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**Shanghai Henlius Biotech, Inc.**

**上海復宏漢霖生物技術股份有限公司**

*(A joint stock company incorporated in the People's Republic of China with limited liability)*

**(Stock code: 2696)**

## **INTERIM RESULTS ANNOUNCEMENT FOR THE SIX MONTHS ENDED 30 JUNE 2022**

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 2022 (the “**Reporting Period**”), prepared under International Financial Reporting Standards (“**IFRSs**”).

### **FINANCIAL SUMMARY:**

1. The Group’s total revenue increased by approximately RMB655.8 million or approximately 103.5% to approximately RMB1,289.4 million for the six months ended 30 June 2022, compared to approximately RMB633.6 million for the six months ended 30 June 2021. 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 2022, the Group recognised R&D clinical expenditure of approximately RMB827.4 million, representing an increase of approximately RMB88.1 million or approximately 11.9% as compared with approximately RMB739.3 million for the six months ended 30 June 2021; the Group continued to increase investment in innovative R&D projects to accelerate the innovation and transformation of the Company.
3. The Group’s loss for the period decreased by approximately RMB141.7 million to approximately RMB252.1 million for the six months ended 30 June 2022, compared to approximately RMB393.8 million for the six months ended 30 June 2021, mainly due to the successive commercialisation of core products and the constant sales expansion.

## **BUSINESS HIGHLIGHTS:**

### **1. HANQUYOU (trastuzumab injection, EU brand name: Zercepac®):**

- HANQUYOU (150mg): completed the tendering process on the procurement platform and was included into the medical insurance procurement platform for all provinces in Mainland China in the first half of 2021.
- HANQUYOU (60mg): completed the tendering process on the procurement platform in 26 provinces and was included into the medical insurance procurement platform in all provinces in Mainland China.
- Tuzucip®/Trastucip®(Australia brand name of trastuzumab injection): Tuzucip®/Trastucip®(150mg) was approved for marketing in Australia in July 2022.

### **2. HANSIZHUANG (serplulimab injection):** was approved for marketing in Mainland China in March 2022. As at the Latest Practicable Date, HANSIZHUANG completed the tendering process on the procurement platform in 18 provinces in Mainland China.

### **3. HANLIKANG (rituximab injection):**

- HANLIKANG (100mg/10ml): completed the tendering process on the procurement platform and was included into the medical insurance procurement platform in 30 provinces in Mainland China, and was procured by more than 70% of major hospitals.
- HANLIKANG (500mg/50ml): completed the tendering process on the procurement platform in 26 provinces and has been included into the medical insurance procurement platform in 14 provinces in Mainland China as at the end of the Reporting Period.

### **4. HANDAYUAN (adalimumab injection):** as at the Latest Practicable Date, completed the tendering process on the procurement platform in all provinces and has been included into the medical insurance procurement platform in 30 provinces in Mainland China.

### **5. HANBEITAI (bevacizumab injection):** the supplemental new drug application (sNDA) of HANBEITAI for the new indication of recurrent glioblastoma has been accepted by the NMPA in July 2022.

## **6. Business Expansion:**

- In February 2022, the Group entered into an agreement with Getz Pharma, pursuant to which, the Group agreed to grant a license to Getz Pharma to commercialise HANDAYUAN in Pakistan, Philippines, Vietnam and other regions.
- In May 2022, the Company entered into an agreement with Eurofarma, pursuant to which, the Company agreed to grant a license to Eurofarma to commercialise HANLIKANG, HANQUYOU and HANBEITAI in Brazil and regions around Brazil.
- In May 2022, the Company entered into an agreement with Abbott, pursuant to which, the Company agreed to grant a license to Abbott to commercialise HANLIKANG and HANQUYOU in Brazil.
- In June 2022, the Company entered into an agreement with Organon LLC, pursuant to which, the Company agreed to grant a license to Organon LLC and its affiliates to commercialise HLX11 (recombinant anti-HER2 domain II humanised monoclonal antibody injection) and HLX14 (recombinant anti-RANKL human monoclonal antibody injection) globally except for Mainland China, Hong Kong, Macau and Taiwan regions.

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

- Progress of international clinical study projects: HANSIZHUANG (serplulimab injection)
  - In January 2022, the phase 3 investigational new drug application (IND) of HANSIZHUANG in combination with chemotherapy (carboplatin/cisplatin-etoposide) and concurrent radiotherapy for the treatment of limited-stage small cell lung cancer (LS-SCLC) was accepted by the NMPA and was approved in March 2022. In May 2022, the first patient has been dosed in an international multi-centre phase 3 clinical study in Mainland China.
  - In April 2022, HANSIZHUANG has been granted orphan-drug designation for the treatment of small cell lung cancer (SCLC) by the United States Food and Drug Administration (FDA).

- Progress of international clinical study projects: Other products
  - In February 2022, HLX301 (recombinant anti-PD-L1 and anti-TIGIT bispecific antibody injection) completed its first patient dosing in a phase 1 clinical trial for the treatment of locally advanced or metastatic solid tumours in Australia.
  - In April 2022, HLX04-O (recombinant anti-VEGF humanised monoclonal antibody injection) completed its first patient dosing in an international multi-centre phase 3 clinical trial for the treatment of wet age-related macular degeneration (wAMD) in Latvia, Australia, etc. As at the Latest Practicable Date, HLX04-O (recombinant anti-VEGF humanised monoclonal antibody injection) for wet age-related macular degeneration (wAMD) has been approved in Australia, the United States, Singapore, and Latvia, Spain, Czech, Poland and other EU countries to carry out phase 3 clinical trial successively.
  - In April 2022, HLX20 (recombinant fully human anti-PD-L1 monoclonal antibody injection) has completed a phase 1 clinical trial conducted in patients with advanced solid tumours in Australia, and HLX20 has demonstrated its good safety and tolerability in this trial.
  - In June 2022, the first patient has been dosed in an international multi-centre phase 3 clinical trial of HLX14 (recombinant anti-RANKL human monoclonal antibody injection) for the treatment of postmenopausal osteoporosis in women with high fracture risks in Mainland China. In July 2022, this international multi-centre phase 3 clinical study was approved to commence in Australia.
- Progress of domestic clinical study projects : HANSIZHUANG (serplulimab injection)
  - In February 2022, the phase 2 investigational new drug application (IND) of HANSIZHUANG in combination with HLX07 (recombinant humanised anti-EGFR monoclonal antibody injection) and HANBEITAI for the first-line treatment of unresectable or metastatic hepatocellular carcinoma (HCC) was accepted by the NMPA and approved in April 2022.
  - In April 2022, the phase 1 investigational new drug application (IND) of HLX26 (recombinant anti-LAG-3 humanised monoclonal antibody injection) in combination with HANSIZHUANG for the treatment of advanced/metastatic solid tumours or lymphomas was approved by the NMPA. In August 2022, the first patient has been dosed in a phase 1 clinical trial of HLX26 in combination with HANSIZHUANG for the treatment of advanced/metastatic solid tumours in Mainland China.

- In May 2022, the phase 3 clinical study of HANSIZHUANG in combination with chemotherapy (Cisplatin + 5-FU) as a first-line treatment for patients with locally advanced/metastatic esophageal squamous cell carcinoma (ESCC), met the co-primary endpoints of progression-free survival (PFS) and overall survival (OS) in a planned interim analysis, evaluated by the Independent Data Monitoring Committee.
  - In June 2022, the enrollment of subjects was completed in a phase 3 clinical study of HANSIZHUANG in combination with HANBEITAI in combination with chemotherapy (carboplatin-pemetrexed) as a first-line treatment for advanced non-squamous, non-small cell lung cancer (nsNSCLC) in Mainland China.
- Progress of domestic clinical study projects: Other products
- In January 2022, the phase 1b/2 investigational new drug application (IND) of HLX208 (BRAF V600E inhibitor) monotherapy or in combination therapy for the treatment of BRAF V600E or BRAF V600 mutation-positive advanced solid tumours was approved by the NMPA. In the same month, the first patient has been dosed in the phase 2 clinical trial of HLX208 (BRAF V600E inhibitor) for the treatment of adult Langerhans Cell Histiocytosis (LCH) and Erdheim-Chester disease (ECD) with BRAF V600E mutation in Mainland China.
  - In January 2022, the investigational new drug application (IND) of HLX35 (recombinant humanised anti-EGFR and anti-4-1BB bispecific antibody injection) for the treatment of advanced malignant solid tumours was approved by the NMPA. In June 2022, HLX35 completed its first patient dosing in a phase 1 clinical trial for the treatment of advanced or metastatic solid tumours in Mainland China. The global commercialisation rights for HLX35 except for China (including Hong Kong, Macau and Taiwan regions) were granted to Binacea in November 2020, and phase 1 clinical study for the relevant indications in Australia has also been approved and progressed.
  - In January 2022, the investigational new drug application (IND) of HLX301 (recombinant anti-PD-L1 and anti-TIGIT bispecific antibody injection) for the treatment of advanced tumours has been accepted by the NMPA and approved in March 2022. In July 2022, the first patient has been dosed in a phase 1/2 clinical trial of HLX301 for the treatment of locally advanced/metastatic solid tumours or lymphomas in Mainland China.
  - In April 2022, the first patient has been dosed in a phase 3 clinical trial of HLX11 (recombinant anti-HER2 domain II humanised monoclonal antibody injection) for the neoadjuvant therapy of HER2-positive, HR-negative early or locally advanced breast cancer in Mainland China.

## **8. Efficient Advancement for Pre-Clinical Development Projects:**

- In April 2022, the phase 1 investigational new drug application (IND) of anti-TIGIT Fc fusion protein HLX53 for the treatment of advanced solid tumours or lymphomas was accepted by the NMPA and approved in June 2022.
- In June 2022, the application for phase 1 clinical trial of HLX60 (recombinant anti-GARP humanised monoclonal antibody injection) in combination with HANSIZHUANG for the treatment of advanced/metastatic solid tumours was submitted in Australia.

## **9. Biopharmaceutical Industrialisation Base Layout with International Standards and High Cost-Efficiency:**

During the Reporting Period, the Group has completed production capacity construction of 24,000L for the Songjiang First Plant in Songjiang District, Shanghai; at the same time, Songjiang First Plant has been approved to adopt the optimised new production process to carry out domestic commercial production of HANQUYOU. It also has passed the EU Qualified Person (QP) certification. The Songjiang First Plant and its supporting quality management system meet the requirements of the EU GMP, and products manufactured by it such as HLX04-O, HLX11 and HLX14 can carry out clinical trials in Europe. During the Reporting Period, the two main production buildings and the supporting public works and warehouses of the first and second stages of the Songjiang Second Plant Phase I project completed the entry and installation of large-scale equipment. For the third stage of the Songjiang Second Plant Phase I project, the foundation work has been completed.

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

# OUR PRODUCT PIPELINE

	Product	Target	Indication	Clinical Development Progress							Global business partners	
				Pre-clinical	IND	Phase 1	Phase 2	Phase 3	NDA	Launched		
Marketed products	HANLIKANG <sup>(1)</sup> (rituximab)	CD20	Non-Hodgkin lymphoma, chronic lymphocytic leukemia and rheumatoid arthritis <sup>(2)</sup>								FOSUNPHARMA 福森药业, CIPMA, Abbott, FOSUNPHARMA 福森药业	
	HANQUYOU <sup>(3)</sup> (trastuzumab)	HER2	Breast cancer and metastatic gastric cancer								accord, Cipla, jacobson, mabience, FOSUNPHARMA 福森药业, Abbott	
	HANDAYUAN <sup>(4)</sup> (adalimumab)	TNF-α	Rheumatoid arthritis, ankylosing spondylitis and psoriasis and uveitis								力邦医药, FOSUNPHARMA 福森药业, Getz	
	HANBEITAI <sup>(5)</sup> (bevacizumab)	VEGF	Metastatic colorectal cancer and locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer								eurofarma	
	HANSIZHUANG <sup>(6)</sup> (serplulimab)	PD-1	MSI-H solid tumours								YKgbio	
Multi research commercial visibility	HLX10 (serplulimab) <sup>(7)</sup>	+Chemo	Squamous non-small cell lung cancer									
			Extensive-stage small cell lung cancer									
	HANBEITAI (bevacizumab)	VEGF	Glioblastoma and hepatocellular carcinoma								eurofarma	
Under clinical research	HLX10 (serplulimab) <sup>(7)</sup>	+Chemo	PD-1	Metastatic esophageal squamous-cell carcinoma							★ Met Primary Endpoint OS & PFS	
			PD-1	Neo-/adjuvant treatment of gastric cancer								
		+Chemo +Radio	PD-1	Limited-stage small cell lung cancer								
				Non-squamous non-small cell lung cancer								
		+HANBEITAI	PD-1+VEGF	Hepatocellular carcinoma								
				Metastatic colorectal cancer								
			PD-1+EGFR	Squamous-cell carcinoma of the head and neck								
				Squamous non-small cell lung cancer								
	+HLX26	PD-1+LAG-3	Solid tumours									
	HLX04-O <sup>(8)</sup>	VEGF	Wet age-related macular degeneration								ESSEX, IZTIE	
	HLX11 (pertuzumab) <sup>(9)</sup>	HER2	Neoadjuvant treatment of breast cancer								Organon	
	HLX14 (denosumab) <sup>(10)</sup>	RANKL	Osteoporosis								Organon	
	HLX22	+HANQUYOU	HER2+HER2	Gastric cancer								
	HLX07 <sup>(11)</sup>		EGFR	Solid tumours (non-small cell lung cancer, esophageal carcinoma, etc.)								
	HLX208 <sup>(12)</sup>		BRAF V600E	Solid tumours (metastatic colorectal cancer, non-small cell lung cancer, etc.) LOH and ECD								
	HLX05 (cetuximab) <sup>(13)</sup>		EGFR	Metastatic colorectal cancer and squamous-cell carcinoma of the head and neck							Jingze	
	HLX12 (ramucirumab)		VEGFR2	Gastric cancer, metastatic non-small cell lung cancer and metastatic colorectal cancer								
	HLX26		LAG-3	Solid tumours and lymphomas								
	HLX35 <sup>(14)</sup>		EGFR x 4-1BB	Solid tumours							BINACEA	
	HLX301 <sup>(15)</sup>		PD-L1 x TIGIT	Solid tumours								
HLX13 (ipilimumab)		CTLA-4	Melanoma, renal cell carcinoma and metastatic colorectal cancer									
HLX15 (daratumumab)		CD38	Multiple myeloma									
HLX23 <sup>(16)</sup>		CD73	Solid tumours									
HLX53		TIGIT	Solid tumours and lymphomas									

(1) Approved by the NMPA in February 2019, being the first domestic biosimilar.  
 (2) The only rituximab injection approved for the treatment of rheumatoid arthritis in China.  
 (3) Approved for marketing in nearly 30 countries such as China, the United Kingdom, Germany, France, Australia, etc.; trade name registered in Europe: Zeropic<sup>®</sup>; trade name registered in Australia: Tuzucip<sup>®</sup> and Trastucip<sup>®</sup>  
 (4) Approved by the NMPA in December 2020.  
 (5) Approved by the NMPA in November 2021.  
 (6) Indication of MSI-H solid tumours approved by the NMPA in March 2022.  
 (7) IND approved in China, the United States, the EU etc.  
 (8) IND approved in China, Australia, the United States, Singapore, and the EU countries.  
 (9) Global commercialisation rights excluding mainland China, Hong Kong, Macao and Taiwan regions granted to Organon.  
 (10) Global commercialisation rights excluding mainland China, Hong Kong, Macao and Taiwan regions granted to Organon.  
 (11) IND approved in China and the United States.  
 (12) Commercialisation rights in China including Hong Kong, Macao and Taiwan regions were obtained.  
 (13) Commercialisation rights in mainland China have been granted to Shanghai Jingze.  
 (14) Global exclusive commercialisation rights excluding mainland China, Hong Kong, Macao and Taiwan regions granted to Binacea.  
 (15) IND approved in China and Australia.  
 (16) IND approved in the United States.

Core Products



## MANAGEMENT DISCUSSION AND ANALYSIS

### I. BUSINESS REVIEW IN THE FIRST HALF OF THE YEAR

As part of our commitment to provide affordable and high-quality biomedicines for patients worldwide, the Group has been dedicated to the continuous innovation and layout of the three major segments of R&D, production and commercialisation. During the Reporting Period, we have worked to promote the efficient development of the global commercialisation of product pipeline and implement production capacity deployment for the biomedicines with high economic benefit based on international standards. With great achievements in clinical development and drug registration of pipeline products, the Group was evolving from Biotech model to Biopharma model that is more scaled up and highly competitive in the market. During the Reporting Period, our marketed biosimilars, including HANLIKANG, HANQUYOU and HANDAYUAN witnessed steady progress in sales. HANLIKANG, for the treatment of the innovative indication of rheumatoid arthritis (RA) and HANSIZHUANG, the first self-developed innovative monoclonal antibody, were approved for marketing during the Reporting Period. In addition, the Group made significant progress in 10 clinical trials, and received approvals for multiple clinical trials worldwide for 5 products and 2 combined therapies, fully demonstrating the Group's strength in innovation and research and development.

As of 13 August 2022, being the latest practicable date for the issuance of this announcement (the "**Latest Practicable Date**"), 5 products (13 indications) of the Group have been successfully marketed in Mainland China (excluding Hong Kong, Macau and Taiwan regions of the People's Republic of China ("**PRC**") or ("**China**")) ("**Mainland China**"), 1 product has been successfully marketed in Europe and Australia, and new drug application for 3 indications of 2 products have been accepted in Mainland China.

#### (I) Strong global product commercialisation capability

During the Reporting Period, the Group actively implemented the concept of excellent commercialisation based on patients' needs. Our commercialisation team comprises of five major segments, namely market promotion, channel management, pricing and market access, domestic sales and strategic planning, covering the whole process of commercialisation, in order to achieve continuous growth in sales scale of products. As of the end of the Reporting Period, the Group's commercialisation team employed more than 800 employees in total, representing an increase of approximately 300 employees as compared to the year-end of 2021. Following the launch of HANLIKANG, the first monoclonal antibody approved in China in accordance with the Guidelines for the R&D and Evaluation of Biosimilars (Trial) (the "**Guidelines for Biosimilars**") in 2019, several core products of the Group such as HANQUYOU, HANDAYUAN, HANBEITAI and HANSIZHUANG, were successively approved for marketing in Mainland China. During the Reporting Period, the Group has also established cooperation with several internationally renowned partners for HANLIKANG, HANQUYOU, HANDAYUAN, HANBEITAI, HLX11 (recombinant anti-HER2 domain II humanised monoclonal antibody injection) and HLX14 (recombinant anti-RANKL human monoclonal antibody injection), obtaining remarkable achievements in internationalisation for self-developed products.

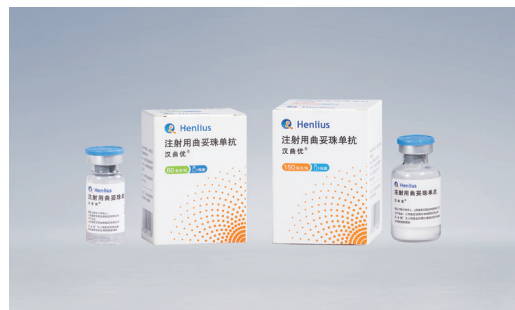


## 1 Commercialisation process of marketed core products

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

#### – Commercial sales of HANQUYOU in Mainland China

HANQUYOU is the core product of the Group in the field of anti-tumour therapy, and also the first product sold and promoted by the Group's in-house commercialisation team in Mainland China. As of the end of the Reporting Period, we hired more than 500 professional marketing personnel for the sales of HANQUYOU, with an aim to penetrate into the Mainland China market with efficient execution capacity. HANQUYOU (150mg) was



launched for commercial sales since August 2020, and completed the tendering process on the procurement platform and was included into the medical insurance procurement platform for all provinces in Mainland China in the first half of 2021. Since its approval for marketing in August 2021, HANQUYOU (60mg) completed the tendering process on the procurement platform in 26 provinces and was included into the medical insurance procurement platform in all provinces in Mainland China. In addition to the efficient market and access strategy providing a strong foundation for the overall sales growth of HANQUYOU, the flexible dose portfolio of 150mg and 60mg also brings personalised and more economical treatment options for patients with different weight ranges. It can also enhance clinical safety with its ready-to-use feature. During the Reporting Period, the Group cooperated with relevant enterprises in respect of physician education, medical big data, HER2 testing, innovative payment, patient management and education and has gained a good market reputation in the construction of diagnosis and treatment ecosystem for patients with HER2-positive breast cancer and gastric cancer, and conducted care action on pandemic response for patients with patients education organisation during Shanghai's pandemic lockdown, to do its best to care for patients in such a special time. In addition, biosimilars were added to the new Chinese Society of Clinical Oncology (CSCO) Guidelines for Diagnosis and Treatment of Breast Cancer in 2021. HANQUYOU was added to the new Chinese Society of Clinical Oncology (CSCO) Guidelines for Diagnosis and Treatment of Gastric Cancer in 2021, and biosimilars were also added to the new China Anti-Cancer Association, Committee of Breast Cancer Society Guidelines in 2021.

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

– Commercial sales of Zercepac® in Europe

Following Zercepac®(150mg) was approved for marketing in the European Union (the “EU”) in July 2020, Zercepac®60mg and 420mg were approved to be marketed in the EU, and Zercepac®150mg also was approved to be marketed in Switzerland as of the end of the Reporting Period.



The Group has worked with its business partner Accord Healthcare Limited (“**Accord**”) to promote the commercialisation of Zercepac® in Europe, parts of the Middle East and North Africa and some countries in Commonwealth of the Independent States. Zercepac® is also the first “Chinese” monoclonal antibody biosimilar drug approved for sale in the EU. As at the end of the Reporting Period, Zercepac® has been successfully marketed in the United Kingdom and approximately 20 European countries including Germany, Spain, France, Italy and Sweden.

– Tuzucip®/Trastucip® was approved for marketing in Australia

In July 2022, trastuzumab injection (150mg) granted by the Company to its business partner Cipla Limited for commercial purpose in Australia and other regions was approved for marketing in Australia under the brand name of Tuzucip® and Trastucip®. This was a further recognition on HANQUYOU by the international markets after marketing in Europe, which was a significant milestone of the Group in achieving the ambitious goal of providing affordable high-quality biomedicines for patients worldwide.

HANQUYOU is a trastuzumab developed and manufactured by the Group in accordance with relevant laws and regulations of China and the EU on biosimilars. As a representative domestic biologics to go global, HANQUYOU has successfully developed business cooperation with international business partners including Accord, Intas Pharmaceuticals Limited, Cipla Limited, Mabxience Research, S.L., Eurofarma Laboratorios S.A. (“**Eurofarma**”), Abbott Operations Uruguay S.R.L. (“**Abbott**”) in Europe, the United States, Canada, Australia, Argentina, Brazil, etc., with licensed-out projects covering approximately 100 countries and regions. The new drug application for HANQUYOU in Argentina is also expected to be approved recently.

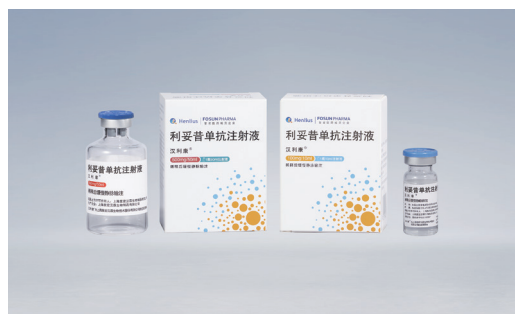
***HANSIZHUANG (serplulimab injection) was approved for marketing, bringing new treatment option for patients with advanced Microsatellite Instability-High (MSI-H) solid tumour***

In March 2022, PD-1 monoclonal antibody product HANSIZHUANG, a core innovative product self-developed by the Group, for the treatment of adult patients with advanced unresectable or metastatic Microsatellite Instability-High (the “MSI-H”) solid tumours that have failed to respond to the standard therapy, was conditionally approved by the NMPA, offering new immunotherapy option for patients. The indication is screened by specific MSI-H tumour markers rather than by cancer type, covering a wide range of patient groups. As of the end of the Reporting Period, HANSIZHUANG’s sales team has about 200 personnel, all of whom have professional operation experience in mature oncology market and have completed professional system training and certification, strengthening the Group’s overall planning for expanding domestic market. As of the Latest Practicable Date, we have completed the tendering process for HANSIZHUANG on the procurement platform in 18 provinces in Mainland China. In July 2022, the Group compiled the White Paper on Immunotherapy for Solid Tumours in China by cooperating with CSCO, laying a foundation for clinical study and standardised treatment, and facilitating the application of standardised immunotherapy.



***Commercial sales of HANLIKANG (rituximab injection) (a therapeutic product for hematological tumours and autoimmune diseases)***

In February 2022, HANLIKANG for the treatment of the innovative indication of rheumatoid arthritis (RA) was approved for marketing, which is used in combination with methotrexate to treat moderate to severe active rheumatoid arthritis (RA) in adult patients who have responded inadequately to one or more TNF- $\alpha$  inhibitors, providing a new drug option for patients with autoimmune diseases. This indication is an innovative indication developed by the Group based on the differentiated development strategy while which of the original drug has not been approved in Mainland China. HANLIKANG has advantages of less dosing frequency and lasting medicine effect in treatment of the innovative indication of rheumatoid arthritis (RA), which is expected to improve patients’ compliance and enhance patients’ quality of life as well as alleviate their medical burden, providing an additional bargaining power for the marketing and sales of HANLIKANG.

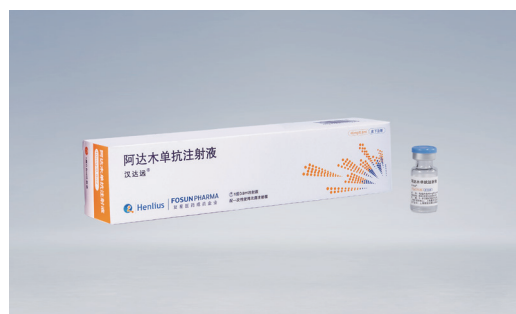


As at the Latest Practicable Date, HANLIKANG (100mg/10ml) has completed the tendering process on the procurement platform and was included into the medical insurance procurement platform in 30 provinces in Mainland China, and was procured by more than 70% of major hospitals, laying a base for the sales of HANLIKANG. HANLIKANG (500mg/50ml) has been launched and supplied since May 2021, and has completed the tendering process on the procurement platform in 26 provinces and was included into the medical insurance procurement platform in 14 provinces in Mainland China as at the end of the Reporting Period.

Jiangsu Fosun Pharmaceutical Sales Co., Ltd. (“**Jiangsu Fosun**”), a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd. (“**Fosun Pharma**”), the controlling shareholder of the Company, was responsible for the domestic commercial sale of HANLIKANG. As of the Latest Practicable Date, the specifications of HANLIKANG covered 100mg/10ml and 500mg/50ml, and its indications were further expanded to the field of autoimmune diseases on the basis of covering all the indications of the original drug approved in Mainland China in the field of hematology oncology. The implementation of both types of indications will cover more patient groups, which is expected to further increase the market influence of HANLIKANG. As the first monoclonal antibody drug approved for marketing under the Guidelines for Biosimilars in China in 2019, HANLIKANG has been approved for marketing for three years. As of the Latest Practicable Date, HANLIKANG has benefited more than 130,000 patients in China.

***Commercial sales of HANLAYUAN (adamumab injection) (a therapeutic product for autoimmune disease)***

HANLAYUAN is the third product of the Group marketed in Mainland China, which was granted marketing approval in December 2020. It has been approved for the indications of rheumatoid arthritis, ankylosing spondylitis, psoriasis and uveitis in Mainland China until now. As of the Latest Practicable Date, HANLAYUAN has completed the tendering process on the procurement platform in all provinces and was included into the medical insurance procurement platform in 30 provinces in Mainland China.



Jiangsu Wanbang (Group) Biopharmaceutical Co., Ltd. (“**Jiangsu Wanbang**”), a subsidiary of Fosun Pharma, the controlling shareholder of the Company, was responsible for the domestic commercial sale of HANLAYUAN. Jiangsu Wanbang has a sizeable Department of Rheumatology and Immunisation and a mixed-line sales team serving the broad market. The marketing team has a high level of professional communication skills and medical knowledge. In order to improve the standardised diagnosis and treatment services for patients with rheumatism in China, Jiangsu Wanbang established the first whole-course care platform “Da’en Home” (formally known as Dayuan Home) targeted for autoimmune patients in China, which integrates the functions of internet hospital, popular science education, public assistance, medical insurance, patient management, drug purchase map, and community care, with an aim to realise the whole-course management of patients from medical treatment to rehabilitation, and benefit more patients with convenient and standardised medical experience. In the first half of the year, Da’en Home served a total of more than 8,000 patients, covering consultation, diagnosis, treatment and prognosis. By giving full play of online platforms, Da’en Home provided assistance to patients during the pandemic. In addition, Jiangsu Wanbang took the lead in launching the “ASSC Ankylosing Spondylitis Standardised Treatment Project” in collaboration with the National Clinical Research Centre for Skin and Immune Diseases in respect of HANLAYUAN. Through a four-tier medical consortium network, we are working together to help standardise the treatment of ankylosing spondylitis in China. In the first half of the year, the project was implemented in other 3 provinces in China, and 4,000 more patients received standardised diagnosis and treatment, which benefited more than 18,000 patients in total.

***HANBEITAI (bevacizumab injection) was approved for marketing, providing high-quality drug options for patients with lung cancer and colorectal cancer***

In November 2021, HANBEITAI, the fourth biosimilar product of the Group, was approved for marketing in Mainland China for the treatment of metastatic colorectal cancer (mCRC), advanced, metastatic or recurrent non-small cell lung cancer, and was the only bevacizumab with phase 3 clinical data of patients with metastatic colorectal cancer in Mainland China. In July 2022, the supplemental new drug application (sNDA) for new indications of HANBEITAI to treat recurrent glioblastoma was accepted by the NMPA. In the second half of 2022, the Group will continue to facilitate the filing of the supplemental new drug application (sNDA) for new indications of HANBEITAI to treat hepatocellular carcinoma, epithelial ovarian, fallopian tube or primary peritoneal cancer and cervical cancer.



***2 Products to be commercialised in the near future***

***HANSIZHUANG (serplulimab injection) indications of squamous non-small cell lung cancer (sqNSCLC) and extensive-stage small cell lung cancer (ES-SCLC)***

An international multi-centre phase 3 clinical trial to compare HANSIZHUANG in combination with chemotherapy (carboplatin nab-paclitaxel) against chemotherapy (carboplatin nab-paclitaxel) as first-line therapy for locally advanced or metastatic squamous non-small cell lung cancer (sqNSCLC) completed enrollment of subjects and met the predefined primary study endpoint in 2021. Study data showed that the combined therapy may significantly prolong the progression-free survival (PFS) of patients. The new drug application (NDA) of this indication, which is the second indication for HANSIZHUANG submitted by the Company in Mainland China, was accepted by the Centre for Drug Evaluation of the NMPA in September 2021.

In April 2022, the new drug application (NDA) for the new indications of HANSIZHUANG in combination with chemotherapy (carboplatin-etoposide) as first-line therapy for previously untreated patients with extensive-stage small cell lung cancer (ES-SCLC) was accepted by the Centre for Drug Evaluation of the NMPA and this is the third indication for HANSIZHUANG submitted by the Company in Mainland China. In April 2022, HANSIZHUANG was granted orphan-drug designation for the treatment of small cell lung cancer (SCLC) by the United States Food and Drug Administration (FDA), which will help HANSIZHUANG to obtain certain policy support in follow-up R&D, registration and commercialisation in the United States. In June 2022, as the first independently developed first-line anti-PD-1 monoclonal antibody in the field of lung cancer in China, HANSIZHUANG was reported orally at the American Society of Clinical Oncology (ASCO) annual meeting. HANSIZHUANG is expected to become the first anti-PD-1 monoclonal antibody product for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC) in global, providing strong support for the differentiated sales strategy of HANSIZHUANG, and will also provide new treatment options for related patients.

### ***3 Commercialisation deployment in international markets during the Reporting Period***

During the Reporting Period, by adhering to the internationalisation strategy, the Group established cooperation globally with international partners such as Abbott, Organon LLC in respect of HANLIKANG, HANQUYOU, HANDAYUAN, HANBEITAI, HLX11 (recombinant anti-HER2 domain II humanised monoclonal antibody injection) and HLX14 (recombinant anti-RANKL human monoclonal antibody injection) within six months.

- In February 2022, the Group entered into an agreement with Getz Pharma (Private) Limited and its affiliated company, Getz Pharma International FZ-LLC (collectively, “**Getz Pharma**”), pursuant to which, the Group agreed to grant a license to Getz Pharma to commercialise HANDAYUAN in Pakistan, Philippines, Vietnam and other regions. According to the agreement, the Company is entitled to receive an upfront payment of \$500,000, and a milestone payment of up to \$7.5 million.
- In May 2022, the Company entered into an agreement with Eurofarma, pursuant to which, the Company agreed to grant a license to Eurofarma to commercialise HANLIKANG, HANQUYOU and HANBEITAI in Brazil and regions around Brazil. According to the agreement, the Company is entitled to receive an upfront payment of \$4.5 million, and a milestone payment of up to \$46.0 million.
- In May 2022, the Company entered into an agreement with Abbott, pursuant to which, the Company agreed to grant a license to Abbott to commercialise HANLIKANG and HANQUYOU in Brazil. According to the agreement, the Company is entitled to receive an upfront payment of \$3.0 million, and a milestone payment of up to \$1.4 million.
- In June 2022, the Company entered into an agreement with Organon LLC, pursuant to which, the Company agreed to grant a license to Organon LLC and its affiliates to commercialise HLX11 (recombinant anti-HER2 domain II humanised monoclonal antibody injection) and HLX14 (recombinant anti-RANKL human monoclonal antibody injection) globally except for Mainland China, Hong Kong, Macau and Taiwan regions. According to the agreement, the Company is entitled to receive an upfront payment of \$70.0 million, and a milestone payment of up to \$468.0 million.

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

As at the end of the Reporting Period, the Group with a total commercial production capacity of 48,000L has fully supported the commercialisation needs of domestic and overseas approved marketing products. Meanwhile, the production capacity of 96,000L was under construction, and it is expected to reach a total production capacity of 144,000L in 2026, with an aim to gradually improve and enhance large-scale commercial production capacity based on a sound quality management system, so that it can expand capacity and improve economic cost-effectiveness while maintaining high quality standards. In addition, the Group have continuously optimised the deployment of production technology, production cost control and other aspects in advance, which laid a solid foundation for the commercialisation of the Group's products in multiple jurisdictions.

### ***Xuhui Facility (granted with dual GMP certification of China and EU, with commercial production capacity of 24,000L)***

As at the end of the Reporting Period, the Group has established Xuhui Facility, a biopharmaceutical production base in Shanghai Caohejing Hi-Tech Park, covering a total area of approximately 11,000 square meters with commercial production capacity of 24,000L, which has been granted with Chinese and EU GMP certificates and achieved normalised supply in China and the EU markets. During the Reporting Period, Xuhui Facility continuously improved production efficiency through a series of lean management and process optimisation measures. Furthermore, during the Reporting Period, the Group also promoted works on the localisation of critical supplies, consumable materials for production, so as to minimise the risk related to material supply and equipment procurement against the prevailing international situation.

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

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

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

In order to meet the long-term demand on commercial production capacity, the construction of the Phase I project of Songjiang Second Plant, with a total planned land area of 200 mu was started in 2019. The designed production capacity for the first and second stages of this project is totaled 36,000L. The entry and installation of large-scale equipment of the two main production buildings and the supporting public works and warehouses has been completed. The main structure of the auxiliary production buildings was completed and accepted, and most of the main production facilities such as the drug substance lines and the drug product lines have completed the factory acceptance testing and been installed in place. In addition, other ancillary projects are progressing steadily. The designed production capacity of the third stage of the Phase I project of Songjiang Second Plant was 60,000L, covering a drug substance line consisting of four 15,000L stainless steel reactors, with its piling works completed in January 2022. The construction of the subsequent stage of Songjiang Second Plant will also be gradually implemented in accordance with the Group's strategy.

**(III) Sustainable global clinical development capability on medical products**

During the Reporting Period, based on clinical needs, the Group has orderly organised the development of innovative products. Clinical trials on indication for products are in further process, including HANSIZHUANG (PD-1) and related combination therapies, HLX301 (PD-L1 x TIGIT), HLX20 (PD-L1), HLX35 (EGFR x 4-1BB), for the treatment of small cell lung cancer (SCLC), solid tumours, adult Langerhans cell histiocytosis (LCH) and Erdheim-Chester disease (ECD), gastric cancer, Esophageal squamous cell carcinoma (ESCC), lymphomas and hepatocellular carcinoma. HANSIZHUANG, as the core innovative monoclonal antibody product of the Group, has been successively approved for clinical trials in China, the United States, the EU and other countries/regions. With HANSIZHUANG as the core, in addition to the indication for the MSI-H solid tumours which has been approved for marketing, 11 clinical studies are in the process in an orderly manner including 3 international multi-centre clinical trials; and as at the end of the Reporting Period, a total of over 3,100 subjects have been enrolled in the trials in China, Turkey, Poland and other countries/regions, representing an increase of approximately 300 subjects for trials as compared with the end of 2021.

As at the end of the Reporting Period, the Group, synergising R&D centres in China and the United States, has established a global product development team with more than 400 staff for advancing the clinical research and drug registration of many candidate drugs across the world, and achieved significant progress in 10 clinical trials and multiple global clinical trial approvals for 5 products and 2 combination therapies during the Reporting Period.



## **1. Continuous and efficient advancement on clinical research product**

As at the Latest Practicable Date, the Group has carried out a total of more than 20 clinical trials for 13 products and 12 combination therapies in an orderly manner in various countries/regions.

### ***Progress of international clinical study projects***

- Progress of HANSIZHUANG (serplulimab injection)
  - In January 2022, the phase 3 investigational new drug application (IND) of HANSIZHUANG in combination with chemotherapy (carboplatin/cisplatin-etoposide) and concurrent radiotherapy for the treatment of limited-stage small cell lung cancer (LS-SCLC) was accepted by the NMPA and was approved in March 2022. In May 2022, the first patient has been dosed in an international multi-centre phase 3 clinical study in Mainland China.
  - In April 2022, HANSIZHUANG has been granted orphan-drug designation for the treatment of small cell lung cancer (SCLC) by the United States Food and Drug Administration (FDA).
- Progress of other products
  - In February 2022, HLX301 (recombinant anti-PD-L1 and anti-TIGIT bispecific antibody injection) completed its first patient dosing in a phase 1 clinical trial for the treatment of locally advanced or metastatic solid tumours in Australia.
  - In April 2022, HLX04-O (recombinant anti-VEGF humanised monoclonal antibody injection) completed its first patient dosing in an international multi-centre phase 3 clinical trial for the treatment of wet age-related macular degeneration (wAMD) in Latvia, Australia, etc. As at the Latest Practicable Date, HLX04-O (recombinant anti-VEGF humanised monoclonal antibody injection) for wet age-related macular degeneration (wAMD) has been approved in Australia, the United States, Singapore, and Latvia, Spain, Czech, Poland and other EU countries to carry out phase 3 clinical trial successively.
  - In April 2022, HLX20 (recombinant fully human anti-PD-L1 monoclonal antibody injection) has completed a phase 1 clinical trial conducted in patients with advanced solid tumours in Australia, and HLX20 has demonstrated its good safety and tolerability in this trial.
  - In June 2022, the first patient has been dosed in an international multi-centre phase 3 clinical trial of HLX14 (recombinant anti-RANKL human monoclonal antibody injection) for the treatment of postmenopausal osteoporosis in women with high fracture risks in Mainland China. In July 2022, this international multi-centre phase 3 clinical study was approved to commence in Australia.

## *Progress of domestic clinical study projects*

- Progress of HANSIZHUANG (serplulimab injection)
  - In February 2022, the phase 2 investigational new drug application (IND) of HANSIZHUANG in combination with HLX07 (recombinant humanised anti-EGFR monoclonal antibody injection) and HANBEITAI for the first-line treatment of unresectable or metastatic hepatocellular carcinoma (HCC) was accepted by the NMPA and approved in April 2022.
  - In April 2022, the phase 1 investigational new drug application (IND) of HLX26 (recombinant anti-LAG-3 humanised monoclonal antibody injection) in combination with HANSIZHUANG for the treatment of advanced/metastatic solid tumours or lymphomas was approved by the NMPA. In August 2022, the first patient has been dosed in a phase 1 clinical trial of HLX26 in combination with HANSIZHUANG for the treatment of advanced/metastatic solid tumours in Mainland China.
  - In May 2022, the phase 3 clinical study of HANSIZHUANG in combination with chemotherapy (Cisplatin + 5-FU) as a first-line treatment for patients with locally advanced/metastatic esophageal squamous cell carcinoma (ESCC), met the co-primary endpoints of progression-free survival (PFS) and overall survival (OS) in a planned interim analysis, evaluated by the Independent Data Monitoring Committee.
  - In June 2022, the enrollment of subjects was completed in a phase 3 clinical study of HANSIZHUANG in combination with HANBEITAI in combination with chemotherapy (carboplatin-pemetrexed) as a first-line treatment for advanced non-squamous, non-small cell lung cancer (nsNSCLC) in Mainland China.
- Progress of other products
  - In January 2022, the phase 1b/2 investigational new drug application (IND) of HLX208 (BRAF V600E inhibitor) monotherapy or in combination therapy for the treatment of BRAF V600E or BRAF V600 mutation-positive advanced solid tumours was approved by the NMPA. In the same month, the first patient has been dosed in the phase 2 clinical trial of HLX208 (BRAF V600E inhibitor) for the treatment of adult Langerhans Cell Histiocytosis (LCH) and Erdheim-Chester disease (ECD) with BRAF V600E mutation in Mainland China.
  - In January 2022, the investigational new drug application (IND) of HLX35 (recombinant humanised anti-EGFR and anti-4-1BB bispecific antibody injection) for the treatment of advanced malignant solid tumours was approved by the NMPA. In June 2022, HLX35 completed its first patient dosing in a phase 1 clinical trial for the treatment of advanced or metastatic solid tumours in Mainland China. The global commercialisation rights for HLX35 except for China (including Hong Kong, Macau and Taiwan regions) were granted to Binacea Pharma, Inc. (“**Binacea**”) in November 2020, and phase 1 clinical study for the relevant indications in Australia has also been approved and progressed.

- In January 2022, the investigational new drug application (IND) of HLX301 (recombinant anti-PD-L1 and anti-TIGIT bispecific antibody injection) for the treatment of advanced tumours has been accepted by the NMPA and approved in March 2022. In July 2022, the first patient has been dosed in a phase 1/2 clinical trial of HLX301 for the treatment of locally advanced/metastatic solid tumours or lymphomas in Mainland China.
- In April 2022, the first patient has been dosed in a phase 3 clinical trial of HLX11 (recombinant anti-HER2 domain II humanised monoclonal antibody injection) for the neoadjuvant therapy of HER2-positive, HR-negative early or locally advanced breast cancer in Mainland China.

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

The Group attached great importance to the pre-clinical project pipeline, and accelerated the submission of investigational new drug application (IND) of pre-clinical research projects covering targets such as TIGIT and GARP successfully during the Reporting Period.

- In April 2022, the phase 1 investigational new drug application (IND) of anti-TIGIT Fc fusion protein HLX53 for the treatment of advanced solid tumours or lymphomas was accepted by the NMPA and approved in June 2022.
- In June 2022, the application for phase 1 clinical trial of HLX60 (recombinant anti-GARP humanised monoclonal antibody injection) in combination with HANSIZHUANG for the treatment of advanced/metastatic solid tumours was submitted in Australia.

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

Product name (targets)	Indications	Progress as at the Latest Practicable Date
<b>Efficient advancement on international clinical study projects</b>		
<b>HANSIZHUANG in combination with chemotherapy concurrent radiotherapy (PD-1)</b>	Limited-stage small cell lung cancer (LS-SCLC)	<p>In January 2022, the phase 3 investigational new drug application was accepted by the NMPA</p> <p>In March 2022, the phase 3 investigational new drug application was approved by the NMPA</p> <p>In May 2022, the first patient dosing was completed in an international multi-centre phase 3 clinical study</p>
<b>HANSIZHUANG (PD-1)</b>	Small cell lung cancer (SCLC)	In April 2022, the United States Food and Drug Administration (FDA) granted orphan-drug designation
<b>HLX301 (PD-L1×TIGIT)</b>	Solid tumour	In February 2022, the first patient dosing was completed in a phase 1 clinical study in Australia
<b>HLX04-O (VEGF)</b>	wet age-related macular degeneration (wAMD)	In April 2022, the first patient dosing was completed in an international multi-centre phase 3 clinical study in Latvia, Australia and other regions
<b>HLX20 (PD-L1)</b>	Solid tumour	In April 2022, the phase 1 clinical study was completed in Australia
<b>HLX14 (RANKL)</b>	Osteoporosis (OP)	<p>In June 2022, the first patient dosing was completed in an international multi-centre phase 3 clinical study in Mainland China</p> <p>In July 2022, an international multi-centre phase 3 clinical study was approved to commence in Australia</p>

Product name (targets)	Indications	Progress as at the Latest Practicable Date
<b>Smooth progress of domestic clinical projects</b>		
<b>HANSIZHUANG in combination with HLX07 and HANBEITAI (PD-1+EGFR+VEGF)</b>	Hepatocellular carcinoma (HCC)	<p>In February 2022, the phase 2 investigational new drug application was accepted by the NMPA</p> <p>In April 2022, the phase 2 investigational new drug application was approved by the NMPA</p>
<b>HLX26 in combination with HANSIZHUANG (LAG-3+PD-1)</b>	Solid tumour	<p>In February 2022, the phase 1 investigational new drug application was accepted by NMPA</p> <p>In April 2022, the phase 1 investigational new drug application was approved by NMPA</p> <p>In August 2022, the first patient dosing was completed in a phase 1 clinical trial</p>
<b>HANSIZHUANG in combination with chemotherapy (PD-1)</b>	Esophageal squamous cell carcinoma (ESCC)	In May 2022, the phase 3 clinical trial met the primary endpoint
<b>HANSIZHUANG in combination with HANBEITAI in combination with chemotherapy (PD-1+VEGF)</b>	non-squamous, non-small cell lung cancer (nsNSCLC),	In June 2022, the enrollment of subjects was completed in a phase 3 clinical trial
<b>HLX208 (BRAF V600E)</b>	Solid tumour, adult langerhans cell histiocytosis (LCH) and erdheim-chester disease (ECD)	<p>In January 2022, a phase 1b/2 investigational new drug application in monotherapy or in combined therapy was approved by the NMPA</p> <p>In January 2022, the first patient dosing was completed in a phase 2 clinical study</p>
<b>HLX35 (EGFR × 4-1BB)</b>	Solid tumour	<p>In January 2022, the investigational new drug application was approved by the NMPA</p> <p>In June 2022, the first patient dosing was completed in a phase 1 clinical trial</p>

<b>Product name (targets)</b>	<b>Indications</b>	<b>Progress as at the Latest Practicable Date</b>
<b>HLX301 (PD-L1 × TIGIT)</b>	Solid tumour, lymphomas	In January 2022, the investigational new drug application was accepted by the NMPA  In March 2022, the investigational new drug application was approved by the NMPA  In July 2022, the first patient dosing was completed in a phase 1/2 clinical trial
<b>HLX11 (HER2)</b>	Breast cancer (BC)	In April 2022, the first patient dosing was completed in a phase 3 clinical trial
<b>Efficient advancement on IND application for pre-clinical development projects</b>		
<b>HLX53 (TIGIT)</b>	Solid tumour, lymphomas	In April 2022, the phase 1 investigational new drug application was accepted by the NMPA  In June 2022, the phase 1 investigational new drug application was approved by the NMPA
<b>HLX60 in combination with HANSIZHUANG (GARP+PD-1)</b>	Solid tumour	In June 2022, the phase 1 investigational new drug application was submitted in Australia

## **II. OUTLOOK FOR THE SECOND HALF OF 2022**

In the second half of the year, the Group will continue to focus on the fields of oncology and autoimmune diseases, and rely on its own innovative R&D strength, supplemented by external cooperation and licensing, to accelerate its innovation progress and consolidate its internationalised capability of “integrating research, production and marketing” while striving to maximise the commercial value of biosimilars, with the aim of gradually evolving into a Biopharma with larger scale and stronger market competitiveness.

### **(I) CAPITALISE ON FIRST-ENTRANT ADVANTAGES AND INCREASE THE GLOBAL MARKET COVERAGE OF OUR PRODUCTS**

As one of the leading biomedicine companies in China, the Group actively responds to the call of the country and supports the national pharmaceutical reform by providing patients with affordable high-quality biological drugs. At the same time, it is determined to uphold the patient-orientated principle and continue to expedite the commercialisation of its products in a comprehensive and efficient mode of operation.

HANQUYOU is the Group’s first core anti-tumour product promoted and sold within Mainland China as led by its in-house commercialisation team. In 2022, the Group will take further actions to promote the inclusion of HANQUYOU (in both 150mg and 60mg dosage forms) into the medical insurance procurement platforms and admission into the hospitals. Also, the Group will rely on its exclusive advantages in HANQUYOU (in both 150mg and 60mg dosage forms) in terms of personalised dosage and cost-effectiveness to continue to promote the products in lower-tier cities. In 2022, the Group will continue to optimise the diagnosis and treatment ecosystem for HER2-positive patients with priority given to improving the patient management and education platform and strive to build a public welfare platform for primary medical care by inviting domestic experts in oncology and relevant teams from professional hospitals to visit the communities and conduct public welfare trainings on the prevention and treatment of breast cancer and other oncology diseases for the frontline medical workers; the Group will effectively promote the cancer prevention, diagnosis and treatment projects by carrying out exchange activities such as large-scale free diagnosis, ward rounds, case discussions, etc. as a symbol to contribute to the standardisation of cancer diagnosis and treatment in the communities; and the Group will further improve and optimise construction of the diagnosis and treatment ecosystem for HER2-positive patients through cooperation with relevant parties in pharmacoeconomics, nursing education, and pharmaceutical education etc. In 2022, the sales network of HANQUYOU will continue to be strengthened to cover approximately 450 cities and nearly 5,500 DTP pharmacies/hospitals across China.

HANSIZHUANG is the Group's core innovative monoclonal antibody product. HANSIZHUANG's indication of unresectable or metastatic microsatellite instability-high (MSI-H) solid tumour that have failed to respond to the standard therapy, was approved for marketing in March 2022. As at the end of the Reporting Period, a professional sales team for HANSIZHUANG has been established. In the second half of the year, the Group will further enhance the coverage of its sales network by increasing the size of its sales team and optimising the team structure, so as to strengthen the competitiveness of HANSIZHUANG in the market. While actively implementing its marketing plans and sales strategies, the Group will continue to cooperate with the genetic testing companies in providing testing solutions for patients, building new patient service models, and improving MSI testing standards and accessibility, and continue to promote the improvement of standardized clinical diagnosis and treatment by cooperating with core academic institutions in the industry in conducting high-quality academic activities, with the aim of gradually establishing an ecosystem of patient diagnosis and treatment focusing on gastrointestinal tumours and gynecological tumours. In this regard, with the successive approvals for other indications (including advanced or metastatic squamous non-small cell lung cancer (sqNSCLC) and extensive stage small cell lung cancer (ES-SCLC), etc.) of HANSIZHUANG obtained in the future, the Group will further consolidate market sales layout in such field as lung cancer treatment and steadily build up a complete oncology patient treatment ecosystem. In the second half of the year, the Group plans to complete the tendering process of HANSIZHUANG in all the provinces in China and explore the feasibility of commercial insurance and innovative payment to further enhance the accessibility of the drug to the patients.

In February 2022, an innovative indication of HANLIKANG, i.e. rheumatoid arthritis (RA), was approved in China, which will provide additional opportunities for the marketing and sales of HANLIKANG. As the first monoclonal antibody approved in China under the Guidelines for Biosimilars, HANLIKANG is currently available in two dosage forms (100mg/10ml and 500mg/50ml) with its indications including not only hematologic oncology for which the original drug has been approved for marketing in China, but also autoimmune diseases, providing quality and flexible treatment options for a larger patient population. The Group will maintain close cooperation with Jiangsu Fosun and make the most of its first-entrant advantages to boost the sales of HANLIKANG. In 2022, we will continue to collaborate with academic groups to promote the standardisation of diagnosis and treatment of lymphoma with HANLIKANG through academic exchange activities, and enter the field of rheumatology to benefit the patients with rheumatoid arthritis.

The Group will continue to cooperate with Jiangsu Wanbang in the sales and marketing of HANDAYUAN in the area of rheumatology (ankylosing spondylitis and rheumatoid arthritis (RA)), dermatology (psoriasis) and ophthalmology (uveitis). In 2022, HANDAYUAN will continue to help ease the pain and suffering of the patients by relying on the platforms such as the "ASSC Ankylosing Spondylitis Standardised Treatment Project" and "Da'en Home" with priority given to the four major indications. It is our intention that HANDAYUAN will be available to 4,500 specialists and approximately 3,500 DTP pharmacies/hospitals by 2022, making it gradually "channel accessible" on the basis of "economically accessible".



At the same time, the Group will actively promote the availability of HANBEITAI on the medical insurance procurement platform as well as its tendering process on the procurement platform in 2022.

While aggressively penetrating the domestic market, the Group will continue to promote the commercial cooperation of its self-developed products in the international market. With the advancement of the R&D and registration of the Group's pipeline products, as well as the gradual understanding and full recognition of their effectiveness by the international market, the Group will continue to seek commercial cooperation with more leading international pharmaceutical companies in the second half of the year, so as to jointly introduce the Group's products to a broader international market, especially emerging markets with huge unmet medical needs for affordable drugs, and benefit overseas patients.

## **(II) CONTINUE TO FACILITATE THE APPROVAL OF MORE PRODUCTS FOR NEW INDICATIONS**

### ***HANSIZHUANG (Serplulimab injection)***

The development and production of HANSIZHUANG, which is the Group's core innovative monoclonal antibody product, is conducted in strict compliance with international quality standards. As of the Latest Practicable Date, in addition to the approved indication of MSI-H solid tumour, 11 combination therapies based on HANSIZHUANG (Serplulimab injection) were undergoing parallel clinical trials in a number of countries and regions around the world.

- The new drug application (NDA) of the second indication of HANSIZHUANG in Mainland China of the first-line therapy for locally advanced or metastatic squamous non-small cell lung cancer (sqNSCLC) is expected to be approved in the second half of 2022.
- The new drug application (NDA) of the third indication of HANSIZHUANG in Mainland China of the first-line therapy for previously untreated extensive stage small cell lung cancer (ES-SCLC) is expected to be approved in the first half of 2023.
- The new drug application (NDA) of HANSIZHUANG in combination with chemotherapy in Mainland China as the first-line therapy for locally advanced/metastatic esophageal squamous cell carcinoma (ESCC) is expected to be submitted in the second half of 2022.
- Based on the outcome of the meeting with the Food and Drug Administration (FDA) of the United States, a bridging study of HANSIZHUANG in combination with chemotherapy among previously untreated United States patients with extensive stage small cell lung cancer (ES-SCLC) is planned to be launched in the second half of 2022 to support the future NDA of the product in the United States.

- Based on the positive feedback from the Scientific Advice Working Party of the European Medicines Agency pointed at the consultation on the registration of HANSIZHUANG for the treatment of extensive stage small cell lung cancer (ES-SCLC), the marketing authorisation application of HANSIZHUANG in combination with chemotherapy in the EU for extensive stage small cell lung cancer (ES-SCLC) is expected to be submitted in 2023.

In the second half of the year, the Group will also actively work with its international partners to facilitate the submission of marketing applications for HANQUYOU, HANLIKANG and HANBEITAI in the United States, Brazil and Egypt, etc.

### **(III) CONTINUE TO BUILD INNOVATIVE PRODUCT PIPELINE THROUGH ITERATIVE R&D CAPABILITIES**

In the second half of the year, the Group will continue to leverage its international resources and strengths, collaborate with its R&D centres in China and the United States to strengthen its translational medicine capabilities and drive differentiated innovation, thereby addressing unmet clinical needs. In terms of early stage R&D, the Group will focus on antibody technology combined with novel molecular coupling technologies to vigorously expand multiple forms of antibody-coupled drugs, explore and continuously promote the “AXC” platform (covering small molecules (ADC), functional enzymes (AEC), isotopes (ARC), cells (ACC), PROTAC (APC) and nucleic acids (AOC) etc.), “IMAC” (Immuno-Modulator Antibody Conjugate) platform, targeted drug delivery platform, trans-blood-brain barrier drug delivery platform, etc., to provide solutions to unmet clinical needs through innovative drug forms, and to continue to build a solid foundation in the oncology field, which we have been cultivating for more than 10 years, while actively expanding into non-oncology disease areas, including metabolic, cardiovascular, renal, inflammatory, etc. At the same time, through the continuous introduction of new scientific concepts, the Group will develop innovative products based on tumour metabolism, immune metabolism, etc., which will inject a steady stream of impetus into the advancement of the Group’s innovative drug research and development and the achievement of its excellent commercialisation goals, thereby truly meeting the needs of patients and the market. A series of innovative products independently developed by the Group are scheduled to be further promoted in the second half of 2022:

- HLX23, recombinant anti-CD73 fully human monoclonal antibody injection, for the phase 1 clinical trial in patients with advanced or metastatic solid tumours is expected to complete the first patient dosing in the United States in the second half of the year.
- HLX53, anti-TIGIT Fc fusion protein, for the phase 1 clinical trial in patients with advanced or metastatic solid tumours or lymphomas is expected to complete the first patient dosing in Mainland China in the second half of the year.

- The investigational new drug application (IND) for HLX60 (recombinant anti-GARP humanised monoclonal antibody injection), HLX22 (anti-human epidermal growth factor receptor-2 (HER2) human monoclonal antibody injection) in combination with HANSIZHUANG and HANQUYOU, HLX208 (BRAF V600E inhibitor) in combination with HANSIZHUANG in Mainland China has been submitted recently and is expected to be approved in the second half of the year.

In addition to independent R&D, the Group will also identify and verify cutting-edge technology platforms to speed up the process of drug discovery and development, and actively accelerate the creation of innovative technology platforms and the expansion of innovative product pipelines through licensing introduction and cooperative development. In June 2022, the Company entered into a cooperation and license agreement with Palleon Pharmaceuticals Inc. for the global co-development and commercialisation of a bifunctional HER2-sialidase fusion protein and another tumour-related target-sialidase bifunctional fusion protein. The Company will obtain the exclusive commercialisation rights of two bifunctional antibody-sialidase fusion protein products in Mainland China, Hong Kong, Macau and Taiwan regions under the agreement, and the first collaborative product, a bifunctional HER2-sialidase fusion protein, is expected to enter clinical trial support studies soon. In 2022, the Group have also reached a cooperation consensus with Novacyte Therapeutics Biomedical Technology (Beijing) Co., Ltd. and MediLink Therapeutics (Suzhou) Co., Ltd. on the introduction of ADC platform technology and the cooperative development of ADC products.

In addition, the Group entered into an agreement with Galaxy Biotech, LLC in February 2018, pursuant to which Galaxy Biotech, LLC granted us an exclusive license to develop and commercialise HLX56 in Greater China. In view of the actual situation in the R&D process, the Group officially terminated the further cooperation with Galaxy Biotech, LLC during the Reporting Period.

#### **(IV) MAINTAIN HIGH QUALITY STANDARDS AND CONTINUE TO PROMOTE INDUSTRIALISATION DEPLOYMENT**

The Group will complete the construction of production base and the expansion of production capacity according to the prospective planning and the product R&D and marketing process, in order to provide a strong guarantee for the commercial sales of products and ensure the efficient utilisation of production capacity. Xuhui Facility continued to improve production efficiency and achieve stable and efficient commercial production during the Reporting Period through a series of lean management and process optimisation initiatives. The relevant measures will continue to be promoted in the second half of this year. In addition, the localisation of production materials and consumables will also continue.

As at the Latest Practicable Date, the Songjiang First Plant's 24,000L production capacity has been inspected for compliance with pharmaceutical GMPs and has been officially approved for the domestic commercial production of HANQUYOU using a new, optimised production process. On the basis of this, the Songjiang First Plant will continue on the improvement of international standard quality system and plans to complete the United States GMP inspection in 2023.

To achieve the long-term production capacity planning, the Group will continue to promote the construction of the Songjiang Second Plant, in order to enhance the overall production capacity. The construction, installation of process equipment for the two main production buildings in the first and second stage of the Songjiang Second Plant Phase I Project are expected to be completed in the second half of 2022 and will enter into the joint commissioning and verification stage. Also, the verification work of facilities and equipment is expected to be completed in the second half of 2022 and will enter into the stage of trial production and process verification. The first batch production of the Songjiang Second Plant project is expected to be completed by the end of 2022. For the third stage of Phase I of the Songjiang Second Plant, piling works completed during the Reporting Period. It is planned to continue the civil construction in the second half of 2022, and the foundation works and structure of the main building are expected to be completed in 2023. The Group will promote the construction and operation of the Songjiang Second Plant as soon as possible. When completed, the Songjiang Second Plant will become the monoclonal antibody biological drug research and development, pilot test and production base of the Group. This will further enhance the market competitiveness of the Group in its core business areas and meet the global commercial production needs of the Group's products.

### **III. FINANCIAL REVIEW**

#### **(I) Revenue**

During the Reporting Period, the Group capitalised on its first-mover advantages and expanded the market coverage of products, actively improved the commercialisation layout to build a powerful commercial organisation with predominant strength, established a comprehensive and efficient business operation model to continuously promote the successful commercialisation of more products, delivering a better performance of doubling its revenue as compared to the same period last year. During the Reporting Period, HANQUYOU, the core product of the Group in the field of anti-tumour therapy and the first product sold and promoted by the Group's in-house commercialisation team in Mainland China, continued to expand its sales; HANSIZHUANG, the first core innovative monoclonal antibody products, was approved for marketing in March 2022, and recorded sales revenue during the Reporting Period; the Group cooperated closely with the professional sales team of Fosun Pharma to boost the sales of HANLIKANG continuously.

With the continuous advancement of the R&D and registration of pipeline products of the Group and the increasing understanding and full recognition of the Group's products from the international market, during the Reporting Period, the Group continued to promote the business cooperation for its self-developed products in the international market. While entering into the mainstream biologics market in Europe and the United States, the Company regards the expansion into emerging markets as the focus of its globalisation strategy. During the Reporting Period, the Group cooperated with partners and continued to expand overseas markets to create more business value, thereby bringing in considerable licensing income and R&D service income.

During the Reporting Period, the Group recorded an operating income of approximately RMB1,289.4 million, representing an increase of approximately 103.5% as compared to the same period last year, mainly including the following:

## **1) *Revenue from product sales***

HANQUYOU was the first domestic trastuzumab approved for marketing independently developed by the Group and was also the first product of the Group to adopt its in-house team to conduct commercialisation promotion. It was commercialised in the domestic market in August 2020. During the Reporting Period, HANQUYOU recorded a sales revenue of approximately RMB800.2 million, representing a significant increase of approximately RMB512.6 million or approximately 178.2% as compared to the same period last year. Meanwhile, drug substance of trastuzumab recorded sales revenue of approximately RMB0.6 million.

In respect of HANLIKANG, 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 RMB272.1 million, representing an increase of approximately 22.5%, and licensing income of approximately RMB9.3 million under the aforementioned profit-sharing arrangement with its partners.

After the successful marketing of HANLIKANG, HANQUYOU (EU brand name: Zercepac<sup>®</sup>), HANDAYUAN, and HANBEITAI, HANSIZHUANG was the first self-developed and approved bioinnovation of the Group. The approval of HANSIZHUANG will further enrich the Company's commercial product line, and will also bring more treatment options for domestic patients. It began commercialisation in the domestic market in March 2022. During the Reporting Period, HANSIZHUANG recorded sales revenue of approximately RMB76.9 million.

In respect of HANDAYUAN, according to the cooperation agreement with Fosun Pharma, Fosun Pharma will reimburse all the expenses related to the clinical trials of HANDAYUAN incurred by the Group after the relevant cooperation agreement is signed, and the Group is responsible for the production of HANDAYUAN in China and the supply of HANDAYUAN to Fosun Pharma after the commercialisation of HANDAYUAN, and shall share the profits from the sales of HANDAYUAN in China. During the Reporting Period, HANDAYUAN recorded sales revenue of approximately RMB19.8 million and licensing income of approximately RMB0.9 million under the aforementioned profit-sharing arrangement with its partners.

During the Reporting Period, the Group recorded revenue of approximately RMB11.9 million for Zercepac<sup>®</sup>.

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

With the continuous improvement of the R&D system and innovation capabilities of the Group, our influence in the international market is expanding, at the same time, the number and overall amounts of licensed-out projects are constantly increasing. During the Reporting Period, the Group carried out business cooperation with multiple partners around the world based on various projects, including intellectual property licensing, joint development, commercialisation, etc.

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

In June 2018, the Group entered into a license agreement with Accord in relation to HANQUYOU (Zercepac<sup>®</sup>), granting Accord exclusive commercial rights in special territories as agreed therein. In July 2020, the marketing authorisation application of HANQUYOU (Zercepac<sup>®</sup>) submitted by a wholly-owned subsidiary of Accord was approved. Since then, HANQUYOU (Zercepac<sup>®</sup>) can be marketed in all EU Member States as well as in Iceland, Liechtenstein and Norway (each in the European Economic Area (EEA)) with its centralised marketing license. The Group has recognised licensing income of approximately RMB2.4 million for the six months ended 30 June 2022.

In September 2019, the Group entered into a co-development and commercialisation agreement with PT Kalbe Genexine Biologics in relation to HANSIZHUANG. With the continuous advancement of R&D services, the Group has recognised revenue from R&D services of approximately RMB2.5 million for the six months ended 30 June 2022.

In October 2020, the Group entered into a co-development and exclusive license agreement with Essex Bio-Investment Limited and Zhuhai Essex Bio-Pharmaceutical Company Limited\* (珠海億勝生物製藥有限公司) in relation to 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 RMB26.7 million for the six months ended 30 June 2022.

In November 2020, the Group entered into a license and co-development agreement with Binacea in relation to HLX35 (recombinant humanised anti-EGFR and anti-4-1BB bispecific antibody injection). The Group has recognised licensing income of approximately RMB19.0 million for the six months ended 30 June 2022.

In June 2022, the Group entered into a license and supply agreement with Organon LLC in relation to HLX11 (recombinant anti-HER2 domain II humanised monoclonal antibody injection) and HLX14 (recombinant anti-RANKL human monoclonal antibody injection). The Group has recognised revenue from R&D services of approximately RMB13.3 million for the six months ended 30 June 2022.

## **3) Other R&D service businesses**

In February 2022, the Group entered into a technical service contract with Shanghai Zhenge Biotech Co., Ltd.\* (上海臻格生物技術有限公司) in relation to the study and production of freeze-dried formulation at IND stage, an antibody drug under development. With the continuous advancement of technical service, the Group recognised revenue from technical service of approximately RMB2.5 million for the six months ended 30 June 2022.

In March 2022, the Group entered into an industrial technical services agreement with Shanghai Fosun Pharmaceutical Industrial Development Company Limited\* (上海復星醫藥產業發展有限公司) in relation to provision of CMC and pre-clinical toxicology research services to Fosun Pharmaceutical Industrial Development Company Limited for an antibody drug FS2101 under development. The Group recognised revenue from R&D services of approximately RMB29.9 million for the six months ended 30 June 2022.

## (II) Cost of sales

The Group's cost of sales primarily represents reagents and consumables, employee compensation, outsourcing expenses, utilities expenses and depreciation and amortisation, etc. During the Reporting Period, the Group recorded cost of sales of approximately RMB305.6 million, representing an increase of approximately RMB84.2 million as compared with that for the six months ended 30 June 2021, due to the increase of the sales volume of the key commercial products in the market.

## (III) Gross profit

During the Reporting Period, the Group recorded a gross profit of approximately RMB983.8 million, representing an increase of approximately RMB571.6 million as compared with that for the six months ended 30 June 2021, mainly due to the gross profit contribution from the commercialisation of the Company's key products.

## (IV) Other income and gains

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

During the Reporting Period, the Group recognised other income and gains of approximately RMB51.2 million.

	Six months ended 30 June	
	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Government grants	22,110	17,944
Exchange gains	28,388	–
Interest income	704	1,219
Others	20	808
<b>Total</b>	<b>51,222</b>	<b>19,971</b>

**(V) R&D expenditure**

	<b>Six months ended 30 June</b>	
	<b>2022</b>	<b>2021</b>
	<b>RMB'000</b>	<b>RMB'000</b>
<b>Expensed R&amp;D expenses</b>		
R&D employee salaries	227,531	143,966
Outsourcing fees	89,755	20,614
Reagents and consumables	59,188	47,857
Utilities expenses	7,288	8,634
Depreciation and amortisation	46,359	40,902
Consulting expense	10,845	5,683
Technical usage fees	19,497	113,969
Clinical trials	45,665	40,600
Share-based compensation	1,242	10,122
Others	27,127	19,466
	<hr/>	<hr/>
<b>Total expensed R&amp;D expenses</b>	<b>534,497</b>	<b>451,813</b>
	<hr/> <hr/>	<hr/> <hr/>
<b>Capitalised R&amp;D expenses</b>		
Clinical trials	161,514	137,110
R&D employee salaries	84,007	82,103
Reagents and consumables	10,309	17,846
Depreciation and amortisation	14,373	19,369
Utilities expenses	1,052	3,679
Outsourcing fees	6,271	12,174
Share-based compensation	2,057	4,306
Consulting expense	1,158	1,357
Others	12,167	9,581
	<hr/>	<hr/>
<b>Total capitalised R&amp;D expenses</b>	<b>292,908</b>	<b>287,525</b>
	<hr/> <hr/>	<hr/> <hr/>

During the Reporting Period, the Group recognised R&D expenses of approximately RMB827.4 million, representing an increase of approximately RMB88.1 million or approximately 11.9% as compared with approximately RMB739.3 million for the six months ended 30 June 2021. Such increase in R&D expenses was mainly due to the increase of investment in innovative R&D projects and the advancement of the Company's innovation and transformation.



## **(VI) Administrative expenses**

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

During the Reporting Period, the Group recognised administrative expenses of approximately RMB160.5 million, representing an increase of approximately 35.7% as compared to that of approximately RMB118.3 million for the six months ended 30 June 2021. The increase in administrative expenses of the Group was mainly due to: (1) the increase in the number of administrative employees in line with the expansion of the Company's operations and development; and (2) the corresponding increase in office administrative expenses, depreciation charges and software costs.

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

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

During the Reporting Period, the Group recognised selling and distribution expenses of approximately RMB378.6 million, which were mainly the marketing expenses incurred in the marketing and commercialisation of the products of HANQUYOU and HANSIZHUANG.

## **(VIII) Income tax expenses**

For the six months ended 30 June 2022, the Group incurred income tax expenses of approximately RMB1.0 million.

## **(IX) Loss for the period**

In view of the above, the Group's loss decreased by approximately RMB141.7 million from approximately RMB393.8 million for the six months ended 30 June 2021 to approximately RMB252.1 million for the six months ended 30 June 2022.

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

As of 30 June 2022, cash and bank balances of the Group were approximately RMB794.7 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 2022, the current assets of the Group were approximately RMB2,077.8 million, including cash and cash equivalents of approximately RMB215.1 million and restricted currency funds of approximately RMB579.6 million.

The inventories were approximately RMB559.1 million, trade receivables were approximately RMB554.0 million, prepayments, deposits and other receivables were approximately RMB170.0 million. As of 30 June 2022, the current liabilities of the Group were approximately RMB4,230.9 million, including trade payables of approximately RMB388.5 million, other payables and accruals of approximately RMB1,059.9 million and interest-bearing bank and other borrowings of approximately RMB2,484.0 million.

As at 30 June 2022, the foreign exchange bank balances of the Group were as follows:

	<i>RMB'000</i>
RMB	143,346
HKD	7,181
USD	637,170
EUR	190
NTD	6,798
	<u><u>          </u></u>
	<i>Original amount in thousand</i>
RMB	143,346
HKD	8,397
USD	94,944
EUR	27
NTD	30,185
	<u><u>          </u></u>

#### **(XI) Inventories**

Inventories of the Group increased from approximately RMB420.1 million as at 31 December 2021 to approximately RMB559.1 million as at 30 June 2022, mainly due to (1) the increased purchases of raw materials and consumables in line with the clinical trial progress and preparation for commercial production; and (2) sufficient stock is prepared to meet the increasing demand for key commercial products in the market.

#### **(XII) Trade receivables**

As at 30 June 2022 and 31 December 2021, trade receivables from customer contracts were approximately RMB554.0 million and RMB295.7 million, respectively. There were no changes in accounting estimates or material assumptions made in both periods.

	<b>30 June 2022 <i>RMB'000</i></b>	31 December 2021 <i>RMB'000</i>
Within 3 months	<u>554,028</u>	<u>295,741</u>
<b>Total</b>	<u><u>554,028</u></u>	<u><u>295,741</u></u>

#### **(XIII) Interest-bearing bank and other borrowings**

As at 30 June 2022, borrowings from banks and other institutions (exclusive of lease liabilities) of the Group were approximately RMB3,274.7 million. The Group incurred new borrowings for the following reasons: ongoing clinical research trials and preclinical research for drug candidates, sales expense from products commercialisation, construction of plants and normal operating expenses. The borrowings of the Group were denominated in RMB and USD.

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

#### (XIV) Maturity structure of outstanding debts

The following table sets forth the maturity structure of outstanding debts as at 30 June 2022 and 31 December 2021, of which lease liabilities were initially recognised upon the adoption of IFRS 16 – Leases on 1 January 2017.

	<b>30 June 2022</b>	31 December 2021
	<b><i>RMB'000</i></b>	<i>RMB'000</i>
Within one year	<b>2,483,959</b>	1,570,674
In the second year	<b>189,271</b>	318,790
In the third to fifth year (inclusive)	<b>102,160</b>	177,956
Over five years	<b>816,330</b>	555,517
<b>Total</b>	<b><u>3,591,720</u></b>	<u>2,622,937</u>

#### (XV) Collateral and pledged assets

As at 30 June 2022, the Group's pledged assets in relation to borrowings included trade receivables of approximately RMB112.5 million, prepayments, deposits and other receivables of approximately RMB8.4 million, property, plant and equipment of approximately RMB521.1 million and land use right of approximately RMB199.0 million.

#### (XVI) Key financial ratios

	<b>30 June 2022</b>	31 December 2021
Current ratio <sup>(1)</sup> :	<b>49.1%</b>	55.7%
Quick ratio <sup>(2)</sup> :	<b>35.9%</b>	41.5%
Gearing ratio <sup>(3)</sup> :	<b>61.9%</b>	51.8%

*Notes:*

- (1) Current ratio is calculated as current assets divided by current liabilities as at the same day.
- (2) Quick ratio is calculated as current assets minus inventories and divided by current liabilities as at the same day.
- (3) Gearing ratio is calculated as net debt divided by equity attributable to owners of the parent plus net debt, multiplied by 100%. Net debt represents the balance of indebtedness less cash and cash equivalents as at the end of the period.

## (XVII) Major 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 research and development, pilot test and production base of the Group when completed, which is conducive to further strengthening the Group's research and development 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.

Except for those disclosed in this announcement, as at 30 June 2022, the Group did not make any other significant investments.

## (XVIII) Capital commitments and capital expenditures

	<b>30 June 2022 RMB'000</b>	31 December 2021 RMB'000
Plant and machinery	<b>10,834</b>	55,745
Construction in progress	<b>451,216</b>	250,773
Electronic equipment	<b>7,519</b>	14,096
Leasehold improvements	<b>3,126</b>	45,706
Others	–	378
<b>Total</b>	<b><u>472,695</u></b>	<b><u>366,698</u></b>

We had capital commitments for plant and machinery contracted but not provided for of approximately RMB462.7 million as at 30 June 2022. These capital commitments primarily relate to expenditures expected to be incurred for the purchase of machinery, renovation of our existing laboratories and buildings and the R&D expenses to be capitalised.

## (XIX) Contingent liabilities

As of 30 June 2022, the Group did not have any material contingent liabilities.

## **(XX) Material acquisitions and disposals**

As of 30 June 2022, the Group did not have any material acquisitions and disposals.

## **(XXI) Interim dividends**

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

## **IV. RISK MANAGEMENT**

### **(I) FOREIGN EXCHANGE RISK**

Up until 30 June 2022, the Group was principally engaged in business in the PRC, in which most of the transactions were settled in RMB with no significant foreign exchange risk. No financial instrument for hedging foreign exchange risk or other hedging purposes was employed.

### **(II) EXCHANGE RATE RISK**

Currently, the major business operation of the Group is in the PRC and most of the revenue and expenses are settled in RMB, which is the Group's reporting currency. With the acceleration of the Group's development in overseas markets, it is expected that the sales revenue and licensing revenue denominated in USD and EUR will increase in the future. Fluctuations in exchange rates may adversely 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, coverage and depth of customer, 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 manner to capture market share. At the same time, in October 2020, in the "Response to the Recommendation of No. 6450 of the Third Session of the 13th NPC", the National Healthcare Security Administration stated that centralised volume-based procurement will commence at an appropriate time, after considering the factors of the biosimilar similarity, production capacity and supply chain stability of companies and the clinical substitutability of specific products. Currently, certain biosimilar has already been included in the application scope of centralised drug procurement at the provincial level. If any of our products are included in the centralised volume-based procurement in the future, our rivals (if they are evaluated on equivalence) may also choose to participate in tenders and be included in centralised procurement, hence bringing potential impact on the pricing of the drugs.

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

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

## **3. Potential Risks of COVID-19**

After the outbreak of COVID-19, the Group immediately adopted anti-epidemic measures, to secure employees' safety and guarantee to carry out a variety of work duties in an orderly manner. In the first half of 2022, the repeated spread of COVID-19 in Shanghai and other cities in China exerted certain negative impacts on the Group's operations in China, there are still uncertainties on its impacts on China and the world in the future. The epidemic of COVID-19 may have potential impacts on the Group's business, including but not limited to commodity sales, the hiring of staff for clinical trials and staff's involvement, approval of regulatory registration, procurement of raw materials, and construction progress of production base. The Group will continue to observe the epidemic situation and make all preparations in advance.

## **4. Force Majeure Risk**

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

## **V. EMPLOYEES AND REMUNERATION POLICIES**

The following table sets forth the breakdown of our employees by function as at 30 June 2022:

<b>Function</b>	<b>Number of employees</b>
R&D and Technology	1,012
Manufacturing	878
Commercial Operation	803
General and Administrative	240
<b>Total</b>	<b>2,933</b>

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

## **EVENTS AFTER THE END OF THE REPORTING PERIOD**

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.

## **COMPLIANCE WITH CORPORATE GOVERNANCE CODE**

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

In the opinion of the Board, the Company has complied with the principles and code provisions set out in the CG Code during the Reporting Period, except for Code Provision C.2.1 which requires that the role of chairman of the Board and chief executive officer should be separated and should not be performed by the same person. Given that Mr. Wenjie Zhang ("**Mr. Zhang**") assumes the roles of both chairman of the Board and chief executive officer, the Company deviates from this code provision. Mr. Zhang joined the Company in March 2019 and has successively served in various key positions in the Company, including the chief commercial operation officer and chief strategy officer of the Company. His familiarity with the business operation of the Company and his roles as the chairman of the Board and the chief executive officer of the Company can facilitate the formulation and implementation of business strategies of the Company. The Board considered that the current structure will not impair the balance of power and authority between the Board and the management of the Company. The Board will make decisions on important matters of the Company within the authority granted by the articles of association of the Company and its shareholders at the general meetings. In addition, the Board, which currently comprises one executive director, five non-executive directors and four independent non-executive directors, is appropriately structured with a balance of power to provide sufficient checks to protect the interests of the Company and its shareholders as a whole.

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

The Company has adopted the Model Code for Securities Transactions by Directors of Listed Issuers (the "**Model Code**") as set out in Appendix 10 to the Listing Rules as its code of conduct regarding directors' securities transactions. Having made specific enquiries to all of the directors of the Company, all directors of the Company confirmed that they have fully complied with all relevant requirements set out in the Model Code during the Reporting Period.

## REVIEW OF INTERIM RESULTS BY THE AUDIT COMMITTEE

The Group's interim results for the six months ended 30 June 2022 have been reviewed by the audit committee of the Company.

### INTERIM DIVIDEND

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

## INTERIM CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS

For the six months ended 30 June 2022

	Notes	2022 (Unaudited) RMB'000	2021 (Unaudited) RMB'000
<b>REVENUE</b>	3	<b>1,289,394</b>	633,595
Cost of sales		<u>(305,609)</u>	<u>(221,417)</u>
<b>Gross profit</b>		<b>983,785</b>	412,178
Other income and gains	4	<b>51,222</b>	19,971
Selling and distribution expenses		<b>(378,642)</b>	(197,331)
Research and development expenses		<b>(534,497)</b>	(451,813)
Administrative expenses		<b>(160,537)</b>	(118,303)
Impairment losses on financial and contract assets, net		<b>(1,080)</b>	(222)
Other expenses		<b>(160,138)</b>	(18,325)
Finance costs	6	<u><b>(51,255)</b></u>	<u>(39,992)</u>
<b>LOSS BEFORE TAX</b>	5	<b>(251,142)</b>	<b>(393,837)</b>
Income tax expense	7	<u><b>(953)</b></u>	<u>–</u>
<b>LOSS FOR THE PERIOD</b>		<u><b>(252,095)</b></u>	<u><b>(393,837)</b></u>
<b>Attributable to:</b>			
Owners of the parent		<b>(252,095)</b>	(393,837)
Non-controlling interests		<u>–</u>	<u>–</u>
		<u><b>(252,095)</b></u>	<u><b>(393,837)</b></u>
<b>LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT</b>			
Basic and diluted (RMB)	9	<u><b>(0.47)</b></u>	<u>(0.73)</u>



# INTERIM CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

For the six months ended 30 June 2022

	2022 (Unaudited) RMB'000	2021 (Unaudited) RMB'000
<b>LOSS FOR THE PERIOD</b>	<b><u>(252,095)</u></b>	<b><u>(393,837)</u></b>
<b>OTHER COMPREHENSIVE LOSS</b>		
Other comprehensive loss that may be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	<u>(1,512)</u>	<u>(458)</u>
<b>OTHER COMPREHENSIVE LOSS FOR THE PERIOD, NET OF TAX</b>	<b><u>(1,512)</u></b>	<b><u>(458)</u></b>
<b>TOTAL COMPREHENSIVE LOSS FOR THE PERIOD</b>	<b><u>(253,607)</u></b>	<b><u>(394,295)</u></b>
<b>Attributable to:</b>		
Owners of the parent	(253,607)	(394,295)
Non-controlling interests	<u>—</u>	<u>—</u>
	<b><u>(253,607)</u></b>	<b><u>(394,295)</u></b>

**INTERIM CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION**  
*30 June 2022*

	<i>Notes</i>	<b>30 June 2022 (Unaudited) RMB'000</b>	31 December 2021 (Audited) RMB'000
<b>NON-CURRENT ASSETS</b>			
Property, plant and equipment		1,642,117	1,228,885
Intangible assets		3,896,054	3,634,931
Right-of-use assets		451,937	438,201
Other non-current assets		116,156	223,668
<b>Total non-current assets</b>		<b>6,106,264</b>	<b>5,525,685</b>
<b>CURRENT ASSETS</b>			
Inventories		559,136	420,112
Trade receivables	10	554,028	295,741
Prepayments, other receivables and other assets		169,971	223,973
Cash and bank balances		794,685	707,333
<b>Total current assets</b>		<b>2,077,820</b>	<b>1,647,159</b>
<b>CURRENT LIABILITIES</b>			
Trade payables	11	388,549	383,470
Other payables and accruals		1,059,856	867,278
Contract liabilities		298,532	138,303
Interest-bearing bank and other borrowings		2,483,959	1,570,674
<b>Total current liabilities</b>		<b>4,230,896</b>	<b>2,959,725</b>
<b>NET CURRENT LIABILITIES</b>		<b>(2,153,076)</b>	<b>(1,312,566)</b>
<b>TOTAL ASSETS LESS CURRENT LIABILITIES</b>		<b>3,953,188</b>	<b>4,213,119</b>
<b>NON-CURRENT LIABILITIES</b>			
Interest-bearing bank and other borrowings		1,107,761	1,052,263
Other long-term payables		51,976	54,425
Contract liabilities		567,021	653,934
Deferred income		148,389	155,741
<b>Total non-current liabilities</b>		<b>1,875,147</b>	<b>1,916,363</b>
<b>Net assets</b>		<b>2,078,041</b>	<b>2,296,756</b>
<b>EQUITY</b>			
Share capital		543,495	543,495
Reserves		1,534,546	1,753,261
<b>Equity attributable to owners of the parent</b>		<b>2,078,041</b>	<b>2,296,756</b>
<b>Total equity</b>		<b>2,078,041</b>	<b>2,296,756</b>

# NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

30 June 2022

## 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 2022 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 2021.

The Group had net current liabilities of RMB2,153,076,000 as at 30 June 2022. Having taken into account the unused banking facilities and the expected cash flows from operating and financing activities, the directors of the Company consider that it is appropriate to prepare the financial statements 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 2021, except for the adoption of the following revised International Financial Reporting Standards ("IFRSs") for the first time for the current period's financial information.

Amendments to IFRS 3	<i>Reference to the Conceptual Framework</i>
Amendments to IAS 16	<i>Property, Plant and Equipment: Proceeds before Intended Use</i>
Amendments to IAS 37	<i>Onerous Contracts – Cost of Fulfilling a Contract</i>
<i>Annual Improvements to IFRSs 2018-2020</i>	<i>Amendments to IFRS 1, IFRS 9, Illustrative Example accompanying IFRS 16, and IFRS 41</i>

The nature and impact of the revised IFRSs are described below:

- (a) Amendments to IFRS 3 replace a reference to the previous *Framework for the Preparation and Presentation of Financial Statements* with a reference to the *Conceptual Framework for Financial Reporting* issued in March 2018 without significantly changing its requirements. The amendments also add to IFRS 3 an exception to its recognition principle for an entity to refer to the Conceptual Framework to determine what constitutes an asset or a liability. The exception specifies that, for liabilities and contingent liabilities that would be within the scope of IAS 37 or IFRIC 21 if they were incurred separately rather than assumed in a business combination, an entity applying IFRS 3 should refer to IAS 37 or IFRIC 21 respectively instead of the Conceptual Framework. Furthermore, the amendments clarify that contingent assets do not qualify for recognition at the acquisition date. The Group has applied the amendments prospectively to business combinations that occurred on or after 1 January 2022. As there were no contingent assets, liabilities and contingent liabilities within the scope of the amendments arising in the business combination that occurred during the period, the amendments did not have any impact on the financial position and performance of the Group.
- (b) Amendment to IAS 16 prohibit an entity from deducting from the cost of an item of property, plant and equipment any proceeds from selling items produced while bringing that asset to the location and condition necessary for it to be capable of operating in the manner intended by management. Instead, an entity recognises the proceeds from selling any such items, and the cost of those items, in profit or loss. The Group has applied the amendments retrospectively to items of property, plant and equipment made available for use on or after 1 January 2021. Since there was no sale of items produced while making property, plant and equipment available for use on or after 1 January 2021, the amendments did not have any impact on the financial position or performance of the Group.

- (c) Amendments to IAS 37 clarify that for the purpose of assessing whether a contract is onerous under IAS 37, the cost of fulfilling the contract comprises the costs that relate directly to the contract. Costs that relate directly to a contract include both the incremental costs of fulfilling that contract (e.g., direct labour and materials) and an allocation of other costs that relate directly to fulfilling that contract (e.g., an allocation of the depreciation charge for an item of property, plant and equipment used in fulfilling the contract as well as contract management and supervision costs). General and administrative costs do not relate directly to a contract and are excluded unless they are explicitly chargeable to the counterparty under the contract. The Group has applied the amendments prospectively to contracts for which it has not yet fulfilled all its obligations at 1 January 2022 and no onerous contracts were identified. Therefore, the amendments did not have any impact on the financial position or performance of the Group.
- (d) *Annual Improvements to IFRSs 2018-2020* sets out amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41. Details of the amendments that are applicable to the Group are as follows:
- IFRS 9 *Financial Instruments*: clarifies the fees that an entity includes when assessing whether the terms of a new or modified financial liability are substantially different from the terms of the original financial liability. These fees include only those paid or received between the borrower and the lender, including fees paid or received by either the borrower or lender on the other's behalf. The Group has applied the amendment prospectively to financial liabilities that are modified or exchanged on or after 1 January 2022. As there was no modification of the Group's financial liabilities during the period, the amendment did not have any impact on the financial position or performance of the Group.
  - IFRS 16 *Leases*: removes the illustration of payments from the lessor relating to leasehold improvements in Illustrative Example 13 accompanying IFRS 16. This removes potential confusion regarding the treatment of lease incentives when applying IFRS 16.

## 2. OPERATING SEGMENT INFORMATION

The Group is engaged in biopharmaceutical R&D, biopharmaceutical service 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	
	2022	2021
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Mainland China	1,239,689	566,261
Overseas	49,705	67,334
	<u>1,289,394</u>	<u>633,595</u>

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	
	2022 RMB'000 (Unaudited)	2021 RMB'000 (Unaudited)
<i>Revenue from contracts with customers</i>	1,288,739	633,595
<i>Revenue from other sources</i>	655	–
	<u>1,289,394</u>	<u>633,595</u>
<u>Revenue from contracts with customers</u>		
<b>Types of goods or services</b>		
Sales of biopharmaceutical products	1,181,622	555,947
Licensing revenue	31,606	9,581
Research and development services	74,964	68,047
Others	547	20
	<u>1,288,739</u>	<u>633,595</u>
<b>Timing of revenue recognition</b>		
Transferred at a point in time	1,201,164	555,967
Transferred over time	87,575	77,628
	<u>1,288,739</u>	<u>633,595</u>
<u>Revenue from other sources</u>		
Rental income	655	–
	<u>655</u>	<u>–</u>

### 4. OTHER INCOME AND GAINS

An analysis of other income and gains is as follows:

	For the six months ended 30 June	
	2022 RMB'000 (Unaudited)	2021 RMB'000 (Unaudited)
Government grants	22,110	17,944
Exchange gains	28,388	–
Interest income	704	1,219
Others	20	808
	<u>51,222</u>	<u>19,971</u>

## 5. LOSS BEFORE TAX

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

	<i>Note</i>	<b>For the six months ended 30 June</b>	
		<b>2022</b>	<b>2021</b>
		<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
		<b>(Unaudited)</b>	<b>(Unaudited)</b>
Cost of inventories sold		<b>230,444</b>	171,520
Cost of services provided		<b>75,165</b>	49,897
Depreciation of property, plant and equipment*		<b>50,552</b>	39,512
Depreciation of right-of-use assets*		<b>20,012</b>	22,339
Amortisation of intangible assets*		<b>20,553</b>	32,835
Research and development expenses:			
Current period expenditure		<b>534,497</b>	451,813
Foreign exchange (gain)/loss, net		<b>(28,388)</b>	8,836
Impairment of financial assets, net		<b>1,081</b>	222
Write-down of inventories to net realisable value		<b>15,069</b>	3,114
Provision for the contract loss		<b>100,671</b>	–
Bank interest income	<i>4</i>	<b>(704)</b>	(1,219)
Loss on disposal of items of property, plant and equipment		<b>–</b>	1,323
		<b><u>                    </u></b>	<b><u>                    </u></b>

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

## 6. FINANCE COSTS

An analysis of finance costs is as follows:

	<b>For the six months ended 30 June</b>	
	<b>2022</b>	<b>2021</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
Interest expense on bank and other borrowings	<b>55,652</b>	39,037
Interest expense on lease liabilities	<b>7,613</b>	8,201
Less: Interest capitalised	<b>(12,010)</b>	(7,246)
	<b><u>                    </u></b>	<b><u>                    </u></b>
	<b><u>51,255</u></b>	<b><u>39,992</u></b>

## 7. INCOME TAX EXPENSE

The provision for Mainland China current income tax is based on the statutory rate of 25% (six months ended 30 June 2021: 25%) of the assessable profits of the Group as determined in accordance with the PRC Corporate Income Tax Law which was approved and became effective on 1 January 2008, except for certain group entities in Mainland China, which are taxed at a preferential rate of 15%.

The provision for current income tax of Henlix Biotech Co., Ltd., Hengenix Biotech, Inc. and Henlius Industrial Co., Limited was based on the statutory rates of 20%, 29.84% and 8.25%, respectively (six months ended 30 June 2021: 20%, 29.84% and 8.25%, respectively), for the six months ended 30 June 2022.

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

	<b>For the six months ended 30 June</b>	
	<b>2022</b>	<b>2021</b>
	<b>RMB'000</b>	<b>RMB'000</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
Current – China	<b>953</b>	–
Current – Other countries	–	–
	<hr/>	<hr/>
Total tax charge for the period	<b>953</b>	–
	<hr/> <hr/>	<hr/> <hr/>

## 8. DIVIDENDS

No dividend has been paid or declared by the Company during the reporting period (six months ended 30 June 2021: Nil).

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

The calculation of the basic loss per share amount is based on the loss for the period attributable to ordinary equity holders of the parent and the weighted average number of ordinary shares of 541,330,076 (six months ended 30 June 2021: 537,862,649) in issue during the period.

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

The calculation of basic and diluted loss per share are based on:

	<b>For the six months ended 30 June</b>	
	<b>2022</b>	<b>2021</b>
	<b>RMB'000</b>	<b>RMB'000</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
<b>Loss</b>		
Loss attributable to ordinary equity holders of the parent used in the basic loss per share calculation	<b>(252,095)</b>	<b>(393,837)</b>
	<hr/> <hr/>	<hr/> <hr/>

	<b>For the six months ended 30 June</b>	
	<b>2022</b>	<b>2021</b>
	<b>RMB'000</b>	<b>RMB'000</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
<b>Shares</b>		
Weighted average number of ordinary shares in issue during the period used in the basic loss per share calculation	<b>541,330,076</b>	537,862,649
Effect of dilution – weighted average number of ordinary shares:		
Restricted shares under the share award scheme	–	–
Weighted average number of ordinary shares in issue during the period used in the diluted loss per share calculation	<b>541,330,076</b>	537,862,649

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

## 10. TRADE RECEIVABLES

An ageing analysis of the trade receivables, based on the invoice date and net of provisions, is as follows:

	<b>30 June</b>	31 December
	<b>2022</b>	2021
	<b>RMB'000</b>	<b>RMB'000</b>
	<b>(Unaudited)</b>	(Audited)
Within 3 months	<b>554,028</b>	295,741

As at 30 June 2022, the Group's trade receivables with the amount of RMB112,525,000 (31 December 2021: RMB69,444,000) were pledged as security for the Group's interest-bearing bank and other borrowings.

## 11. TRADE PAYABLES

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

	<b>30 June</b>	31 December
	<b>2022</b>	2021
	<b>RMB'000</b>	<b>RMB'000</b>
	<b>(Unaudited)</b>	(Audited)
Within 1 year	<b>388,549</b>	383,470

## 12. EVENTS AFTER THE REPORTING PERIOD

There have been no significant events since the end of the reporting period.



## **PUBLICATION OF INTERIM RESULTS AND INTERIM REPORT**

This announcement is published on the website of the Stock Exchange at <http://www.hkexnews.hk> and on the website of the Company at <http://www.henlius.com>. The 2022 Interim Report containing all the information required by the Listing Rules will be despatched to the shareholders of the Company and will be made available on the websites of the Company and the Stock Exchange.

### **APPRECIATION**

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

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

Hong Kong, 18 August 2022

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

\* *for identification purpose only*