**
PD-1
Neo/adjuvant treatment for GC

Serplulimab [1] **+ Chemo + Radio**
PD-1
LS-SCLC 1L

Serplulimab [1] **+ bevacizumab + Chemo**
PD-1+VEGF
mCRC 1L

HLX04-O [8]
VEGF
Wet AMD

HLX22 [11] **+ trastuzumab+Chemo**
HER2+HER2
GC

HLX87 [12]
HER2
HER2+ BC

HLX78 [13] (lasofoxifene)
SERM
BC

Phase 2

Serplulimab [1] **+ HLX07** [14]
PD-1+EGFR
Solid tumours (sqNSCLC, etc.)

Serplulimab [1] **+ HLX26 +Chemo**
PD-1+LAG-3
NSCLC 1L

HLX07 [14]
EGFR
Solid tumours (cSCC, etc.)

HLX53 + Serplulimab [1] **+ bevacizumab**
TIGIT + PD-1 + VEGF
HCC

HLX22 [11] **+ T-DXd**
HER2
HER2-low/HR+ BC

HLX43 [15]
PD-L1 ADC
Solid tumours (NSCLC, etc.)

HLX208 [16]
BRAF V600E
LCH/ECD, MEL, NSCLC, etc.

HLX208 [16] **+ Serplulimab** [1]
BRAF V600E + PD-1
NSCLC

HLX79 [17] **+ Rituximab** [2]
Sialidase Fc Fusion Protein + CD20
Active Glomerular Diseases

Phase 1

HLX6018
GARP/TGF-β1
IPF

HLX701 [18]
CD47-SIPRα Blockade
Solid tumour

HLX42 [19]
EGFR ADC
Solid tumours

HLX43 [15] **+ Serplulimab** [1]
PD-L1 ADC + PD-1
Solid tumours

HLX05 [20] (cetuximab)
EGFR
mCRC, HNSCC

HLX15 [21] (daratumumab)
CD38
Multiple myeloma

HLX13 [22] (ipilimumab)
CTLA-4
Melanoma, HCC, etc.

Pre-IND / IND

HLX17 (pembrolizumab)
PD-1
NSCLC, TNBC, etc.

HLX316
B7H3 x Sialidase
Solid tumor

HLX105
Fusion protein
Solid tumor

HLX318
BAFF x TACI x BCMA
autoimmune disease

HLX37
PD-L1 x VEGF Bispeciifc
Solid tumors

HLX3901
DLL3 x CD3 x CD28 TsAb
SCLC

HLX3902
STEAP1 x CD3 x CD28 TsAb
PCa

HLX41
LIV-1 ADC
BC

HLX48
EGFR x cMet BsADC
NSCLC, CRC

HLX97
KAT6A/B
ERα + Breast Cancer

HLX18 (nivolumab)
PD-1
Solid tumours (NSCLC, MEL, etc.)

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

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

(1) Approved in ~40 countries, including China, the UK, Germany, India, Singapore, trade name: Hetronifly® in Europe. Business partners: KGbio/Fosun Pharma/Intas/Lotus
(2) Approved in countries such as China and Peru. The first biosimilar approved in China. Business partners: Fosun Pharma/Eurofarma/Abbott/Boston Oncology.
(3) The first rituximab approved for the indication in China.
(4) Approved in 50+ countries, including China, U.S., the UK, Germany, France and Australia, trade name in U.S.: HERCESSI™. Trade name in Europe: Zercepac®. Business partners: Accord/ Cipla/ Jacobson/ Elea/ Eurofarma/ Abbott/ KGbio/ Getz
(5) Business partners: Fosun Wanbang/Getz Pharma.
(6) Approved in countries such as China and Bolivia. Business partners: Eurofarma.
(7) Exclusive license obtained in China.
(8) NDA under review in China. IND approvals obtained in Australia/the U.S./Singapore/EU countries, etc. Business partner: Essex.
(9) Marketing applications under review in the EU and the U.S. Business partner: Organon.
(10) Marketing applications under review in China, the U.S. and the EU. Business partner: Organon.
(11) IND approvals obtained in China/the U.S./Japan/the EU.
(12) The development and exclusive commercialisation 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 license obtained in China.
(18) 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.
(19) IND approvals obtained in China/the U.S. and granted FDA Fast Track Designation.
(20) Business partner: Shanghai Jingze.
(21) Business partner: Dr. Reddy's, etc.
(22) Business partner: Sandoz, etc.

MANAGEMENT DISCUSSION AND ANALYSIS

I. BUSINESS REVIEW FOR THE FIRST HALF OF THE YEAR

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 22 August 2025, being the latest practicable date (the "**Latest Practicable Date**") for the publication of this announcement, 6 products (25 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 4 products approved for marketing in multiple overseas markets. Such 6 products reached nearly 60 countries/regions, benefiting over 850,000 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 July 2025, a biosimilar of denosumab HLX14 (recombinant anti-RANKL human monoclonal antibody injection) received a positive opinions from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), recommending the approvals of the two marketing authorization applications (MAAs) for two strengths, laying the foundation for HLX14 to entry a broader overseas market imminently.

(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 development process of pipeline products both at home and abroad. During the Reporting Period, the Group achieved 12 investigational new drug application (IND) approvals and 11 new drug application (NDA) approvals spanning approximately 50 countries, including China, the United States, and Europe. 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 develop, manufacture and commercialise a biosimilar of daratumumab HLX15 (recombinant anti-CD38 human monoclonal antibody injection) in the United States and agreed European region.

- In March 2025, the Group entered into a product exclusive license and supply agreement with Fosun Industrial Co., Limited, pursuant to which the Company agreed to grant an exclusive license to commercialise HANSIZHUANG (serplulimab injection) in Hong Kong and Macau regions of China.

- 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 develop and commercialise HANSIZHUANG (serplulimab injection) in the Republic of Korea.

- In April 2025, the Company entered into a license agreement with Sandoz AG, pursuant to which the Company agreed to grant a license to develop, manufacture, and commercialize 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.

Separately, in light of the actual progress of the earlier licensing collaboration with FARMA DE COLOMBIA S.A.S. for HANLIKANG in Colombia, Peru, and other markets, the Group signed a termination agreement in August 2025. The Group will continue to explore new partnering opportunities for HANLIKANG worldwide.

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 licenses-out areas covering the United States, Europe, Southeast Asia, India, the Republic of Korea and emerging countries and regions, 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 for adult patients with extensive-stage small cell lung cancer (ES-SCLC) was approved for marketing in the EU.

- During May to June 2025, 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 30 countries and regions and has been granted Orphan-drug Designations by drug regulatory authorities in the United States, the EU, Switzerland and the Republic of Korea, respectively.

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 country level, covering over 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. The Group will also work closely with partners such as Abbott, Europharma, 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.

- 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, relevant production lines at Songjiang First Plant also underwent pre-approval GMP inspections by the FDA for HLX11 and HLX14, and, in parallel, pre-approval GMP inspections by the Shanghai Medical Products Administration for HLX11, along with production license inspections for HLX14 registration in Mainland China (excluding Hong Kong, Macau and Taiwan regions of the People's Republic of China (the "**PRC**" or "**China**") ("**Mainland China**")). In addition, during the Reporting Period, the Plant has successfully passed the ISO 14001 environmental management system certification and ISO 45001 occupational health and safety management system certification, and obtained the accreditation marks of International Accreditation Forum (IAF) and Deutsche Akkreditierungsstelle GmbH (DAkkS).

- In order to meet the Group's long-term demand for commercial production capacity, the construction of the Phase I project of Songjiang Second Plant, with a total planned land area of 200 acres, started in 2019. The designed production capacity for the first and second stages of this project 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.

(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 patients 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 SIRPα-Fc fusion protein within Mainland China, Hong Kong and Macau regions of China, and specific countries in Southeast Asia. In August 2025, the Company entered into a strategic collaboration with GeneQuantum Healthcare (Suzhou) Co., Ltd., pursuant to which, the Company obtained the development and exclusive commercialisation rights for the innovative HER2-targeted antibody-drug conjugate (ADC) GQ1005 in China and specific overseas countries and regions.

As of the Latest Practicable Date, the Group has a total of approximately 50 molecules in its pipeline and over 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 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 and the human sialidase fusion protein + CD20 project.

- 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 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 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 July 2025, an investigational new drug application (IND) for a phase 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 patients with advanced/metastatic solid tumours was submitted to the NMPA and was accepted in the same month.

- In August 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 submitted to the United States Food and Drug Administration (FDA) and was 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) and HLX04-O (VEGF), for a range of indications, such as solid tumours, non-small cell lung cancer (NSCLC), gastric cancer (GC), breast cancer (BC), small cell lung cancer (SCLC), wet age-related macular degeneration (wAMD) and hepatocellular carcinoma (HCC). As of 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 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 Mainland China 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 Mainland China. During the Reporting Period, the Company commenced several phase 2 clinical trials of HLX43 for different indications in Mainland China.

- In June and August 2025, the first patient in China and the first patient in the United States were dosed in an international multi-centre phase 2 clinical study of HLX43 in patients with advanced non-small cell lung cancer (NSCLC), respectively. Such international multi-centre clinical study was also permitted to commence in Australia and Japan in June and July 2025, respectively.

- In July 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.

During the Reporting Period, the phase 1 clinical trial results of HLX43 were first released at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting. The data demonstrated that HLX43 has good safety profiles across all dose levels and exhibited encouraging anti-tumour activity in patients with advanced/metastatic solid tumours, particularly in non-small cell lung cancer (NSCLC) and thymic squamous cell carcinoma (TSCC). Investigator-assessed objective response rate (ORR) in solid tumour (phase 1a) was 36.8%, among which, ORR in thymic squamous cell carcinoma (TSCC) was 75% (3/4). Investigator-assessed ORR in non-small cell lung cancer (NSCLC) (phase 1b 2.0 mg/kg cohort) was 38.1%, among which, ORR in squamous NSCLC was 40%, and the disease control rate (DCR) in NSCLC patients with brain metastasis reached 100%.

In addition, updated data from the phase 1 clinical study results of HLX43 will be released at the World Conference on Lung Cancer (WCLC) 2025. According to the selected research abstracts released by the conference, HLX43 continues to demonstrate a high response rate in patients with advanced solid tumors, particularly in pretreated non-small cell lung cancer (NSCLC) patients who failed checkpoint inhibitor therapy. HLX43 exhibits superior efficacy in specific subgroups, with an objective response rate (ORR) of 47.4% in EGFR wild-type non-squamous NSCLC, while maintaining a favorable safety profile.

HLX22 (recombinant humanised anti-HER2 monoclonal antibody injection)

- In March and May 2025, Orphan-drug Designations 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 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 Mainland China.

- In March and July 2025, the first patients in Japan and the United States 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 was also permitted to commence in an EU country (Germany) in April 2025. The study is currently being conducted simultaneously in Mainland China, the United States, Australia, Japan and other countries/regions.

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 months (95% CI: 5.7, 21.4). Objective response rate (ORR) was 87.1% (95% CI: 70.2, 96.4) and 80.6% (95% CI: 62.5, 92.5), respectively. Safety profiles were comparable between the two groups. These updated findings further confirm the significant 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).

- As at the Latest Practicable Date, over 100 sites have been set for the bridging study in the United States for HANSIZHUANG in combination with chemotherapy for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC), and the recruitment of subjects is progressing steadily.

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 of 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.

Other products

- In January and March 2025, the new drug applications for a biosimilar of pertuzumab HLX11 (recombinant anti-HER2 domain II humanised monoclonal antibody injection) were accepted by the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA), respectively.

- In April 2025, a phase 3 clinical study of HLX04-O (recombinant anti-VEGF humanised monoclonal antibody injection) for the treatment of wet age-related macular degeneration (wAMD) in Chinese patients met the primary study endpoints. 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 human monoclonal antibody injection) for the first-line treatment of patients with unresectable advanced hepatocellular carcinoma (HCC) in Mainland China.

- In July 2025, a biosimilar of denosumab HLX14 (recombinant anti-RANKL human monoclonal antibody injection) received positive opinions from the Committee for Medicinal Products for Human Use (CHMP) of the EMA, recommending the approvals of the two marketing authorisation applications (MAAs) for two strengths.

- In August 2025, the first patient was dosed in a phase 2 clinical study of HLX79 injection (human sialidase fusion protein) in combination with HANLIKANG (rituximab injection) for the treatment of active glomerulonephritis in Mainland China.

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)	In June 2025, the first patient has been dosed in an international multi-centre phase 2 clinical study in Mainland China In June 2025, the international multi-centre phase 2 clinical study was permitted to be conducted in Australia In July 2025, the international multi-centre phase 2 clinical study was permitted to be conducted in Japan In August 2025, first patient in the United States has been dosed in an international multi-centre phase 2 clinical study
HLX43 (PD-L1 ADC)	Solid tumour	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
HLX43 (PD-L1 ADC)	Solid tumour (including esophageal squamous cell carcinoma (ESCC))	In January 2025, the first patient has been dosed in a phase 2 clinical study for the treatment of recurrent/metastatic esophageal squamous cell carcinoma During the Reporting Period, the Company has initiated several phase 2 clinical studies for different indications in Mainland China
HLX43 in combination with HANSIZHUANG (PD-L1 ADC+PD-1)	Solid tumour	In January 2025, an investigational new drug application for the phase 1b/2 clinical trial was approved by the NMPA In April 2025, the first patient has been dosed in a phase 1b/2 clinical study in Mainland China

Product name (targets)	Indications	Progress as of the Latest Practicable Date
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	In March 2025, first patient in Japan has been dosed in an international multi-centre phase 3 clinical trial In April 2025, the international multi-centre phase 3 clinical study was permitted to be conducted in EU countries (Germany) In July 2025, first patient in the United States has been 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 has been dosed in a phase 2 clinical study in Mainland China
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 be conducted in Japan In June 2025, the first patient in the bridging study in Japan has been dosed As at the Latest Practicable Date, over 100 sites have been set for the bridging study in the United States, and the recruitment of subjects is progressing steadily
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

Product name (targets)	Indications	Progress as of the Latest Practicable Date
Global development progress of other products		
HLX11 (HER2)	Breast cancer (BC)	In January 2025, the biologic license application (BLA) was accepted by the FDA In March 2025, the marketing authorisation application (MAA) was accepted by the EMA
HLX04-O (VEGF)	Wet age-related macular degeneration (wAMD)	In April 2025, a phase 3 clinical study met the primary study endpoint In August 2025, the new drug application (NDA) was accepted by the NMPA
HLX13 (CTLA-4)	Hepatocellular carcinoma (HCC)	In May 2025, the first patient has been dosed in a phase 1/3 clinical study in Mainland China
HLX14 (RANKL)	Osteoporosis (OP) etc.	In July 2025, received positive opinions from the Committee for Medicinal Products for Human Use (CHMP) of the EMA, recommending the approval of the two marketing authorisation applications (MAAs) for two strengths
HLX79 in combination with HANLIKANG (Human sialidase fusion protein + CD20)	Active glomerulonephritis	In August 2025, the first patient has been dosed in a phase 2 clinical study in Mainland China

Product name (targets)	Indications	Progress as of the Latest Practicable Date
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 for phase 1b/2 clinical trial was approved by the NMPA (Already in clinical phase in Mainland China)
HLX99 (Polypharmacology)	Amyotrophic lateral sclerosis (ALS)	In February 2025, an investigational new drug application was approved by the FDA
HLX79 in combination with HANLIKANG (Human sialidase fusion protein + CD20)	Active glomerulonephritis	In March 2025, an investigational new drug application for a phase 2 clinical trial was approved by the NMPA (Already in clinical phase in Mainland China)
HLX43 in combination with HLX07 (PD-L1 ADC+EGFR)	Advanced/metastatic solid tumors	In July 2025, an investigational new drug application for phase 2 clinical trial was submitted to and accepted by the NMPA
HLX17 (PD-1)	Various resected solid tumours	In August 2025, an investigational new drug application for phase 1 clinical trial was submitted to and accepted by the FDA

(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 1,500 people, promoting the commercialisation of six products, including HANQUYOU and HANSIZHUANG, in an orderly manner in Mainland China.

1. 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

HANQUYOU is the core product of the Group in the field of anti-tumour therapy, and was independently developed by the Group in accordance with the relevant regulations on biosimilar drugs of Mainland China, the EU, and the United States. In Mainland China, HANQUYOU has continued to penetrate the domestic market and generate significant sales revenue for the Group leveraging the Group's efficient market access and sales execution capabilities, as well as the differentiated advantages offered by HANQUYOU's flexible dose portfolio of 150mg and 60mg. 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.

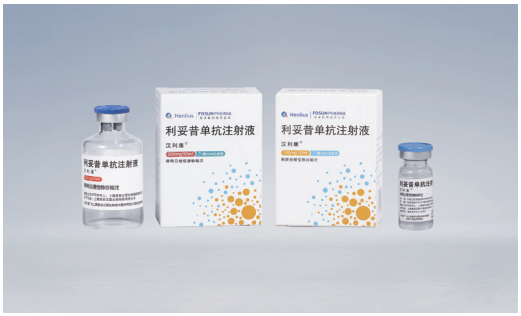
HANNAIJIA is an oral small-molecule pan-HER tyrosine kinase inhibitor (TKI) for the extended adjuvant therapy of HER2-positive early breast cancer in adult patients after adjuvant therapy containing trastuzumab. HANNAIJIA and HANQUYOU can achieve sequential synergy, with the potential to further reduce 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 Mainland China. 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.

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

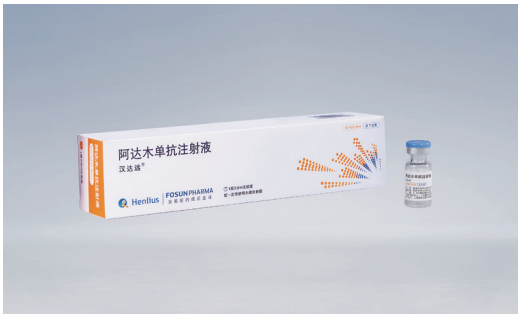
HANSIZHUANG is a core innovative PD-1 monoclonal antibody product independently developed by the Group. Several of its key clinical study results have been published in prestigious journals, including the Journal of the American Medical Association (JAMA) (《美國醫學會雜誌》), Nature Medicine (《自然－醫學》), Cancer 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 Mainland China for the first-line treatment in combination with chemotherapy for squamous non-small cell lung cancer (sqNSCLC), extensive-stage small cell lung cancer (ES-SCLC), esophageal squamous cell carcinoma (ESCC), and non-squamous non-small cell lung cancer (nsNSCLC). It has become the first monoclonal antibody drug targeting PD-1 approved for first-line treatment of extensive-stage small cell lung cancer (ES-SCLC) around the world, and its differentiated advantages of focusing on small cell lung cancer are uniquely competitive in the PD-1 market.

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 Mainland China. Its domestic commercial sale is undertaken by Fosun Wanbang (Jiangsu) Pharmaceutial 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 Mainland China, 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 Mainland China, 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.

II. OUTLOOK FOR THE SECOND HALF OF 2025

In the second half of the year, 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". At the same time, as the Group increased shipment in overseas markets, its revenue and profit are expected to grow considerably in overseas markets throughout 2025 and maintain high-speed growth in 2026, with global profitability rising to a new level.

(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 the second half of the year, the Group will continuously promote the marketing approval process of more products in the global market with experiences gained along the way.

- In the second half of the year, HANSIZHUANG in combination with chemotherapy for extensive-stage small cell lung cancer (ES-SCLC) and squamous non-small cell lung cancer (sqNSCLC) indications is expected to be approved for marketing in more countries or regions, accelerating the penetration of Europe, Latin America, Southeast Asia and other markets.

- The biologic license application (BLA) for a biosimilar of pertuzumab HLX11 is expected to be approved in the United States in the second half of the year.

- The marketing authorisation applications for a biosimilar of denosumab HLX14 are expected to be approved in the United States, EU and Canada in the second half of the year, while its new drug application in Mainland China is planned to be submitted to the NMPA in the second half of the year.

- Over 100 sites have been set for the bridging study in the United States for HANSIZHUANG in combination with chemotherapy for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC), and all subject recruitment and enrolment are expected to be completed in the second half of the year.

- In the second half of the year, 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 Mainland China, the United States, the EU, Canada, Japan, the United Kingdom, Switzerland, 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, further expanding the international influence of its products. The Group will also continuously work closely with international partners and leverage the commercial capability of partners in their own field to effectively integrate the Group's products into the local market to benefit a wide range of overseas patients and achieve long-term win-win results.

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

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 the second half of the year, several products, such as small molecule drug HLX97 (KAT6A/B), monoclonal antibody, bispecific and multispecific antibody products HLX18 (PD-1), HLX37 (PD-L1 × VEGF) and HLX3901 (DLL3 × CD3 × CD28), and targeting sialidase fusion protein HLX316 (B7-H3 × Sialidase), are planned to submit Investigational New Drug (IND) applications in Mainland China and the United States, respectively, further enriching the Group's product pipeline.

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. Songjiang First Plant will continue to improve its international standard quality system and is expected to undergo pre-marketing GMP inspections for HLX04-O and HLX14 in Mainland China in the second half of 2025. In the second half of the year, the supply scope of Songjiang First Plant is expected to expand from the current China and U.S. markets to include the supply of more products to the U.S. and European markets. Songjiang Second Plant will expedite the preparatory work for the market supply of HLX14 in the EU the United States, and 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 the second half of the year, 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, in leading hospitals, 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.

- 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 the second half of the year, the Group will continue to uphold the differentiated product strategy, strengthen the competitive advantages of HANSIZHUANG, consolidate its leading position in the treatment of small cell lung cancer, and further expand its market share in the treatment fields including non-small cell lung cancer and esophageal cancer, so that more patients can benefit from it.

- In the second half of the year, HANBEITAI will continue to focus on the dual-channel market 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 the second half of the year, 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, the Group remained committed to the mission of "benefiting patients worldwide with high-quality biomedicines" and the principle of "patient-centered". We, underpinned by our innovation efforts and driven by globalization, have continued to enhance our commercial and operational capabilities and our core competitiveness. We also followed the strategy of differentiation, concentrating on the unmet clinical demands and maximizing the strength of our integrated platform. To further improve and streamline our management system, we constantly improved our strategic blueprint and operational efficiency. Steadily and continuously, our Group recorded profits by expanding product portfolio in strategic areas and widening our sales channels during the Reporting Period. Also, we have engaged in diverse strategic collaborations with more partners, laying a solid foundation for the sustainable development and accelerating the expansion of the global markets. During the Reporting Period, revenue from sales of overseas products of the Group amounted to approximately RMB40.6 million, and profit from overseas products achieved more than 2 times as compared with the same period of last year.

As an international and innovative biopharmaceutical company, the Group has upheld the principle of prioritizing clinical demands. Our core products have successively gained authoritative recognition both in the global mainstream biopharmaceutical markets and emerging markets, significantly accelerating our overseas market expansion. The Group will continue to integrate international resources and our own strengths to explore cutting-edge innovative products with outstanding clinical value. While actively expanding the Chinese market, we will propel and implement business collaboration for our self-developed products in international markets.

(I) Revenue

During the Reporting Period, the Group realised an operating income of approximately RMB2,819.5 million, representing an increase of approximately 2.7% compared to the same period 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 in-house team to conduct commercialisation promotion. It was commercially available on the domestic market in August 2020. During the Reporting Period, HANQUYOU recorded a sales revenue of approximately RMB1,407.4 million, representing an increase of approximately RMB1.2 million as compared to the same period in the last year. Zercepac® and HERCESSI™ recorded overseas sales revenue of approximately RMB36.8 million.

HANSIZHUANG (serplulimab) was the first self-developed and approved bioinnovative drug of the Group and was commercially available in the domestic market in March 2022. The approval of HANSIZHUANG will further enrich the Group's commercial product line and will also bring more treatment options for domestic patients. During the Reporting Period, HANSIZHUANG recorded sales revenue of approximately RMB593.9 million. Zerpidio® and Hetronifly® recorded sales revenue of approximately RMB3.8 million.

HANBEITAI (bevacizumab) is the fourth biosimilar product of the Group approved for marketing in Mainland China and commercialised by the Group's in-house team. It was commercially available in the domestic market in January 2023. During the Reporting Period, HANBEITAI recorded sales revenue of approximately RMB116.3 million, representing an increase of approximately RMB29.6 million as compared to the same period last year.

In respect of HANLIKANG (rituximab), according to the cooperation agreement with Fosun Pharma, Fosun Pharma would reimburse all the expenses related to the clinical trials of HANLIKANG incurred by the Group after the relevant cooperation agreement was signed, and the Group was responsible for the production of HANLIKANG in China and the supply of HANLIKANG to Fosun Pharma after the commercialisation of HANLIKANG, and shall share the profits from the sales of HANLIKANG in China. During the Reporting Period, the Group recorded sales revenue of approximately RMB274.3 million, and licensing income of approximately RMB11.0 million under the aforementioned profit-sharing arrangement with its partners.

In respect of HANDAYUAN (adalimumab), according to the cooperation agreement with Fosun Pharma, Fosun Pharma would reimburse all the expenses related to the clinical trials of HANDAYUAN incurred by the Group after the relevant cooperation agreement was signed, and the Group was responsible for the production of HANDAYUAN in China and the supply of HANDAYUAN to Fosun Pharma after the commercialisation of HANDAYUAN, and shall share the profits from the sales of HANDAYUAN in China. During the Reporting Period, HANDAYUAN recorded sales revenue of approximately RMB27.4 million and licensing income 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 RMB96.8 million.

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

Adhering to a patient-centered strategy, the Group is committed to providing affordable and high-quality biomedicines for patients worldwide, and extending the licensed-out projects of these drugs to cover major mainstream biopharmaceutical markets in Europe and the United States and many emerging markets by making forward-looking steps in deploying a diversified and quality product pipeline. 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, commercialisation licensing, 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 licensing revenue of approximately RMB2.0 million for the six months ended 30 June 2025.

In September 2019, the Group entered into a co-development and commercialisation agreement with PT Kalbe Genexine Biologics in relation to HANSIZHUANG (serplulimab). With the continuous advancement of R&D services, the Group has recognised revenue from R&D services of approximately RMB6.1 million for the six months ended 30 June 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 RMB12.0 million for the six months ended 30 June 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 human monoclonal antibody injection) worldwide except for China, fully covering the United States., EU, Japan and other major biomedicine markets and many emerging markets. The Group has recognised revenue from R&D services of approximately RMB79.2 million for the six months ended 30 June 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), granting it the right of exclusive commercialisation of HANSIZHUANG (serplulimab) independently developed by the Group in the United States. The Group has recognised revenue from R&D services of approximately RMB66.7 million for the six months ended 30 June 2025.

In October 2023, the Group entered into a license agreement with Intas Pharmaceuticals Limited ("**Intas**") in relation to HANSIZHUANG (serplulimab), granting Intas exclusive developing and commercial rights in special territories as agreed therein. The Group has recognised licensing revenue of approximately RMB20.2 million for the six months ended 30 June 2025.

In December 2024, the Group entered into an agreement with Abbott, agreeing to grant Abbott a license to commercialize 5 products in specified territories, covering 69 countries and regions in Asia, Latin America, etc. The Group has recognised licensing revenue of approximately RMB40.7 million for the six months ended 30 June 2025.

3) Other R&D service businesses

The Group has recognised revenue from CMC technical service of approximately RMB21.5 million for the six months ended 30 June 2025.

(II) Cost of sales

Cost of sales of the Group primarily represents reagents and consumables, employee compensation, outsourcing expenses, utilities expenses and depreciation and amortisation. During the Reporting Period, the Group recorded cost of sales of approximately RMB620.4 million, representing a decrease of approximately RMB135.0 million as compared with that for the six months ended 30 June 2024, due to the decrease in the license cost of the Group.

(III) Gross profit

During the Reporting Period, the Group recorded a gross profit of approximately RMB2,199.2 million, representing an increase of approximately RMB208.5 million, as compared with that for the six months ended 30 June 2024, mainly due to the gross profit contribution from the license and the increase in the sales volume of 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 mainly 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 RMB20.1 million.

	Six months ended 30 June	
	2025	2024
	RMB'000	*RMB'000*
Government grants	**10,615**	10,706
Exchange gains	**–**	3,566
Interest income	**9,483**	10,309
Others	**28**	158
Total	**20,126**	24,739

(V) R&D expenditure

	Six months ended 30 June	
	2025	2024
	RMB'000	*RMB'000*
Expensed R&D expenses		
R&D employee salaries	**151,688**	152,537
Outsourcing fees	**128,078**	63,137
Reagents and consumables	**64,424**	50,821
Utilities expenses	**8,209**	5,104
Depreciation and amortisation	**24,314**	21,292
Consulting expense	**5,515**	16,365
Technology expense	**30,185**	11,261
Clinical trials	**150,208**	140,868
Others	**22,845**	21,081
Total expensed R&D expenses	**585,466**	482,466
Capitalised R&D expenses		
Clinical trials	**186,135**	95,010
R&D employee salaries	**86,502**	86,123
Reagents and consumables	**38,958**	42,164
Depreciation and amortisation	**17,872**	21,372
Utilities expenses	**5,791**	4,226
Outsourcing fees	**21,714**	14,421
Technology expense	**39,887**	65,493
Consulting expense	**2,072**	1,058
Others	**11,032**	13,272
Total capitalised R&D expenses	**409,963**	343,139

During the Reporting Period, the Group recognised R&D expenses of approximately RMB995.4 million, representing an increase of approximately RMB169.8 million as compared with approximately RMB825.6 million for the six months ended 30 June 2024. Such R&D expenses were mainly used to increase investment in innovative R&D projects to accelerate the Group's innovation and transformation.

(VI) Administrative expenses

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

During the Reporting Period, the Group recognised administrative expenses of approximately RMB185.4 million, representing an increase of approximately 15.9% as compared with that of approximately RMB159.9 million for the six months ended 30 June 2024. The increase in the Group's administrative expenses was mainly due to (1) the corresponding increase in conference fees and consulting expenses to improve the Company's operational efficiency; (2) the increase in office administrative expenses, housing-related expenses (property fee) and travel expenses.

(VII) Selling and distribution expenses

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

During the Reporting Period, the Group recognised selling and distribution expenses of approximately RMB987.8 million, which were mainly due to the marketing expenses incurred in the selling of HANQUYOU, HANSIZHUANG and HANBEITAI.

(VIII) Other expenses

The Group recognised other expenses of approximately RMB9.6 million, which were mainly impairment losses on assets of approximately RMB7.5 million, mainly including provision for loss on devaluation of inventories of certain raw materials, semi-finished products and finished products.

(IX) Income tax expense

For the six months ended 30 June 2025, the Group incurred income tax expenses of approximately RMB3.6 million.

(X) Profit for the period

In view of the above, profit of the Group increased by approximately RMB3.8 million from a profit of approximately RMB386.3 million for the six months ended 30 June 2024 to a profit of approximately RMB390.1 million for the six months ended 30 June 2025.

(XI) Liquidity and capital resources

As of 30 June 2025, cash and bank balances of the Group were approximately RMB889.2 million, mainly denominated in Renminbi ("**RMB**"), United States Dollars ("**USD**"), New Taiwan Dollars ("**NTD**"), Hong Kong Dollars ("**HKD**") and Euro ("**EUR**"). As of 30 June 2025, the current assets of the Group were approximately RMB3,222.1 million, including cash and cash equivalents of approximately RMB660.5 million and time deposits with maturity over three months of approximately RMB193.0 million.

As of 30 June 2025, the inventories were approximately RMB838.1 million, trade receivables were approximately RMB1,184.5 million, prepayments, deposits and other receivables were approximately RMB304.1 million and contract assets of approximately RMB6.2 million.

As of 30 June 2025, the current liabilities of the Group were approximately RMB4,724.8 million, including trade payables of approximately RMB774.0 million, other payables and accruals of approximately RMB975.6 million and contract liabilities of approximately RMB394.3 million and interest-bearing bank and other borrowings of approximately RMB2,580.9 million.

As at 30 June 2025, the foreign exchange bank balances of the Group were as follows:

	RMB'000
RMB	471,163
HKD	1,307
USD	411,192
EUR	2,704
NTD	2,794

	Original amount'000
RMB	471,163
HKD	1,433
USD	57,440
EUR	322
NTD	10,680

(XII) Inventories

Inventories of the Group increased from approximately RMB728.3 million as at 31 December 2024 to approximately RMB838.1 million as at 30 June 2025, mainly due to the increase in contract fulfillment costs.

(XIII) Trade receivables

As of 30 June 2025 and 31 December 2024, trade receivables from customer contracts were approximately RMB1,184.5 million and RMB857.4 million, respectively. There were no changes in accounting estimates or material assumptions made in the provision of the expected credit losses of trade receivables in both periods.

	30 June 2025	31 December 2024
	RMB'000	*RMB'000*
Within 3 months	**1,184,299**	856,286
3 to 6 months	**141**	1,144
6 to 12 months	**67**	–
Total	**1,184,507**	857,430

(XIV) Interest-bearing bank and other borrowings

As of 30 June 2025, borrowings from bank and other institutions (exclusive of lease liabilities) of the Group were approximately RMB3,465.8 million. The Group incurred new borrowings for the following reasons: ongoing clinical research trials and preclinical research for drug candidates, selling expenses of commercialisation of products, plant construction and normal operating expenses. The borrowings of the Group were denominated in RMB.

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

(XV) Maturity structure of outstanding debts

The following table sets forth the maturity structure of outstanding debts as at 30 June 2025 and 31 December 2024, of which lease liabilities were initially recognised upon the adoption of IFRS 16 – Leases on 1 January 2017.

	30 June 2025	31 December 2024
	RMB'000	*RMB'000*
Within one year	**2,580,880**	2,559,515
In the second year	**461,050**	348,137
In the third to fifth year (inclusive)	**616,471**	726,050
Over five years	**11,381**	14,484
Total	**3,669,782**	3,648,186

(XVI) Collateral and pledged assets

As of 30 June 2025, the Group's pledged assets in relation to borrowings included property, plant and equipment of approximately RMB1,120.4 million, land use right of approximately RMB186.3 million.

(XVII) Key financial ratios

	30 June 2025	31 December 2024
Current ratio[(1)]:	**68.2%**	49.9%
Quick ratio[(2)]:	**50.5%**	35.4%
Gearing ratio[(3)]:	**46.9%**	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 of the same day.

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

(XVIII) Material investment

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

The Company 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.

Save as disclosed in this announcement, as of 30 June 2025, the Group did not make other material investments.

(XIX) Capital commitments and capital expenditures

	30 June 2025	31 December 2024
	RMB'000	*RMB'000*
Construction in progress	**21,174**	256,114
Plant and machinery	**–**	14,881
Electronic equipment	**765**	2,968
Leasehold improvements	**6,211**	15,887
Total	**28,150**	289,850

We had capital commitments for plant and machinery contracted but not provided for of approximately RMB92.8 million as of 30 June 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 30 June 2025, the Group did not have any material contingent liabilities.

(XXI) Material acquisitions and disposals

As of 30 June 2025, the Group did not have any material acquisitions and disposals.

(XXII) Interim dividends

The Company did not pay or declare any dividend for the Reporting Period.

IV. RISK MANAGEMENT

(I) Foreign exchange risk

As at 30 June 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

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

3. Force Majeure Risk

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

V. EMPLOYEES AND REMUNERATION POLICIES

The following table sets forth the breakdown of our employees by function as at 30 June 2025:

Function	Number of employees
R&D and technology	943
Manufacturing	841
Commercial Operation	1,496
General and administrative	257
Total	**3,537**

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.

EVENTS AFTER THE REPORTING PERIOD

On 21 July 2025, the ordinary resolutions regarding the adoptions of the Share Option Scheme and the RSU Scheme of the Company were approved at the Company's extraordinary general meeting. For details of these schemes, please refer to the announcement of the Company dated 27 June 2025 and the circular of the Company dated 3 July 2025.

Except for those disclosed in this announcement, no major subsequent events have occurred since the end of the Reporting Period and up to the date of this announcement.

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 the sale of treasury shares).

INTERIM DIVIDEND

The Board does not recommend the distribution of any interim dividend for the Reporting Period.

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.

REVIEW OF INTERIM RESULTS BY THE AUDIT COMMITTEE

The Group's interim results for the six months ended 30 June 2025 have been reviewed by the audit committee of the Company.

INTERIM CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS

For the six months ended 30 June 2025

	Notes	**2025 (Unaudited) *RMB'000***	2024 (Unaudited) *RMB'000*
REVENUE	*3*	**2,819,540**	2,746,109
Cost of sales		**(620,359)**	(755,414)
Gross profit		**2,199,181**	1,990,695
Other income and gains	*4*	**20,126**	24,739
Selling and distribution expenses		**(987,798)**	(900,217)
Research and development expenses		**(585,466)**	(482,466)
Administrative expenses		**(185,408)**	(159,949)
Impairment losses on financial assets, net		**(3,002)**	–
Other expenses		**(9,562)**	(14,288)
Finance costs	*6*	**(54,337)**	(62,796)
PROFIT BEFORE TAX	*5*	**393,734**	395,718
Income tax expense	*7*	**(3,607)**	(9,417)
PROFIT FOR THE PERIOD		**390,127**	386,301
Attributable to:			
Owners of the parent		**390,127**	386,301
Non-controlling interests		**–**	–
		390,127	386,301
EARNINGS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic for profit for the period (RMB)	*9*	**0.72**	0.71
Diluted for profit for the period (RMB)	*9*	**0.72**	0.71

INTERIM CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

For the six months ended 30 June 2025

	2025 (Unaudited) *RMB'000*	2024 (Unaudited) *RMB'000*
PROFIT FOR THE PERIOD	**390,127**	386,301
OTHER COMPREHENSIVE INCOME/(LOSS)		
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	**2,698**	(345)
OTHER COMPREHENSIVE INCOME/(LOSS) FOR THE PERIOD, NET OF TAX	**2,698**	(345)
TOTAL COMPREHENSIVE INCOME FOR THE PERIOD	**392,825**	385,956
Attributable to:		
Owners of the parent	**392,825**	385,956
Non-controlling interests	**–**	–
	392,825	385,956

INTERIM CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

30 June 2025

	Notes	**30 June 2025 (Unaudited) *RMB'000***	31 December 2024 (Audited) *RMB'000*
NON-CURRENT ASSETS			
Property, plant and equipment		**2,274,669**	2,343,354
Intangible assets		**5,668,074**	5,355,204
Right-of-use assets		**357,684**	357,103
Other non-current assets		**27,469**	30,335
Total non-current assets		**8,327,896**	8,085,996
CURRENT ASSETS			
Inventories		**838,122**	728,266
Trade receivables	*10*	**1,184,507**	857,430
Contract assets		**6,212**	43,928
Prepayments, deposits and other receivables	*11*	**304,112**	108,938
Cash and bank balances		**889,160**	772,962
Total current assets		**3,222,113**	2,511,524
CURRENT LIABILITIES			
Trade payables	*12*	**774,022**	729,099
Other payables and accruals		**975,634**	1,299,350
Contract liabilities		**394,284**	444,033
Interest-bearing bank and other borrowings		**2,580,880**	2,559,514
Total current liabilities		**4,724,820**	5,031,996
NET CURRENT LIABILITIES		**(1,502,707)**	(2,520,472)
TOTAL ASSETS LESS CURRENT LIABILITIES		**6,825,189**	5,565,524

	30 June 2025 (Unaudited) *RMB'000*	31 December 2024 (Audited) *RMB'000*
NON-CURRENT LIABILITIES		
Interest-bearing bank and other borrowings	**1,088,902**	1,088,671
Other long-term payables	**170,433**	149,266
Contract liabilities	**1,903,915**	1,075,238
Deferred income	**253,791**	238,728
Total non-current liabilities	**3,417,041**	2,551,903
Net assets	**3,408,148**	3,013,621
EQUITY		
Share capital	**543,495**	543,495
Reserves	**2,864,653**	2,470,126
Equity attributable to owners of the parent	**3,408,148**	3,013,621
Total equity	**3,408,148**	3,013,621

1. BASIS OF PRESENTATION AND CHANGES TO THE GROUP'S ACCOUNTING POLICIES

1.1 BASIS OF PREPARATION

The interim condensed consolidated financial information for the six months ended 30 June 2025 has been prepared in accordance with IAS 34 *Interim Financial Reporting*. The interim condensed consolidated financial information does not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Group's annual consolidated financial statements for the year ended 31 December 2024.

The Group had net current liabilities of RMB1,502,707,000 as at 30 June 2025. Having taken into account the unused banking facilities and the expected cash flows from operating, investing and financing activities, the directors of the Company consider that it is appropriate to prepare the financial information on a going concern basis.

1.2 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The accounting policies adopted in the preparation of the interim condensed consolidated financial information are consistent with those applied in the preparation of the Group's annual consolidated financial statements for the year ended 31 December 2024, except for the adoption of the following amended IFRS Accounting Standard for the first time for the current period's financial information.

Amendments to IAS 21	*Lack of Exchangeability*

The nature and impact of the amended IFRS Accounting Standard are described below:

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 with and the functional currencies of group entities for translation into the Group's presentation currency were exchangeable, the amendments did not have any impact on the interim condensed consolidated financial information.

2. OPERATING SEGMENT INFORMATION

The Group is engaged in biopharmaceutical R&D, biopharmaceutical services and biopharmaceutical production and sales, which are 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

	For the six months ended 30 June	
	2025	2024
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Mainland China	**2,627,840**	2,489,605
Asia Pacific (excluding Mainland China)	**28,037**	2,171
North America	**101,513**	182,708
South America	**16,327**	5,161
Europe	**45,475**	66,331
Others	**348**	133
Total	**2,819,540**	2,746,109

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

Seasonality of operations

The Group's operations are not subject to seasonality.

3. REVENUE

An analysis of revenue is as follows:

	For the six months ended 30 June	
	2025	2024
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Revenue from contracts with customers	**2,818,116**	2,744,708
Revenue from other source		
Gross rental income	**1,424**	1,401
Total	**2,819,540**	2,746,109

Disaggregated revenue information for revenue from contracts with customers

Types of goods or services		
Sales of biopharmaceutical products	**2,556,783**	2,479,351
Licensing revenue	**74,441**	14,258
Research and development services	**185,418**	251,014
Others	**1,474**	85
Total	**2,818,116**	2,744,708
Timing of revenue recognition		
Transferred at a point in time	**2,619,814**	2,498,899
Transferred over time	**198,302**	245,809
Total	**2,818,116**	2,744,708

4. OTHER INCOME AND GAINS

An analysis of other income and gains is as follows:

	For the six months ended 30 June	
	2025	2024
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Government grants	**10,615**	10,706
Exchange gains	**–**	3,566
Interest income	**9,483**	10,309
Others	**28**	158
Total	**20,126**	24,739

5. PROFIT BEFORE TAX

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

		For the six months ended 30 June	
		2025	2024
		RMB'000	*RMB'000*
	Note	**(Unaudited)**	(Unaudited)
Cost of inventories sold		**457,574**	430,380
Cost of services provided		**162,785**	325,034
Depreciation of property, plant and equipment*		**82,240**	70,213
Depreciation of right-of-use assets*		**36,594**	34,323
Amortisation of intangible assets*		**101,755**	68,072
Research and development expenses:			
Current year expenditure		**585,466**	482,466
Foreign exchange gains, net		**1,660**	(3,566)
Write-down of inventories to net realisable value		**7,472**	13,254
Bank interest income	*4*	**(9,483)**	(10,309)
Loss on disposal of items of property, plant and equipment		**168**	46
Impairment of trade receivables		**3,092**	–
Reversal of impairment loss of other receivables		**(89)**	–
Gain on disposal of items of right-of-use assets		**(41)**	–
Loss on disposal of intangible assets		**132**	–

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

6. FINANCE COSTS

An analysis of finance costs is as follows:

	For the six months ended 30 June	
	2025	2024
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Interest expense on bank and other borrowings	**55,753**	69,150
Interest expense on lease liabilities	**5,117**	6,241
Less: Interest capitalised	**(6,533)**	(12,595)
Total	**54,337**	62,796

7. INCOME TAX

The provision for Mainland China current income tax is based on the statutory rate of 25% (six months ended 30 June 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 Mainland China, which are taxed at a preferential rate of 15%.

The provision for current income tax of Henlius USA Inc. incorporated in the United States and Henlius Industrial Co., Limited incorporated in Hong Kong are based on the statutory rates of 29.84% and 8.25% (six months ended 30 June 2024: 29.84% and 8.25%, respectively), respectively, for the six months ended 30 June 2025.

Taxes on profits assessable elsewhere have been calculated at the tax rates prevailing in the jurisdictions in which the Group operates.

	For the six months ended 30 June	
	2025	2024
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Current – Mainland China	**3,594**	9,417
Current – Europe	**13**	–
Total tax charge for the period	**3,607**	9,417

8. DIVIDENDS

No dividend has been paid or declared by the Company during the Reporting Period (six months ended 30 June 2024: Nil).

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 for the period attributable to ordinary equity holders of the parent and the weighted average number of ordinary shares of 543,494,853 (six months ended 30 June 2024: 543,494,853) in issue during the period.

The calculation of the diluted earnings per share amounts is based on the profit for the period attributable to ordinary equity holders of the parent. The weighted average number of ordinary shares used in the calculation is the weighted average number of ordinary shares in issue during the period, 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:

	For the six months ended 30 June	
	2025	2024
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Earnings		
Profit attributable to ordinary equity holders of the parent used in the basic earnings per share calculation	**390,127**	386,301

	Numbers of shares For the six months ended 30 June	
	2025	2024
	(Unaudited)	(Unaudited)
Shares		
Weighted average number of ordinary shares in issue during the period used in the basic and diluted earnings per share calculation	**543,494,853**	543,494,853

10. TRADE RECEIVABLES

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

	30 June 2025	31 December 2024
	RMB'000	*RMB'000*
	(Unaudited)	(Audited)
Within 3 months	**1,184,299**	856,286
3 to 6 months	**141**	1,144
6 to 12 months	**67**	–
Total	**1,184,507**	857,430

11. PREPAYMENTS, DEPOSITS AND OTHER RECEIVABLES

	Note	**30 June 2025** ***RMB'000*** **(Unaudited)**	31 December 2024 *RMB'000* (Audited)
Prepayments		**94,392**	44,278
Value added tax to be deducted and certified		**126,384**	23,890
Deposits and other receivables		**83,336**	40,770
Due from AMTD	*(i)*	**475,052**	477,029
		779,164	585,967
Impairment allowance	*(i)*	**(475,052)**	(477,029)
Total		**304,112**	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. During the year ended 31 December 2023, the Company further recovered an amount of USD20,000,000 from AMTD. As at 30 June 2025 and 31 December 2024, the outstanding balances of the investment principal in AMTD Account amounted to USD66,360,000 (equivalent to RMB475,052,000 and RMB477,029,000 respectively).

Based on the analysis by the Company's management and with the assistance of the Company's external legal counsel, it is clarified that when the IMA was terminated on 25 September 2021, the Company had the legal rights to recover all the outstanding investment amounts from AMTD. Therefore, the outstanding investment amount 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 amounting to USD66,360,000 was provided for the amount due from AMTD as at 30 June 2025 and 31 December 2024.

12. TRADE PAYABLES

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

	30 June 2025	31 December 2024
	RMB'000	*RMB'000*
	(Unaudited)	(Audited)
Within 1 year	**738,922**	692,208
1 to 2 years	**25,790**	36,869
2 to 3 years	**9,288**	–
Over 3 years	**22**	22
Total	**774,022**	729,099

13. EVENTS AFTER THE REPORTING PERIOD

On 27 June 2025, the Board resolved to approve the proposed adoption of the 2025 share option scheme and the restricted share unit scheme of the Company. The resolution was further approved at the extraordinary general meeting on 21 July 2025.

PUBLICATION OF INTERIM RESULTS AND INTERIM REPORT

This announcement is published on the website of the Hong Kong Stock Exchange at www.hkexnews.hk and on the website of the Company at www.henlius.com. The 2025 Interim Report containing all the information required by the Listing Rules will be published on the websites of the Company and the Hong Kong Stock Exchange in due course.

APPRECIATION

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

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

Hong Kong, 25 August 2025

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