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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 2021**

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 2021 (the “**Reporting Period**”), prepared under International Financial Reporting Standards (“**IFRSs**”).

### **FINANCIAL SUMMARY:**

1. The Group’s total revenue increased by approximately RMB523.2 million or approximately 474% to approximately RMB633.6 million for the six months ended 30 June 2021, compared to approximately RMB110.4 million for the six months ended 30 June 2020. Such revenue was mainly from drug sales, research and development (“**R&D**”) services provided to customers, and license revenue.
2. For the six months ended 30 June 2021, the Group recognised R&D clinical expenditure of approximately RMB739.3 million, representing a decrease of approximately RMB17.6 million as compared with approximately RMB756.9 million for the six months ended 30 June 2020, mainly due to strategic adjustments in projects and timing differences.
3. The Group’s total loss decreased by approximately RMB54.2 million to approximately RMB393.8 million for the six months ended 30 June 2021, compared to approximately RMB448.0 million for the six months ended 30 June 2020, mainly due to the successive commercialization of key products.

## **BUSINESS HIGHLIGHTS:**

### **1. 漢利康® (rituximab injection) :**

- 30 provinces and municipalities in mainland China, had approved the inclusion of 漢利康®(100mg/10ml) into the medical insurance procurement platform, among which 28 provinces and municipalities had completed official platform/filed procurement, and more than 70% of the core hospitals had admitted the drug.
- The marketing and supply of 漢利康®(500mg/50ml) had been launched since May 2021, and 4 provinces and municipalities in mainland China had completed official platform/filed procurement as of June 2021.

### **2. 漢曲優®(trastuzumab injection, EU brand name: Zercepac®):**

- 漢曲優® (150mg) had completed the tendering process on the procurement platform and had been included into the medical insurance procurement platform for all provinces and municipalities in mainland China.
- After Zercepac® (150mg) was approved for marketing in EU in July 2020, Zercepac® (60mg and 420mg dosage forms) were approved for marketing in EU in April 2021 and June 2021, respectively. The marketing application of Zercepac® (150mg) was also approved by Swissmedic in July 2021.

### **3. 漢達遠® (adalimumab):** The supplemental new drug application (sNDA) of 漢達遠® for the new indication of uveitis has been accepted by the NMPA in January 2021, and such sNDA was approved in April 2021. As at the Latest Practicable Date, 漢達遠® has been successfully included into the medical insurance procurement platform for 27 provinces and municipalities.

#### **4. Business Development:**

- Since entering into the binding term sheet with Accord Healthcare Inc. in September 2020, the Group entered into a formal agreement with Intas (the parent company of Accord Healthcare Inc.) in January 2021, pursuant to which the Company agreed to grant it a license to develop and commercialize 漢曲優® (trastuzumab injection, EU brand name: Zercepac®) in the United States and Canada.
- In January 2021, the Company signed an exclusive license agreement with Chiome Bioscience, Inc., to in-license an exclusive right to research, develop, produce and commercialize the antibodies against human TROP2 (Trophoblast cell-surface antigen 2) and the relevant intellectual property in China (including Hong Kong, Macau and Taiwan, China).
- In March 2021, the Company entered into a binding term sheet with Suzhou NeuPharma Co., Ltd.\* (蘇州潤新生物科技有限公司) to in-license exclusive rights to develop, manufacture, commercialize and sublicense of HLX208, a small-molecule inhibitor targeting V600E mutation in human BRAF protein in China (including Hong Kong, Macau and Taiwan, China), and the formal agreement for relevant cooperation was officially signed in May 2021.

















#### **5. Efficient Advancement of the Domestic and International Clinical Research Projects:**

- In January 2021, the enrollment of subjects was completed in a phase 2 clinical research of serplulimab injection (PD-1) in combination with bevacizumab injection against advanced hepatocellular carcinoma (HCC).
- In March 2021, the first patient dosing was completed in a phase 2/3 clinical research of serplulimab injection in combination with bevacizumab injection and chemotherapy(XELOX) as first-line treatment for metastatic colorectal cancer (mCRC) in mainland China.
- In March 2021, the single-armed, open-label, multi-center phase 2 clinical research of serplulimab injection for the treatment of unresectable or metastatic microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) solid tumors that fail to respond to the standard therapy met the primary endpoint.
- Since January 2021, the HLX04-O (recombinant humanized anti-VEGF monoclonal antibody injection) for the treatment of wet age-related macular degeneration (wAMD) was approved to commence the phase 3 clinical trial in Australia, the United States, EU countries such as Latvia, Hungary and Spain, as well as Singapore. The international multi-center phase 3 clinical study of the project is intended to be launched in the near future. In July 2021, the first patient dosing was completed in the phase 1 clinical study of HLX04-O for the treatment of wet age-related macular degeneration (wAMD) in mainland China.

- 6. Efficient Advancement of the Pre-clinical Development Projects:** During the Reporting Period, the Group also continuously placed importance on the pre-clinical project pipeline, sped up the investigational new drug application (IND) of pre-clinical research projects covering targets such as CD38, LAG-3 and CD73, and continuously advanced the progress of pre-clinical research and development of pipeline products including HLX301(PD-L1xTIGIT) and HLX35(EGFRx4-1BB) dual antibody.
- 7. Biopharmaceutical Industrialization Base Layout with International Standards and High Cost-Efficiency:** During the Reporting Period, Xuhui Facility with commercial production capacity of 20,000L continuously improved production efficiency through a series of lean management and process optimization measures, which effectively reduced the production costs. As at the latest Practicable Date, the Songjiang First Plant with a planned production capacity of 24,000L has completed the commissioning and verification for all the twelve 2,000L bioreactors for the drug substance line and the lyophilized preparation line, and completed various production for process verification purpose. The first batch of non-GMP production for downstream continuous production process of a single project was successfully completed. As at the latest Practicable Date, the structure, acceptance of the main structure, and construction of all parts of the two main production buildings for the first phase project of the Songjiang Second Plant with a design capacity of 36,000L, and the structure of production auxiliary building and the acceptance of the main structure were completed, and the factory acceptance test for the main production facilities such as the drug substance line and the drug product line has fully commenced.

For details of the matters above, please refer to this announcement and, if applicable, announcements previously published by the Company on the website of the Stock Exchange and the website of the Company.

## OUR PRODUCT PIPELINE

Product (Reference Drug)		Target	Indication									
Marketed products	漢利康® (rituximab) <sup>(1)</sup>	CD20	Non-Hodgkin lymphoma and chronic lymphocytic leukemia									
	漢曲優® (trastuzumab) <sup>(2)</sup>	HER2	Breast cancer and metastatic gastric cancer								 	
	漢達遠® (adalimumab) <sup>(3)</sup>	TNF-α	Rheumatoid arthritis, ankylosing spondylitis, psoriasis and uveitis									
With near-term commercial viability	HLX01 (rituximab)	CD20	Rheumatoid arthritis <sup>(4)</sup>									
	HLX04 (bevacizumab)	VEGF	Metastatic colorectal cancer and non-squamous non-small cell lung cancer									
	HLX10 (serplulimab) <sup>(5)</sup>	PD-1	MSI-H solid tumours							Included in priority reviewing process		
Under clinical research	HLX10 (serplulimab) <sup>(6)</sup>	+Chemo	PD-1	Metastatic esophageal squamous-cell carcinoma								
				Squamous non-small cell lung cancer								
				Extensive-stage small cell lung cancer								
				Gastric cancer								
		+HLX04	PD-1+VEGF	PD-1	Non-squamous non-small cell lung cancer							
					Hepatocellular carcinoma							
					Metastatic colorectal cancer							
		+HLX07	PD-1+EGFR	PD-1	Squamous-cell carcinoma of the head and neck							
	HLX07 <sup>(8)</sup>	EGFR	EGFR	Solid tumours								
	HLX22	HER2	HER2	Breast cancer and gastric cancer								
	HLX55 <sup>(7)</sup>	c-MET	c-MET	Solid tumours								
	HLX11 (pertuzumab)	HER2	HER2	Breast cancer								
	HLX71 <sup>(8)</sup>	S1 Protein of SARS-CoV-2	S1 Protein of SARS-CoV-2	COVID-19								
	HLX208 <sup>(9)</sup>	BRAF V600E	BRAF	Solid tumours								
	HLX05 (cetuximab) <sup>(10)</sup>	EGFR	EGFR	Metastatic colorectal cancer and squamous-cell carcinoma of the head and neck								
	HLX12 (ramucirumab)	VEGFR2	VEGFR2	Gastric cancer, metastatic non-small cell lung cancer and metastatic colorectal cancer								
	HLX20 <sup>(11)</sup>	PD-L1	PD-L1	Solid tumours								
	HLX14 (denosumab)	RANKL	RANKL	Osteoporosis								
	HLX04-O <sup>(12)</sup>	VEGF	VEGF	Wet age-related macular degeneration								
	HLX26	LAG-3	LAG-3	Solid tumours and lymphoma								
	HLX13 (ipilimumab)	CTLA-4	CTLA-4	Melanoma, renal cell carcinoma and metastatic colorectal cancer								
	HLX70 <sup>(8)</sup>	S1 Protein of SARS-CoV-2	S1 Protein of SARS-CoV-2	COVID-19								
	HLX15 (daratumumab)	CD38	CD38	Multiple myeloma								
	HLX23 <sup>(8)</sup>	CD73	CD73	Solid tumors								
Pre-clinical	HLX301	PD-L1 x TIGIT	Solid tumors									
	HLX35 <sup>(13)</sup>	EGFR x 4-1BB	Solid tumors								Binacea	

- (1) Approved by the NMPA in February 2019, being the first domestic biosimilar  
(2) Approved in the EU in July 2020 (EU brand name: Zoroeapac<sup>®</sup>); approved in China in August 2020  
(3) Approved by the NMPA in December 2020  
(4) Considered as biologic medicine since the reference product has not yet been approved for the relevant indications  
(5) IND approved in China, the United States, EU and other countries/regions  
(6) IND approved in China and the United States  
(7) Commercialization rights in China and certain countries in Southeast, Central and South Asia were obtained  
(8) IND approved in the United States  
(9) Commercialization rights in China (including Hong Kong, Macau and Taiwan) were obtained  
(10) Commercialization rights in China have been granted to Shanghai Jingze  
(11) IND approved in China and Australia  
(12) IND approved in China, Australia, the United States, Singapore, EU and other countries/regions  
(13) Global exclusive commercialization rights other than in Mainland China, Hong Kong Special Administrative Region, Macao Special Administrative Region and Taiwan have been granted to Binacea

Core Products



## MANAGEMENT DISCUSSION AND ANALYSIS

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

Committed to “Affordable Innovation”, the Group continued to promote the efficient development of the global commercialization of product pipeline during the Reporting Period, and further implemented production capacity deployment for the biomedicines with high economic benefit based on international standards. Great achievements have been made in clinical development and regulatory affairs of the products in the pipeline. During the Reporting Period, the Group made significant progress in 4 clinical trials, received approvals for multiple clinical trials worldwide for 4 products and made steady progress in the sales of its various marketed products.

As of 16 August 2021, being the latest practicable date for the publication of this announcement (the “**Latest Practicable Date**”), 3 products of the Group have been successfully marketed in mainland China, 1 product has been successfully marketed in the European Union (the “**EU**”), 3 new drug applications have been accepted in China, more than 40 clinical trials have been approved worldwide, and a total of more than 20 clinical trials have been carried out in various countries/regions, including China, the EU, the United States, Australia, Ukraine, the Philippines and Turkey.

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

During the Reporting Period, the Group actively implemented the concept of excellent commercialization, and created a complete value chain covering R&D, production and traditional commercialization. Based on the needs of patients and beginning with the end in mind, we have implemented a commercialization strategy of “focusing on product portfolio, manufacturing capacity and commercial operations to become the leader in biological medicine in China”. The Group’s commercialization team is divided into five sections: marketing promotion, channel management, pricing and market access, domestic sales, and strategic planning, covering the whole process of commercialization, and realized steady growth of the scale of product sales. After the launch of 漢利康®, China’s first monoclonal antibody approved in accordance with the Guidelines for the R&D and Evaluation of Biosimilars (Trial) in 2019, the other two core products of the Group, 漢曲優® (trastuzumab injection, EU brand name: Zercepac®) and 漢達遠®, successively achieved commercial sales. During the Reporting Period, we have entered into formal sales partnerships with international partners in the United States and Canada for 漢曲優® (trastuzumab injection, EU brand name: Zercepac®).

## 1. Commercial sales of three core products during the Reporting Period

### Commercial sales of 漢利康® (rituximab injection) (hematological oncology products)

As at the Latest Practicable Date, 30 provinces and municipalities approved 漢利康® (100mg/10ml)'s inclusion into the medical insurance procurement platform, of which 28 provinces and municipalities completed official platform/filed procurement, and over 70% of the core hospitals admitted the drug, providing a foundation for the sales of 漢利康®.

The launch and supply of 漢利康® (500mg/50ml) commenced in May 2021 and the official platform/ the filing of procurement of the product was completed in 4 provinces and municipalities in mainland China as of June 2021.

As the first domestic biosimilar drug in the strict sense, 漢利康® was successfully approved for marketing in 2019. The indications currently include all indications for which the original drug was approved in mainland China, with specifications covering 100mg/10ml and 500mg/50ml. The domestic commercial sales of 漢利康® were handled by Jiangsu Fosun Pharmaceutical Sales Co., Ltd.\* (“江蘇復星醫藥銷售有限公司”) (“**Jiangsu Fosun**”), a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd.\* (“上海復星醫藥(集團)股份有限公司”) (“**Fosun Pharma**”), the controlling shareholder of the Company.





***The commercialization process of 漢曲優® (trastuzumab injection, EU brand name: Zercepac®) in mainland China and EU***

- Commercial sales of 漢曲優® (a breast cancer and gastric cancer treatment product) in mainland China

漢曲優® is the core product of the Group in the field of anti-tumor therapy. It is also the first product sold and promoted by the Group's inhouse commercialization team in mainland China. As at the Latest Practicable Date, 漢曲優® (150mg) had completed the tendering process on the procurement platform and had been included into the medical insurance procurement platform for all provinces and municipalities in mainland China, providing a strong foundation for the comprehensive improvement in sales of 漢曲優®.



The Group has an experienced commercialization core management team, with a commercialization team covering five sectors, including market promotion, channel management, pricing and market access, domestic sales and strategic planning (commercialization team size increased from approximately 400 at the end of last year to approximately 450 at the end of the Reporting Period, including a sales team composed of more than 360 professionals). We made full efforts to develop and penetrate the market in mainland China.



- Commercial sales of Zercepac® (trastuzumab injection) in the international market (a breast cancer and gastric cancer treatment product)

Following Zercepac® (150mg)’s approval to market in the EU in July 2020, Zercepac® (60mg) and Zercepac® (420mg) were approved to market in the EU in April 2021 and June 2021 respectively, providing local patients with a wider choice of dosage forms and a more flexible combination of medications. In July 2021, the Swissmedic approved the application for marketing of Zercepac® (150mg), which symbolized further recognition of the Group’s products in the EU market.



The Group has worked with its business partner Accord Healthcare Limited (“**Accord**”) to promote the commercialization of Zercepac® in the EU, 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® (150mg) has been successfully marketed in the United Kingdom and nearly 20 EU countries and regions including Germany, Spain, France, Italy, Ireland, and Hungary.

### **Commercial sales of 漢達遠® (adamumab) (an autoimmune disease treatment product)**

In December 2020, the new drug application (NDA) of 漢達遠® was approved by the National Medical Products Administration of the PRC (the “NMPA”) for the treatment of rheumatoid arthritis, ankylosing spondylitis and psoriasis. It is the third product of the Group marketed in mainland China. In January 2021, the supplemental new drug application (sNDA) of 漢達遠® for the new indication of uveitis was accepted by the NMPA, and such supplemental new drug application (sNDA) was approved in April 2021. As at the Latest Practicable Date, 漢達遠® had been successfully included into the medical insurance procurement platform for 27 provinces and municipalities.



According to the cooperation agreement between the Company and Jiangsu Wanbang Biopharmaceutical (Group) Co., Ltd.\* (“江蘇萬邦生化醫藥集團有限責任公司”) (“**Jiangsu Wanbang**”), a subsidiary of Fosun Pharma, Jiangsu Wanbang will be responsible for the domestic commercial sales of 漢達遠® after its launch. Jiangsu Wanbang has a sizeable Department of Rheumatology and Immunization and a mixed-line sales team serving the broad market. The marketing team has a high level of professional communication skills and medical knowledge, and boasts successful experience in the commercialization of the rheumatoid treatment product 優立通® (Febuxostat Tablet). In order to improve the standardized diagnosis and treatment services for Chinese patients with rheumatism, Jiangsu Wanbang established the first whole-course care platform “Dayuan Home (達遠之家)” for autoimmune patients in China, which integrates the functions of an Internet hospital, popular science education, public assistance, medical insurance, patient management, drug purchase map, and community care, with an aim to realize the whole-course management of patients from medical treatment to rehabilitation, and benefit more patients with convenient and standardized medical service. In addition, Jiangsu Wanbang took the lead in launching the “ASSC Ankylosing Spondylitis Standardized Treatment Project” in collaboration with the National Clinical Research Center for Skin and Immune Diseases in respect of 漢達遠®. Through a four-tier medical consortium network, we are working together to help standardize the treatment of ankylosing spondylitis in China.

## **2. Products to be commercialized in the near future**

- ***Bevacizumab injection (recombinant humanized anti-VEGF monoclonal antibody injection, original project code: HLX04)***

Bevacizumab injection is independently developed by the Group. The new drug application (NDA) of bevacizumab injection for the treatment of metastatic colorectal cancer (mCRC) and advanced, metastatic or recurrent non-small cell lung cancer was accepted by the NMPA in September 2020. In April 2021, the Group's Xuhui Facility successfully passed the on-site inspection conducted by the Shanghai Medical Products Administration at the drug substance south line and drug product no.1 line for the production of bevacizumab injection.

- ***Rituximab for rheumatoid arthritis (RA) indication***

In order to benefit a wider patient population, the Group has adopted a differentiated development strategy for rituximab injection. In addition to the rituximab injection for all the indications in mainland China, including the original drug for non-Hodgkin's lymphoma that has been approved for the marketing, we also conducted clinical studies on the rheumatoid arthritis indication for which the original drug has not been approved in mainland China. In December 2020, the new drug application (NDA) of rituximab injection rheumatoid arthritis (RA) for new indication was accepted by the NMPA.

- ***Serplulimab injection (recombinant humanized anti-PD-1 monoclonal antibody injection, original project code: HLX10)***

Serplulimab injection is the core innovative mAb product in the Group's product pipeline. The phase 2 clinical research for indications of unresectable or metastatic microsatellite instability-high (MSI-H) solid tumors that fail to respond to the standard therapy met the primary endpoint in March 2021, and the new drug application (NDA) was accepted by the Center for Drug Evaluation of the NMPA in April 2021, and has been formally included in the priority assessment process.

In addition, a global multi-center phase 3 clinical trial to compare serplulimab injection 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) has completed enrollment of subjects. The new drug application (NDA) is expected to be submitted in mainland China in the second half of 2021.

### **3. Commercialization deployment in international markets during the Reporting Period**

During the Reporting Period, the Group adhered to the internationalization strategy by adding 漢曲優® (trastuzumab injection, EU brand name: Zercepac®) to its commercialization portfolio in the United States and Canada. In September 2020, the Group entered into the binding term sheet with Accord Healthcare Inc.. In January 2021, the Group entered into a formal agreement with Intas Pharmaceuticals Limited (“**Intas**”, the parent company of Accord Healthcare Inc.), based on which the Group agreed to grant a license to Intas for the development and commercialization of 漢曲優® (trastuzumab injection, EU brand name: Zercepac®) in the United States and Canada, with the Company to receive a down payment of \$27 million, a regulatory milestone payment of up to \$13 million, a commercial sales milestone payment of \$25 million for each \$500 million in cumulative net sales of the licensed product in the territories, and a tiered royalty of 18% to 50% of the net profit of the licensed product. The partnership is not only a significant milestone for the first entry into the North American market of 漢曲優®, but also a sign of its commercialization to cover the mainstream biologics market in Europe and the United States.

In the meantime, given the slow implementation of the collaboration on 漢利康® in the licensed territories (including Argentina, Paraguay, Uruguay and Bolivia) entered into with Biosidus S.A. (“**Biosidus**”) in May 2018, the Group signed a cooperation termination agreement with Biosidus during the Reporting Period. The Group will continue to seek other partners for cooperation on 漢利康® in such licensed territories.

As at the Latest Practicable Date, the Group has signed business cooperation agreements for several products of the Company with various international pharmaceutical companies including Accord, Cipla Limited, Jacobson Medical (Hong Kong) Limited, PT Kalbe Genexine Biologices (“**KG Bio**”), Farma De Colombia S.A.S, Mabxience Research, S.L. (“**Mabxience**”), Intas, Essex (namely, Essex Bio-Investment Limited and Zhuhai Essex Bio-Pharmaceutical Company Limited\* (珠海億勝生物製藥有限公司)) and Binacea pharma Inc.. The Group will continue to actively promote the global commercialization deployment through strategic commercialization cooperation with the world’s leading pharmaceutical companies.

## **(II) Industrialization-based distribution for biomedicines with high economic benefit based on international standards**

In order to meet the need for the gradual realization of commercial sales of drug candidates in the product pipeline of the Group, the Group has formulated phased capacity planning for different product development cycles, with an aim to gradually improve and enhance large-scale commercial production capacity based on a sound quality management systems, expand capacity and improve economic cost-effectiveness while maintaining high quality standards. In addition, by optimizing the deployment of production technology, production cost control and other aspects in advance, we created a complete value chain integrating research and development, production and traditional commercialization with a focus on excellent commercialization, which laid a solid foundation for the commercialization of the Group's products in multiple jurisdictions and regions.

### ***Xuhui Facility (commercial production capacity of 20,000 liters, the dual GMP certification of China and EU passed)***

As at the end of the Reporting Period, the Group has established Xuhui Facility, a biopharmaceutical production facility in Shanghai Caohejing Hi-Tech Park, covering a total area of approximately 11,000 square meters, which has been certified with Chinese and EU GMP and normalized dual market supply between China and the EU. With a commercial production capacity of 20,000 liters, Xuhui Facility is able to meet the short-term production needs of the Group. During the Reporting Period, the Xuhui Facility continuously improved production efficiency through a series of lean management and process optimization measures, which effectively reduced the production costs. At the same time, the Group also promoted research and change on the production of critical consumables domestically, so as to minimize the risk of material supply in the current international situation.

### ***Songjiang First Plant (production capacity construction of 24,000 liters, the verification of pilot workshop for the continuous production completed)***

In order to further improve medium and long-term production capacity planning, 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 lyophilized preparation line, to prepare for meeting the production demand before the Songjiang Second Plant is put into operation. The drug substance production workshop of the Songjiang First Plant has started GMP production of clinical samples since May 2020. The verification of the remaining eight 2,000L bioreactors was completed on schedule during the Reporting Period. To date, the Songjiang First Plant has completed the commissioning and verification for all the twelve 2,000L bioreactors for the drug substance line and the lyophilized preparation line, and successfully completed various production for process verification purpose. During the Reporting Period, the Group continued to promote the development and industrialization of continuous flow technology in Songjiang First Plant. The Group also completed the first batch of non-GMP production for downstream continuous processing of a single project.

***Songjiang Second Plant (total planned land area of 200 mu and designed production capacity of 36,000 liters for Phase I project)***

In order to meet the long-term commercial production capacity demand, the construction of the Phase I project of the Songjiang Second Plant, with a total planned land area of 200 mu and designed production capacity of 36,000L was started in 2019 and is currently under construction. As at the Latest Practicable Date, for the Phase I project of the Songjiang Second Plant, the foundation works and structure of the two main production buildings have been completed, the main structure of the main production buildings has been checked and accepted and all building sections completed. The structure of the supplementary production facilities have been completed, the main structure of the facilities has been checked and accepted, and the factory acceptance testing for the main production facilities such as the drug substance lines and the drug product lines has fully commenced. The construction of the Songjiang Second Plant in the subsequent phase will be gradually implemented in accordance with the Group's strategy.

**(III) Sustainable global product development capability**

The Group took the lead in launching 3 monoclonal antibody biosimilar drugs – 漢利康®, 漢曲優® (trastuzumab injection, EU brand name: Zercepac®), and 漢達遠®, to provide strong financial support for further innovation. During the Reporting Period, based on clinical needs, the Group gradually improved the deployment of the innovation pipeline including serplulimab injection (PD-1), HLX208 (small-molecule inhibitor targeting V600E mutation in human BRAF protein). The Group has been working to develop innovative products around MSI-H solid tumours, colorectal cancer, lung cancer and other indications in an orderly manner.

Serplulimab injection is the core innovative mAb in the Group's product pipeline, based on which the Group also pioneered the introduction of combined immunotherapy. As at the Latest Practicable Date, serplulimab injection has been successively approved for clinical trials in China, the United States, EU and other countries/regions; multiple clinical researches are in the process, including 2 international multi-center clinical trials; and as at the end of the Reporting Period, a total of approximately 2,300 subjects have been enrolled in the trials in China, Turkey, Poland, Ukraine, Russia and other countries/regions, representing an increase of approximately 300 subjects for trials as compared with the end of last year. HLX208 (BRAF V600E inhibitor), an innovative product in-licensed by the Group during the Reporting Period, is currently in Phase 1 clinical study and early clinical data have also demonstrated preliminary efficacy and minimal side effects, and may have synergy with the Group's EGFR or PD-1 targeted antibodies to enhance a high-quality, differentiated and innovative product portfolio for the treatment of various cancers. The clinical studies of HLX208 (BRAF V600E inhibitor) on the indications of metastatic colorectal cancer, metastatic non-small cell lung cancer, undifferentiated thyroid cancer, brain cancer and others are also in the process of active promotion.



In 2021, the Group appointed Mr. Zhu Jun (朱俊) as senior vice president and chief medical officer to build a global product development team and a new clinical operations and regulatory affair system comprising clinical operations, medicine, data, clinical compliance and quality assurance, pharmacovigilance and regulatory affair. Mr. Zhu has nearly 20 years of experience in the biotechnology and pharmaceutical industry, etc.. He had cooperated with over 70 China local pharmaceutical and biotech companies and led the design and execution of over 100 phase 1 to 4 clinical trials. Prior to joining the Group, Mr. Zhu was the China general manager of Omnicare Clinical Research Inc. , the global vice president of IQVIA Holdings Inc. and the founder and chief executive officer of PPC China Corporation Limited\* (上海百利佳生醫藥科技有限公司). As at the end of the Reporting Period, the Group has established a global product development team with more than 300 staff, to actively promote the clinical research and regulatory affairs of many candidate drugs across the world, and achieved significant progress in 4 clinical trials and multiple global clinical trial approvals for 4 products during the Reporting Period.

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

As at the Latest Practicable Date, the Group has obtained in total more than 40 clinical trial approvals worldwide, and more than a total of 20 clinical trials for 11 products and 8 combination therapies have been carried out in an orderly manner in various countries/regions, including China, the EU, the United States, Australia, Ukraine, the Philippines and Turkey.

#### ***Progress of international clinical research projects***

- In January 2021, the application for a clinical trial for HLX04-O (recombinant humanized anti-VEGF monoclonal antibody injection) for the treatment of wet age-related macular degeneration (wAMD) was approved by the Therapeutic Goods Administration, Australia, and the phase 3 clinical trial was given permission to commence in Australia. The phase 3 investigational new drug application (IND) was also approved by FDA and the State Agency of Medicines of Latvia in March 2021 and April 2021, respectively. In addition, HLX04-O has been successively approved to commence the phase 3 clinical trial in EU countries such as Hungary and Spain as well as in Singapore. The phase 3 international multi-center clinical trial is intended to be launched soon.
- In April 2021, the first subject was dosed in the Phase 1 clinical trial of HLX71 (ACE2-Fc receptor fusion protein) for the treatment of novel coronavirus pneumonia (COVID-19) in the United States. The enrollment of subjects was completed during the Reporting Period.

The deployment of international clinical research is not only conducive to the global market coverage of the Group's products in the future, but also lays the foundation for the Group's products to benefit patients worldwide.



## ***Progress of domestic clinical research projects***

- In January 2021, the enrollment of subjects was completed in a phase 2 clinical trial of serplulimab injection (PD-1) in combination with bevacizumab injection against advanced hepatocellular carcinoma (HCC).
- In March 2021, the first patient dosing was completed in a phase 2/3 clinical trial of serplulimab injection in combination with bevacizumab injection and chemotherapy (XELOX) as first-line treatment for metastatic colorectal cancer (mCRC) in mainland China.
- In March 2021, a single-arm, open-label, multi-center and the phase 2 clinical trial of serplulimab injection for the treatment of unresectable or metastatic microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) solid tumors that fail to respond to the standard therapy met the primary endpoint.
- In July 2021, the first patient dosing was completed in a phase 1 clinical trial of HLX04-O (recombinant humanized anti-VEGF monoclonal antibody injection) for the treatment of wet age-related macular degeneration (wAMD) in mainland China.

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

During the Reporting Period, the Group continued to attach 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 CD38, LAG-3 and CD73.

- In January 2021, the investigational new drug application (IND) of recombinant anti-CD38 human monoclonal antibody injection (HLX15) for the treatment of multiple myeloma was approved by the NMPA.
- In January 2021, the investigational new drug application (IND) of recombinant anti-LAG-3 human monoclonal antibody injection (HLX26) for the treatment of solid tumors and lymphomas was accepted by the NMPA. Such application was approved by the NMPA in April 2021.
- In May 2021, the investigational new drug application (IND) of recombinant anti-CD73 fully human monoclonal antibody injection (HLX23) for the treatment of advanced solid tumors was approved by FDA.

The clinical and pre-clinical application results of the products of the Group from the beginning of 2021 to the Latest Practicable Date:

<b>Product name (reference drugs/targets)</b>	<b>Indications</b>	<b>Progress as at the Latest Practicable Date</b>
<b>Efficient advancement on international clinical research projects</b>		
<b>HLX04-O</b> (recombinant humanized anti-VEGF monoclonal antibody injection)	wet age-related macular degeneration (wAMD)	<p>In January 2021, the investigational new drug application (IND) was approved by Therapeutic Goods Administration, Australia</p> <p>In March 2021, the investigational new drug application (IND) was approved by FDA</p> <p>In April 2021, the investigational new drug application (IND) was approved by the State Agency of Medicines of Latvia</p>
<b>HLX71</b> (ACE2-Fc receptor fusion protein)	COVID-19	In April 2021, the first subject dosing was completed in a phase 1 clinical trial in the United States. The enrollment of subjects was completed during the Reporting Period.
<b>Smooth progress of domestic clinical projects</b>		
<b>HLX10+HLX04</b> (PD-1+VEGF)	Hepatocellular Carcinoma (HCC)	In January 2021, the enrollment of subjects was completed in a phase 2 clinical trial
<b>HLX10+HLX04</b> (PD-1+VEGF)	Metastatic colorectal cancer (mCRC)	In March 2021, the first patient dosing was completed in a phase 2/3 clinical trial in mainland China
<b>HLX10</b> (PD-1)	Solid tumor (MSI-H/dMMR)	In March 2021, the phase 2 clinical trial met the primary endpoint
<b>HLX04-O</b> (recombinant humanized anti-VEGF monoclonal antibody injection)	wet age-related macular degeneration (wAMD)	In July 2021, the first patient dosing was completed in a phase 1 clinical trial in mainland China

<b>Product name (reference drugs/targets)</b>	<b>Indications</b>	<b>Progress as at the Latest Practicable Date</b>
<b>Efficient advancement on IND application for pre-clinical development projects</b>		
<b>HLX15</b> (daratumumab)	Multiple myeloma (MM)	In January 2021, the investigational new drug application (IND) was approved by the NMPA
<b>HLX26</b> (recombinant anti- LAG-3 human monoclonal antibody injection)	Solid tumor, lymphoma	In January 2021, the investigational new drug application (IND) was accepted by the NMPA  In April 2021, the investigational new drug application (IND) was approved by the NMPA
<b>HLX23</b> (recombinant anti- CD73 fully human monoclonal antibody injection)	Advanced solid tumor	In May 2021, the investigational new drug application (IND) was approved by FDA

**WARNING STATEMENT REQUIRED BY RULE 18A.05 OF THE RULES GOVERNING THE LISTING OF SECURITIES ON THE STOCK EXCHANGE OF HONG KONG LIMITED (“Listing Rules”): We may not be able to ultimately develop and market our core products.**

## **II. BUSINESS OUTLOOK FOR THE SECOND HALF OF THE YEAR**

In the second half of 2021, the Group will further expand its biopharmaceutical product pipeline covering oncology, auto-immune diseases and more fields, capitalise on the achieved first-entrant advantages to further advance the implementation of the Group's innovative transformation and internationalisation strategy, improve the production base construction, expand production capacity and accelerate the commercialization of more high-quality biological products to benefit more patients worldwide.

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

As one of the leading biomedicine companies in China, the Group actively responds to the national call, cooperates with the national pharmaceutical reform, and provides patients with affordable high quality biological drugs. At the same time, based on the patient-oriented principle, the Group has established a comprehensive and efficient business operation model in five segments, including marketing, channel management, pricing and market access, domestic sales and strategic planning, to continuously promote the successful commercialization of more products, so as to improve the accessibility and affordability of biological drugs.

漢曲優® is the anti-tumor core product sold and promoted by the Group's inhouse commercialization team in mainland China. Following the launch of 漢曲優® with the dosage form of 150mg in August 2020, supplemental new drug application (sNDA) for the product with the dosage form of 60mg was accepted by the NMPA in October 2020 and it was approved recently. With the launch of 150mg and 60mg dosage forms, we can flexibly meet the clinical medication needs of breast cancer patients with different body weight through more dosage forms, and provide patients with personalized and more economical treatment plans. In the first half of 2021, the Group gained an excellent market reputation in the construction of the diagnosis and treatment ecosystem for patients with HER2-positive breast cancer and gastric cancer. In the second half of the year, the Group will continue to actively cooperate with relevant enterprises in terms of medical big data, HER2 testing, innovative payment, patient management and education, doctor education and other aspects, with an aim to further consolidate the construction of the diagnosis and treatment ecosystem for HER2-positive patients. On this basis, the Group will constantly strengthen market access, accelerate commercialization and promotion in the domestic market, and drive the market expansion of its products. At the same time, the inclusion of biosimilars to the 2021 edition of the Chinese Society of Clinical Oncology (CSCO) Guidelines for treatment of breast cancer and the inclusion of 漢曲優® to the 2021 edition of the Chinese Society of Clinical Oncology (CSCO) Guidelines for treatment of gastric cancer will also actively accelerate the Group's promotion of 漢曲優® in the domestic market in the second half of the year. In 2021, the sales network of 漢曲優® will be continually strengthened. The sales team is expected to be further expanded to span across approximately 390 cities in China, covering nearly 4,500 DTP pharmacies/hospitals.

In the second half of 2021, the Group will continue to strengthen the sales of 漢利康® (100mg/10ml), capitalize on their first-entrant advantage, maintain close cooperation with Jiangsu Fosun, and focus on the continuous growth of 漢利康® in the field of blood tumors. The Group will also cooperate with Jiangsu Fosun to promote the inclusion of 漢利康® (500mg/50ml) into medical insurance procurement platforms and admission into hospitals in all provinces across China, so as to provide more clinical dosage forms. In addition, the cooperation between 漢利康® and academic organizations will be further strengthened, with a view to effectively promoting the standardized treatment of lymphoma through academic exchange activities. The Group will also promote the approval of the new drug application (NDA) for the rituximab injection for innovative indication rheumatoid arthritis (RA), so as to expand patient population of the rituximab injection to further benefit a wider patient population suffering from rheumatoid arthritis.

In addition, the Group will continue to cooperate with Jiangsu Wanbang to prepare for the sales of 漢達遠®, and advance in both the field of rheumatism (for indications of ankylosing spondylitis and rheumatoid arthritis (RA)) and the field of skin (for indications of psoriasis). The coverage of 漢達遠® is expected to be extended to 4,000 specialists and about 3,000 DTP pharmacies/hospitals in 2021, so as to ensure the channel accessibility of 漢達遠® on the basis of economic accessibility and strive to achieve the target that patients can purchase the drugs without leaving their own county. In the second half of the year, the “ASSC Standardized Diagnosis and Treatment Project for Ankylosing Spondylitis” focusing on 漢達遠® ankylosing spondylitis indications, coupled with cooperation in relation to indications of psoriasis such as various lectures, free consultations and patient education by Dermatovenereology Branch of Chinese Medical Association will be further accelerated in hope of bringing an end to the pain and suffering of a wider patient population, and striving to fulfill the mission of 漢達遠® to treat every autoimmune disease patient in China as much as possible.

While actively deploying the domestic market, the Group will continue to promote the business cooperation of self-developed products in the international market. Based on the continuous development of R&D and progress in registration of various products in the Group’s product pipeline, as well as the gradual understanding and full recognition of its products in the international market, the Group will continue to actively explore the global market and seek strategic cooperation with more leading international pharmaceutical companies in the second half of the year, with an aim to jointly promote the global registration and clinical research of projects and extend the coverage of its products to a broader international market, especially the emerging markets where there is a huge unmet demand for affordable drugs, through the influence of the international strategic partners, thus benefiting overseas patients.

## **(II) CONTINUE TO COMMERCIALIZE MORE PRODUCTS**

### ***BEVACIZUMAB INJECTION (RECOMBINANT HUMANIZED ANTI-VEGF MONOCLONAL ANTIBODY INJECTION, ORIGINAL PROJECT CODE: HLX04)***

Bevacizumab injection is independently developed by the Group. Different from the biosimilar drugs of bevacizumab currently on the market in China, metastatic colorectal cancer (mCRC) was selected in the design of a phase 3 comparative study on the clinical efficacy and safety of bevacizumab injection. It is the only current biosimilar drug of bevacizumab with clinical data of metastatic colorectal cancer in China, and more the clinical data and experience can be accumulated for the application of bevacizumab in colorectal cancer patients in China. It is expected that the new drug application (NDA) of bevacizumab injection will be approved in the fourth quarter of 2021 or early 2022. Given the fact that a new indication of glioma (GBM) was added for the reference Bevacizumab in China in 2020, the Group also plans to start the supplemental new drug application (sNDA) for the new indication after the launch of bevacizumab injection.

### ***RITUXIMAB FOR RHEUMATOID ARTHRITIS (RA) INDICATIONS***

The rituximab injection for a new indication of rheumatoid arthritis (RA) was independently developed by the Group with a differentiated strategy. The new drug application (NDA) of the injection for a new indication of rheumatoid arthritis (RA) was accepted by the NMPA in December 2020. It is expected to fully realise the clinical potential of the rituximab injection in the field of rheumatic immunity. The rituximab injection has the advantages of low frequency of administration and long duration of drug effectiveness, which is expected to improve patients' medication compliance, effectively improve the quality of life of patients and reduce the medical burden of patients. The Group will actively promote the approval of new drug application (NDA) of rituximab injection for the treatment of rheumatoid arthritis (RA) indication, and it is expected that it will be approved by the end of 2021 or in the first half of 2022.

### ***SERPLULIMAB INJECTION (RECOMBINANT HUMANIZED ANTI-PD-1 MONOCLONAL ANTIBODY INJECTION, ORIGINAL PROJECT CODE: HLX10)***

Serplulimab injection is the core innovative monoclonal antibody product in the Group's product pipeline, and the related production and R&D are in strict compliance with international quality standards. As at the Latest Practicable Date, clinical trials of 1 serplulimab injection monotherapy and 8 combination therapies with serplulimab injection at their core have been simultaneously carried out in many countries and regions around the world. In addition, the business cooperation for serplulimab injection in 10 countries in Southeast Asia based on the cooperation agreement entered into with KG Bio in 2019 will be further carried out following the gradual approval of the product. The new drug application (NDA) of serplulimab injection for indications of unresectable or metastatic microsatellite instability-high (MSI-H) solid tumors that fail to respond to the standard therapy was accepted by the NMPA in April 2021 and officially included in the list of "Priority Review", which is expected to be approved in the first half of 2022. The Group is expecting to submit the new drug application (NDA) of indication of serplulimab injection combining chemotherapy (carboplatin-albumin paclitaxel) in first-line treatment of locally advanced or metastatic squamous non-small cell lung cancer (sqNSCLC) in mainland China in the second half of 2021. The commercialization strategy formulation and market deployment in various therapeutic fields of serplulimab injection will be promoted simultaneously.



### **(III) CONTINUE TO BUILD INNOVATIVE PRODUCT PIPELINE THROUGH INDEPENDENT R&D AND LICENSE-IN**

#### ***1. CONTINUOUS INDEPENDENT INNOVATION RESEARCH AND DEVELOPMENT BASED ON ITS OWN RICH PIPELINE***

In 2021, the Group will, by making full use of international resources and advantages, following the international frontier trend to continue expansion, enrich the innovative product target layout, optimize the development platform of dual specific antibodies, and continue to create a high-quality, affordable and differentiated innovative product pipeline, so as to promote R&D in innovative drugs, achieve excellence in commercialization, and truly meet the needs of patients and the market. The new drug application (NDA) of Group's independently developed core product, serplulimab injection for the indication of unresectable or metastatic microsatellite instability-high (MSI-H) solid tumors that fail to respond to the standard therapy, was accepted in April 2021 and included in the list of "Priority Review". It is expected that the new drug application (NDA) of the indication of serplulimab injection combining chemotherapy as first-line therapy for locally advanced or metastatic squamous non-small cell lung cancer (sqNSCLC) will be submitted in the second half of 2021. In addition, it is expected that the serplulimab injection based clinical trial of tumor immunocombination therapy for indications of squamous non-small cell lung cancer, non-squamous non-small cell lung cancer, extensive stage small cell lung cancer, esophageal squamous cell carcinoma, gastric cancer, hepatocellular carcinoma, head and neck squamous cell carcinoma, and metastatic colorectal cancer will be further promoted in 2021. Among them: five indications are currently in phase 3 clinical studies (four of which are expected to have the subjects enrolled for the phase 3 clinical trials in 2021); three indications are currently in phase 2 clinical studies. The Group will continue to promote the further development of the research, the release of relevant clinical trial data at important international industry conferences (including ESMO, ASCO, etc.) and the subsequent application for product marketing.

While rapidly advancing the clinical trials of drug candidates in the pipeline, the Group will continue to efficiently advance the pre-clinical development process of products under research, promote the global registration and approval of products in the pipeline, including several innovative monoclonal antibody, dual clonal antibody including HLX301(PD-L1xTIGIT) and HLX35(EGFRx4-1BB) and antibody-drug conjugates (ADC) products, and carry out the corresponding clinical research plans.



## **2. *License-in and cooperative development***

In order to actively deploy the pipeline of innovative products, the Group plans to accelerate the expansion of innovative potential targets, dual-target antibody platform, antibody-drug conjugates (ADC) products, radioimmunotherapy and cancer vaccine products through the in-licensed projects. Relying on the Group's rich experience in target development and integrated R&D platforms, we will actively develop more innovative products that are needed by the market based on the in-licensed projects, and seek synergies between them and the existing pipeline of innovative products. In January 2021, the Company signed an exclusive license agreement with Chiome Bioscience, Inc. to introduce an exclusive right to research, develop, produce and commercialize the antibodies against human TROP2 (Trophoblast cell-surface antigen 2) and the relevant intellectual property in China (including Hong Kong, Macau and Taiwan, China). TROP2, expressed in triple negative breast cancer, non-small cell lung cancer, urothelial carcinoma and many types of solid tumors, is expected to be a therapeutic target with broad spectrum anti-tumor effects, and has the potential of development in the direction of antibody-drug conjugates (ADC), bispecific antibodies and combination therapy. In March 2021, the Company entered into a binding term sheet with Suzhou NeuPharma Co., Ltd.\* (蘇州潤新生物科技有限公司) to introduce an exclusive license to develop, manufacture, commercialize and sublicense HLX208, a small-molecule inhibitor targeting V600E mutation in human BRAF protein, in China (including Hong Kong, Macau and Taiwan, China). The product has brand-new chemical parent nucleus structures, and preclinical study results show that it has outstanding tumor suppression activity and sound safety. The formal agreement for the relevant cooperation was officially signed in May 2021. In addition, the Group also plans to actively expand products at various development stages in the field of cancer and other diseases by way of cooperative development with its partners on the basis of cost and risk sharing, and explores more innovative possibilities based on clinical needs by leveraging the strengths and expertise of their respective fields of expertise.

### **(IV) Maintain high quality standards and continue to promote industrialization deployment**

The Group will complete the construction of production base and the expansion of production capacity according to the planning and the product R&D and marketing process, in order to provide a strong guarantee for the continuous commercial sales of products and realize an efficient utilization of production capacity. Xuhui Facility has made further progress in improving production efficiency and reducing production costs during the Reporting Period through a series of lean management and process optimization initiatives. The relevant measures will continue to be promoted in the second half of 2021. In addition, Xuhui Facility also plans to add a prefilled syringe production line in 2021, with installation and commissioning to be completed by the end of 2021, so as to provide further supply for the short-term market demand of our marketed products.

As at the Latest Practicable Date, the Songjiang First Plant has completed the commissioning and verification for all the twelve 2,000L bioreactors for the drug substance line and the drug product line, and successfully completed various production for process verification purpose. On that basis, a product packaging line is planned to be built for the Songjiang First Plant for the purpose of further optimizing the control system of production workshop and facility devices so as to be well positioned for the verification of relevant medical products administration in respect of GMP and production license in the second half of 2021. Also, the Songjiang First Plant plans to submit a supplementary application for the second-generation process of 漢曲優® to the NMPA in the second half of 2021, and it is expected to be formally put into commercial production in 2022. The Songjiang First Plant also plans to continue on the improvement of international standard quality system and to complete the GMP inspection by the United States Food and Drug Administration (FDA) in 2022. In addition to production capacity construction, the continuous production pilot workshop of the Songjiang First Plant shall complete the consecutive production test of at least two products within 2021, so as to ensure the production efficiency and quality for the future large-scale commercial production.

To achieve the long-term capacity planning, we will continue to promote the construction of the Songjiang Second Plant to enhance the overall production capacity of the Group. The construction of major production buildings and installation of process equipment of the Phase I project of the Songjiang Second Plant are expected to complete and enter into the phase of coordinated commissioning and verification by the end of 2021, while the verification work of facility equipment is expected to complete and enter into the phase of trial production and process verification in the first half of 2022. 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 of 2021, the Group continued to adhere to the core philosophy of providing “Reliable Quality, Affordable Innovation” drugs, bringing more and better new treatment options to patients around the world. Taking excellent commercialization as its main pursuit, the Company used its best endeavors to promote the commercialization of products in both China and global market while tapping the market potential to further maximize the commercial value of biosimilar. During the Reporting Period, with the successful commercialization of the three core products over the past two years and leveraging on precise, mature and sound marketing strategic positioning and a highly effective and well-developed commercialization team, the Company saw a constant increase in its product sales, which was an encouraging achievement.

In addition to the above, being an international innovative biopharmaceutical company, Henlius continually kept to the international strategic planning during the Reporting Period, strategically authorizing commercialization rights of out-licensed products based on extensive product pipeline and cooperated with international partners while proactively promoting its global presence, thereby bringing in considerable licensing and R&D service income to the Group.

During the six months of the Reporting Period, the Group realized revenue of RMB633.6 million, representing an increase of 474% as compared to the six months of the same period last year, which was mainly due to the sales income derived from the commercialization of various products and incomes from the R&D services and licensing provided to customers. The main income components are as follows:

**1) *Revenue from Chinese market:***

漢利康®, the Group's first commercial product that was successfully marketed, duly received a new drug application (NDA) approval from the NMPA in February 2019. It was the first-of-its-kind biosimilar in China, the domestic commercial sales of which were handled by Jiangsu Fosun, a subsidiary of Fosun Pharma. According to the cooperation agreement with Fosun Pharma, Fosun Pharma will reimburse all the expenses related to the clinical trials of 漢利康® incurred by the Group after the relevant cooperation agreement is signed, while the Group is responsible for the production of 漢利康® in China and the supply of 漢利康® to Fosun Pharma upon its commercialization, and shall share the profits from the sales of 漢利康® in China. During the Reporting Period, the Group realized sales revenue of approximately RMB222.2 million and licensing revenue of approximately RMB5.2 million for 漢利康® during the Reporting Period under the aforementioned profit sharing arrangement with its partners.

漢達遠®, the Company's third monoclonal antibody biologic drug marketed in China, and also the first product to treat autoimmune disorders, was approved by the NMPA for marketing in December 2020. The Group has entered into a commercialization agreement with Fosun Pharma to promote the commercial development of 漢達遠® by fully relying on the successful experience of Fosun Pharma, which has been deeply engaged in the field of rheumatic immunity for many years. According to the cooperation agreement with Fosun Pharma, Fosun Pharma will reimburse all the expenses related to the clinical trials of 漢達遠® incurred by the Group after the relevant cooperation agreement is signed. After the commercialization of 漢達遠®, the Group will be responsible for the production of 漢達遠® in China and the supply of 漢達遠® to Fosun Pharma, and shall share the profits from the sales of 漢達遠® in mainland China. During the Reporting Period, the Group realized sales revenue of approximately RMB8.5 million and licensing revenue of approximately RMB2.2 million for 漢達遠® under the aforementioned profit sharing arrangement with its partners.

漢曲優<sup>®</sup>, a biosimilar drug of monoclonal antibody independently developed by the Group, which has great market potential, began to be commercialized in the domestic market in August 2020. Based on the long-term development strategy of the Group, we mainly commercialized 漢曲優<sup>®</sup> through our own team. Since 漢曲優<sup>®</sup> was approved for marketing, our own sales team has been expanding, aiming to strengthen the sales network plan with a focus on consolidating the construction of the diagnosis and treatment ecosystem for HER2-positive patients while at the same time being proactive in cooperating with relevant enterprises to drive the market expansion of its products, with the aim of leaving no HER2-positive patient behind. During the Reporting Period, the Group realized sales revenue of approximately RMB287.6 million for 漢曲優<sup>®</sup>.

## **2) *Revenue from international market***

In order to better develop the international market and bring high-quality and low-cost treatment solutions to patients around the world, the Group proactively practiced a comprehensive international R&D and operation strategy, and promoted the commercialization of its products in the international market by entering into strategic commercialization cooperation with international leading pharmaceutical companies. 漢曲優<sup>®</sup> (trastuzumab injection, EU trade name: Zercepac<sup>®</sup>), the first China-developed mAb biosimilar approved both in China and in the EU, set a precedent for Chinese enterprises to participate in the “World Cup” competition, further opening up the way to internationalization of domestic monoclonal antibody drugs. The Group continued to work with Accord, its business partner to actively promote the commercialization of Zercepac<sup>®</sup> in the EU to expedite the implementation of commercialization in overseas markets. As at the end of the Reporting Period, the Group realized revenue of approximately RMB26.7 million for Zercepac<sup>®</sup>, while realizing sales revenue of drug substance of trastuzumab of approximately RMB11.0 million.

## **3) *Joint development and technology transfer/commercialization licensing revenue***

During the Reporting Period, the Group also carried out business cooperation with many partners around the world based on various projects, including intellectual property licensing, joint development, commercialization licensing, etc.

In June 2018, the Group entered into a license agreement with Accord in relation to Zercepac<sup>®</sup>, granting Accord exclusive commercial rights in specific regions as agreed therein. In July 2020, the marketing authorization application (MAA) of Zercepac<sup>®</sup> submitted by a wholly-owned subsidiary of Accord was approved. Since then, 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 centralized marketing license. During the Reporting Period, the Group realized licensing revenue and revenue from R&D services of approximately RMB7.1 million.

In September 2019, the Group entered into a collaborative research, development and commercialization agreement with KG Bio for serplulimab injection, a biologically innovative anti-PD-1 mAb in which the Group has exclusive patent and technical expertise. With the continued performance of R&D services, the Group has recognised revenue from R&D services of approximately RMB10.7 million for the Reporting Period.

In September 2020, the Group entered into a co-development and exclusive license agreement with Essex in relation to HLX04-O (recombinant humanized anti-VEGF monoclonal antibody injection) independently developed by the Group. The Group has recognised licensing revenue and revenue from R&D services of approximately RMB40.6 million for the Reporting Period.

In January 2021, the Group and Intas entered into a license agreement in relation to 漢曲優® (trastuzumab injection, EU trade name: Zercepac®), granting Intas exclusive rights to develop, produce and commercialize in specific regions as agreed therein. During the Reporting Period, the Group realized revenue from R&D services of approximately RMB11.9 million.

## (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 RMB221.4 million, representing an increase of approximately RMB163.1 million as compared with that for the six months ended 30 June 2020, which was mainly due to the increase in production cost as a result of the increased production volume of the commercialization of key products.

## (III) Gross profit

During the Reporting Period, the Group recorded a gross profit of RMB412.2 million, representing an increase of approximately RMB360.2 million, or 692.3% as compared with that for the six months ended 30 June 2020, mainly due to the gross profit contribution from the commercialization 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); (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 RMB20.0 million.

	Six months ended 30 June	
	2021 RMB'000	2020 RMB'000
Government grants	17,944	15,785
Exchange gains	–	10,227
Interest income	1,219	7,763
Others	808	479
<b>Total</b>	<b>19,971</b>	<b>34,254</b>

## (V) R&D expenditure

	Six months ended 30 June	
	2021	2020
	RMB'000	RMB'000
<b>Expensed R&amp;D expenses</b>		
Share-based compensation	10,122	24,270
R&D employee salaries	143,966	121,901
Outsourcing fees	20,614	17,244
Reagents and consumables	47,857	64,377
Utilities expenses	8,634	7,287
Depreciation and amortisation	40,902	33,240
Consulting expense	5,683	5,636
Technical usage fees	113,969	—
Clinical trials	40,600	93,523
Others	19,466	25,497
<b>Total expensed R&amp;D expenses</b>	<b>451,813</b>	<b>392,975</b>
<b>Capitalised R&amp;D expenses</b>		
Clinical trials	137,110	219,010
R&D employee salaries	82,103	66,983
Reagents and consumables	17,846	30,887
Depreciation and amortisation	19,369	2,526
Utilities expenses	3,679	7,715
Outsourcing fees	12,174	14,159
Share-based compensation	4,306	19,917
Consulting expense	1,357	—
Others	9,581	2,732
<b>Total capitalised R&amp;D expenses</b>	<b>287,525</b>	<b>363,929</b>

During the Reporting Period, the Group recognised R&D expenditure of approximately RMB739.3 million, representing a decrease of approximately RMB17.6 million or approximately 2.3% as compared with approximately RMB756.9 million for the six months ended 30 June 2020, which was mainly due to the strategic adjustment to projects and time difference.

## (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 RMB118.3 million, representing an increase of 87.2% as compared to that of approximately RMB63.2 million for the six months ended 30 June 2020. 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; (2) the increase in office administrative expenses in conjunction with business development.



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

The Group's selling and distribution expenses mainly included salaries, other expenses and promotional activity expenses.

During the Reporting Period, the Group recognised selling and distribution expenses of approximately RMB197.3 million, which were mainly the marketing expenses incurred in the marketing and commercialization of 漢曲優® products.

## **(VIII) Other expenses**

During the Reporting Period, the Group incurred other expenses of RMB18.3 million, representing an increase of RMB13.8 million from RMB4.5 million for the six months ended 30 June 2020. Such other expenses comprised exchange loss of RMB8.8 million due to the fluctuation of the foreign-currency exchange rates and RMB5.0 million mainly related to donations to various charitable organisations and provisions of RMB3.1 million for inventory impairment.

## **(IX) Income tax expenses**

During the Reporting Period, the Group did not incur any income tax expenses.

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

In view of the above, the Group's loss decreased by approximately RMB54.2 million from approximately RMB448.0 million for the six months ended 30 June 2020 to approximately RMB393.8 million for the six months ended 30 June 2021.

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

As at 30 June 2021, the cash and cash equivalents of the Group were approximately RMB1,232.0 million, mainly denominated in Renminbi ("RMB"), United States Dollars ("USD"), New Taiwan Dollars ("NTD"), Hong Kong Dollars ("HKD") and Euro. As of 30 June 2021, the current assets of the Group were approximately RMB1,992.3 million, including cash and cash equivalents of approximately RMB1,232.0 million. There is no pledged deposits.

The inventories were approximately RMB346.7 million, trade receivables were approximately RMB216.4 million, prepayments, deposits and other receivables were approximately RMB197.1 million. As at 30 June 2021, the current liabilities of the Group were approximately RMB2,277.7 million, including trade payables of approximately RMB186.1 million, other payables and accruals of approximately RMB406.9 million and interest-bearing bank borrowings and other borrowings of approximately RMB1,627.5 million.



As at 30 June 2021, the foreign exchange bank balances of the Group were as follows:

	<i>RMB'000</i>
RMB	469,357
HKD	1,238
USD	759,434
Euro	259
NTD	1,714
	<u>          </u>
	<i>Original amount</i>
RMB	469,357
HKD	1,488
USD	117,564
Euro	34
NTD	7,406
	<u>          </u>

## **(XII) Inventories**

Inventories of the Group increased from approximately RMB305.2 million as at 31 December 2020 to approximately RMB346.7 million as at 30 June 2021, which was mainly due to the increase in the inventory volume of finished products, so as to provide better support for the product supply in response to increasing demand in the market.

## **(XIII) Trade receivables**

As at 30 June 2021 and 31 December 2020, trade receivables from customer contracts were approximately RMB216.4 million and RMB196.2 million, respectively. There were no changes in accounting estimates or material assumptions made in both periods.

	<b>30 June 2021 <i>RMB'000</i></b>	<b>31 December 2020 <i>RMB'000</i></b>
Within 3 months	<u>216,405</u>	<u>196,213</u>
<b>Total</b>	<u>216,405</u>	<u>196,213</u>

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

As at 30 June 2021, borrowings from banks and other institutions (exclusive of lease liabilities) of the Group were approximately RMB2,303.0 million. The Group incurred new borrowings for the following reasons: ongoing clinical research trials and preclinical research for drug candidates, commercialization of products, construction of plants and normal operating expenses. The borrowings of the Group were denominated in RMB, USD and NTD.

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

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

The following table sets forth the maturity structure of outstanding debts as at 30 June 2021 and 31 December 2020, of which lease liabilities were initially recognised upon the adoption of IFRS 16 – Leases on 1 January 2017.

	<b>30 June 2021 RMB'000</b>	<b>31 December 2020 RMB'000</b>
Within one year	<b>1,627,497</b>	1,188,486
In the second year	<b>377,966</b>	82,089
In the third to fifth year (inclusive)	<b>322,299</b>	320,792
Over five years	<b>277,013</b>	242,250
<b>Total</b>	<b><u>2,604,775</u></b>	<b><u>1,833,617</u></b>

#### (XVI) Collateral and pledged assets

As at 30 June 2021, the Group's pledged assets in relation to borrowings included trade receivables and other receivables of approximately RMB10.8 million, construction in progress of approximately RMB249.5 million and land use right of approximately RMB203.2 million.

## (XVII) Key financial ratios

	30 June 2021	31 December 2020
Current ratio <sup>(1)</sup> :	87.5%	96.5%
Quick ratio <sup>(2)</sup> :	72.2%	81.1%
Gearing ratio <sup>(3)</sup> :	32.3%	18.4%

### 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.

## (XVIII) Major investment

In order to satisfy the expected market demand for drugs in our pipeline, 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 RMB1.72 billion for the construction of the Phase I project of the Songjiang Second Plant (first stage and second stage). As at the end of the Reporting Period, the facility is under construction and the subsequent stages of construction will be gradually carried out based on the strategy of the Group. The capital expenditure of the construction of the Songjiang Second Plant will be mainly funded through debt financing.

Save as disclosed in this announcement, as at 30 June 2021, the Group did not make other significant investments.

#### (XIX) Capital commitments and capital expenditures

	<b>30 June 2021 RMB'000</b>	<b>31 December 2020 RMB'000</b>
Plant and machinery	<b>49,405</b>	170,240
Construction in progress	<b>109,678</b>	274,769
Leasehold improvements	<b>24,010</b>	106,058
Electronic equipment	<b>6,311</b>	15,822
Others	<b>377</b>	473
<b>Total</b>	<b><u>189,781</u></b>	<b><u>567,362</u></b>

We had capital commitments for plant and machinery contracted but not provided for of RMB685.2 million as at 30 June 2021. 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 cost to be capitalised.

#### (XX) Contingent liabilities

As at 30 June 2021, the Group did not have any material contingent liabilities.

#### (XXI) Material acquisitions and disposals

As at 30 June 2021, the Group did not have any material acquisitions and disposals.

#### (XXII) Interim dividends

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

### IV. RISK MANAGEMENT

#### (I) Foreign exchange risk

Up until 30 June 2021, 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 denominated in USD and Euro and other currencies will increase to certain degrees 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 commercialized products and products that may be commercialized in the future face competition from pharmaceutical companies around the world in respect of various factors such as treatment indication, drug novelty, drug quality and reputation, breadth of drug portfolio, manufacturing and distribution capacity, drug price, coverage and depth of customers, consumer behaviour and supply chain relationships. The Group's ability to remain competitive depends to a large extent on our ability to innovate, develop and promote new products and technologies that meet market needs in a timely manner to capture market share. At the same time, in October 2020, in the "Response to the Recommendation of No. 6450 of the Third Session of the 13th NPC", the National Healthcare Security Administration stated that centralized 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, biosimilar is not yet included in the drug application of centralized drug procurement. If any products are included in the centralized 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 centralized 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 in R&D, to develop, enhance or acquire technologies that will allow the Group to expand the scope and improve the quality of the services. The currently available products of the Group include: 漢利康®, 漢曲優® (trastuzumab injection, EU brand name: Zercepac®) and 漢達遠®. Most of the Group's drug candidates are still under development and are in the clinical development stages, and the course of clinical development is a lengthy and expensive process and involves uncertainties in various aspects, as such there can be no assurance from the Group as to 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 commercialization of the Group's drug candidates in a timely manner may be adversely affected.

#### **3. *Potential Risks of Novel Coronavirus***

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. Despite the weakened impact of COVID-19 on the Group's operations in China in the first half of 2021, there are still uncertainties about its impact 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 and involvement of staff for clinical trials, approval of regulatory affairs, procurement of raw materials, and construction progress of production base. The Group will continue to monitor the development of the epidemic and make all preparations in advance.

## V. EMPLOYEES AND REMUNERATION POLICIES

The following table sets forth the breakdown of our employees by function as at 30 June 2021:

<b>Function</b>	<b>Number of employees</b>
Management and administrative	172
R&D	305
Quality and technical support	241
Manufacturing	544
Clinical medical affairs	259
Commercial Operation	451
<b>Total</b>	<b>1,972</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**

Save for those disclosed in this announcement, no major subsequent event has 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 has 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 and Corporate Governance Report (the "**CG Code**") contained in Appendix 14 to the Listing Rules.

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

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

The Company has adopted the Model Code for Securities Transactions by Directors of Listed Issuers (the "**Model Code**") as set out in Appendix 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 2021 have been reviewed by the audit committee of the Company.



## INTERIM DIVIDEND

The Board does not recommend an interim dividend for the Reporting Period.

## INTERIM CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS

For the six months ended 30 June 2021

		2021 (Unaudited) RMB'000	2020 (Unaudited) RMB'000
	Notes		
<b>REVENUE</b>	3	<b>633,595</b>	110,392
Cost of sales		<u>(221,417)</u>	<u>(58,367)</u>
<b>Gross profit</b>		<b>412,178</b>	52,025
Other income and gains	4	<b>19,971</b>	34,254
Selling and distribution costs		<b>(197,331)</b>	(56,577)
Research and development expenses		<b>(451,813)</b>	(392,975)
Administrative expenses		<b>(118,303)</b>	(63,201)
Impairment losses on financial and contract assets, net		<b>(222)</b>	(431)
Other expenses		<b>(18,325)</b>	(4,490)
Finance costs	6	<u><b>(39,992)</b></u>	<u>(16,587)</u>
<b>LOSS BEFORE TAX</b>	5	<b>(393,837)</b>	(447,982)
Income tax expense	7	<u>—</u>	<u>—</u>
<b>LOSS FOR THE PERIOD</b>		<u><b>(393,837)</b></u>	<u>(447,982)</u>
<b>Attributable to:</b>			
Owners of the parent		<b>(393,837)</b>	(447,982)
Non-controlling interests		<u>—</u>	<u>—</u>
		<u><b>(393,837)</b></u>	<u>(447,982)</u>
<b>LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT</b>			
Basic and diluted (RMB)	9	<u><b>(0.73)</b></u>	<u>(0.85)</u>

**INTERIM CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME***For the six months ended 30 June 2021*

	<b>2021</b> <b>(Unaudited)</b> <b>RMB'000</b>	<b>2020</b> <b>(Unaudited)</b> <b>RMB'000</b>
<b>LOSS FOR THE PERIOD</b>	<b><u>(393,837)</u></b>	<b><u>(447,982)</u></b>
<b>OTHER COMPREHENSIVE INCOME</b>		
Other comprehensive (loss)/income that may be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	<u>(458)</u>	<u>1,632</u>
<b>OTHER COMPREHENSIVE (LOSS)/INCOME FOR THE PERIOD, NET OF TAX</b>	<b><u>(458)</u></b>	<b><u>1,632</u></b>
<b>TOTAL COMPREHENSIVE LOSS FOR THE PERIOD</b>	<b><u>(394,295)</u></b>	<b><u>(446,350)</u></b>
<b>Attributable to:</b>		
Owners of the parent	<b>(394,295)</b>	<b>(446,350)</b>
Non-controlling interests	<u>—</u>	<u>—</u>
	<b><u>(394,295)</u></b>	<b><u>(446,350)</u></b>

**INTERIM CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION**  
**30 June 2021**

		<b>30 June 2021 (Unaudited) RMB'000</b>	<b>31 December 2020 (Audited) RMB'000</b>
	<i>Notes</i>		
<b>NON-CURRENT ASSETS</b>			
Property, plant and equipment		<b>1,121,172</b>	984,909
Intangible assets		<b>3,197,035</b>	2,942,454
Right-of-use assets		<b>460,346</b>	452,279
Other non-current assets		<b>159,341</b>	149,540
<b>Total non-current assets</b>		<b>4,937,894</b>	4,529,182
<b>CURRENT ASSETS</b>			
Inventories		<b>346,739</b>	305,224
Trade receivables	10	<b>216,405</b>	196,213
Prepayments, other receivables and other assets		<b>197,116</b>	294,248
Cash and cash equivalents		<b>1,232,002</b>	1,114,309
<b>Total current assets</b>		<b>1,992,262</b>	1,909,994
<b>CURRENT LIABILITIES</b>			
Trade payables	11	<b>186,130</b>	298,952
Other payables and accruals		<b>406,894</b>	439,845
Contract liabilities		<b>57,177</b>	52,225
Interest-bearing bank and other borrowings		<b>1,627,497</b>	1,188,486
<b>Total current liabilities</b>		<b>2,277,698</b>	1,979,508
<b>NET CURRENT LIABILITIES</b>		<b>(285,436)</b>	(69,514)
<b>TOTAL ASSETS LESS CURRENT LIABILITIES</b>		<b>4,652,458</b>	4,459,668
<b>NON-CURRENT LIABILITIES</b>			
Interest-bearing bank and other borrowings		<b>977,278</b>	645,131
Contract liabilities		<b>656,312</b>	520,870
Deferred income		<b>148,014</b>	94,895
<b>Total non-current liabilities</b>		<b>1,781,604</b>	1,260,896
<b>Net assets</b>		<b>2,870,854</b>	3,198,772
<b>EQUITY</b>			
Share capital		<b>543,495</b>	543,495
Reserves		<b>2,327,359</b>	2,655,277
<b>Equity attributable to owners of the parent</b>		<b>2,870,854</b>	3,198,772
<b>Total equity</b>		<b>2,870,854</b>	3,198,772

# NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

30 June 2021

## 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 2021 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 2020.

The Group had net current liabilities of RMB285,436,000 as at 30 June 2021. 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 2020, 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 9, IAS 39,  
IFRS 7, IFRS 4 and IFRS 16  
Amendment to IFRS 16

*Interest Rate Benchmark Reform – Phase 2*

*Covid-19-Related Rent Concessions beyond 30 June 2021  
(early adopted)*

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

- (a) Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16 address issues not dealt with in the previous amendments which affect financial reporting when an existing interest rate benchmark is replaced with an alternative risk-free rate ("RFR"). The phase 2 amendments provide a practical expedient to allow the effective interest rate to be updated without adjusting the carrying amount of financial assets and liabilities when accounting for changes in the basis for determining the contractual cash flows of financial assets and liabilities, if the change is a direct consequence of the interest rate benchmark reform and the new basis for determining the contractual cash flows is economically equivalent to the previous basis immediately preceding the change. In addition, the amendments permit changes required by the interest rate benchmark reform to be made to hedge designations and hedge documentation without the hedging relationship being discontinued. Any gains or losses that could arise on transition are dealt with through the normal requirements of IFRS 9 or IAS39 to measure and recognise hedge ineffectiveness. The amendments also provide a temporary relief to entities from having to meet the separately identifiable requirement when an RFR is designated as a risk component. The relief allows an entity, upon designation of the hedge, to assume that the separately identifiable requirement is met, provided the entity reasonably expects the RFR risk component to become separately identifiable within the next 24 months. Furthermore, the amendments require an entity to disclose additional information to enable users of financial statements to understand the effect of interest rate benchmark reform on an entity's financial instruments and risk management strategy.

The Group had certain interest-bearing bank borrowings denominated in Renminbi based on the Loan Prime Rate (“LPR”) as at 30 June 2021. Since the interest rates of these borrowings were not replaced by RFRs during the period, the amendments did not have any impact on the financial position and performance of the Group. If the interest rates of these borrowings are replaced by RFRs in a future period, the Group will apply this practical expedient upon the modification of these borrowings provided that the “economically equivalent” criterion is met.

- (b) Amendment to IFRS 16 issued in April 2021 extends the availability of the practical expedient for lessees to elect not to apply lease modification accounting for rent concessions arising as a direct consequence of the covid-19 pandemic by 12 months. Accordingly, the practical expedient applies to rent concessions for which any reduction in lease payments affects only payments originally due on or before 30 June 2022, provided the other conditions for applying the practical expedient are met. The amendment is effective retrospectively for annual periods beginning on or after 1 April 2021 with any cumulative effect of initially applying the amendment recognised as an adjustment to the opening balance of retained profits at the beginning of the current accounting period. Earlier application is permitted.

The Group has early adopted the amendment on 1 January 2021 and applied the practical expedient during the period ended 30 June 2021 to all rent concessions granted by the lessors that affected only payments originally due on or before 30 June 2022 as a direct consequence of the covid-19 pandemic. The amendment had no impact on the Group’s financial statements for the period ended 30 June 2021.

## 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	
	2021 RMB’000 (Unaudited)	2020 RMB’000 (Unaudited)
Mainland China	566,261	101,144
Overseas	67,334	9,248
	<u>633,595</u>	<u>110,392</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:

	<b>For the six months ended 30 June</b>	
	<b>2021</b>	<b>2020</b>
	<b>RMB'000</b>	<b>RMB'000</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
<u>Revenue from contracts with customers</u>		
<b>Types of goods or services</b>		
Sales of biopharmaceutical products	555,947	95,828
Licensing revenue	9,581	5,199
Research and development services	68,047	9,238
Others	20	127
	<hr/>	<hr/>
Total revenue from contracts with customers	<b>633,595</b>	<b>110,392</b>
	<hr/> <hr/>	<hr/> <hr/>
<b>Timing of revenue recognition</b>		
transferred at a point in time	555,967	95,955
transferred over time	77,628	14,437
	<hr/>	<hr/>
Total revenue from contracts with customers	<b>633,595</b>	<b>110,392</b>
	<hr/> <hr/>	<hr/> <hr/>

### 4. OTHER INCOME AND GAINS

An analysis of other income and gains is as follows:

	<b>For the six months ended 30 June</b>	
	<b>2021</b>	<b>2020</b>
	<b>RMB'000</b>	<b>RMB'000</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
Government grants	17,944	15,785
Interest income	1,219	7,763
Exchange gains	–	10,227
Others	808	479
	<hr/>	<hr/>
	<b>19,971</b>	<b>34,254</b>
	<hr/> <hr/>	<hr/> <hr/>

## 5. LOSS BEFORE TAX

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

	<i>Notes</i>	<b>For the six months ended 30 June</b>	
		<b>2021</b> <b>RMB'000</b> <b>(Unaudited)</b>	<b>2020</b> <b>RMB'000</b> <b>(Unaudited)</b>
Cost of inventories sold		<b>171,520</b>	57,844
Cost of services provided		<b>49,897</b>	523
Depreciation of property, plant and equipment*		<b>39,512</b>	27,624
Depreciation of right-of-use assets*		<b>22,339</b>	19,985
Amortisation of intangible assets*		<b>32,835</b>	10,106
Research and development expenses:			
Current year expenditure		<b>451,813</b>	392,975
Foreign exchange loss/(gain), net		<b>8,836</b>	(10,227)
Impairment of financial assets, net		<b>222</b>	431
Write-down of inventories to net realisable value		<b>3,114</b>	—
Bank interest income	4	<b>(1,219)</b>	(7,763)
Covid-19-related rent concession from lessors		<b>—</b>	(81)
Loss on disposal of items of property, plant and equipment		<b>1,323</b>	118

\* 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 costs" 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>2021</b> <b>RMB'000</b> <b>(Unaudited)</b>	<b>2020</b> <b>RMB'000</b> <b>(Unaudited)</b>
Interest expense on bank and other borrowings	<b>39,037</b>	9,791
Interest expense on lease liabilities	<b>8,201</b>	6,796
Less: Interest capitalised	<b>(7,246)</b>	—
	<b>39,992</b>	16,587



## 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 2020: 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 and Hengenix Biotech, Inc., is based on the statutory rates of 20% and 29.84%, respectively (six months ended 30 June 2020: 20% and 29.84%, respectively), for the six months ended 30 June 2021.

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>2021</b>	<b>2020</b>
	<b>RMB'000</b>	<b>RMB'000</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
Current – China	–	–
Current – Other countries	–	–
	<hr/>	<hr/>
Total tax charge for the period	–	–
	<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 2020: 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 attributable to ordinary equity holders of the parent and the weighted average number of ordinary shares of 537,862,649 (six months ended 30 June 2020: 524,850,249) in issue during the period, which does not include the non-vested restricted shares.

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 number of ordinary shares in issue during the six months ended 30 June 2021, 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.

	<b>For the six months ended 30 June</b>	
	<b>2021</b>	<b>2020</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	<u><b>(393,837)</b></u>	<u><b>(447,982)</b></u>
<b>Shares</b>		
Weighted average number of ordinary shares in issue during the period used in the basic loss per share calculation	<u><b>537,862,649</b></u>	<u><b>524,850,249</b></u>
Effect of dilution – weighted average number of ordinary shares:		
Restricted shares under the share award scheme	<u><b>–</b></u>	<u><b>–</b></u>
Weighted average number of ordinary shares in issue during the period used in the diluted loss per share calculation	<u><b>537,862,649</b></u>	<u><b>524,850,249</b></u>

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

#### 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>	<b>31 December</b>
	<b>2021</b>	<b>2020</b>
	<b>RMB'000</b>	<b>RMB'000</b>
	<b>(Unaudited)</b>	<b>(Audited)</b>
Within 3 months	<u><b>216,405</b></u>	<u><b>196,213</b></u>

#### 11. TRADE PAYABLES

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

	<b>30 June</b>	<b>31 December</b>
	<b>2021</b>	<b>2020</b>
	<b>RMB'000</b>	<b>RMB'000</b>
	<b>(Unaudited)</b>	<b>(Audited)</b>
Within 1 year	<b>185,313</b>	298,148
1 to 2 years	<u><b>817</b></u>	<u><b>804</b></u>
	<u><b>186,130</b></u>	<u><b>298,952</b></u>

#### 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 2021 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.**  
**Qiyu CHEN**  
*Chairman*

Hong Kong, 18 August 2021

*As at the date of this announcement, the board of directors of the Company comprises Mr. Wenjie Zhang as the executive director, Mr. Qiyu Chen as the chairman and non-executive director, Mr. Yifang Wu, Ms. Xiaohui Guan, Dr. Aimin Hui 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.*