Shanghai Henlius Biotech, Inc.
上海復宏漢霖生物技術股份有限公司

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

(Stock Code: 2696)

ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED 31 DECEMBER 2021

The board of directors (the "**Board**") of Shanghai Henlius Biotech, Inc. (the "**Company**" or "**Henlius**") is pleased to announce the audited consolidated financial results of the Company and its subsidiaries (collectively referred to as the "**Group**" or "**we**") for the year ended 31 December 2021 (the "**Reporting Period**"), prepared under International Financial Reporting Standards ("**IFRSs**").

FINANCIAL SUMMARY:

1. The Group's total revenue was approximately RMB1,682.5 million for the year ended 31 December 2021, representing an increase of approximately RMB1,094.9 million, or approximately 186.3% compared to approximately RMB587.6 million for the year ended 31 December 2020. Such revenue was from drug sales, research and development ("**R&D**") services provided to customers, and license revenue.

2. During the year ended 31 December 2021, the Group recognised R&D expenditure of approximately RMB1,763.7 million, representing an increase of approximately RMB52.8 million as compared with approximately RMB1,710.9 million for the year ended 31 December 2020.

3. The Group's total loss was approximately RMB984.1 million for the year ended 31 December 2021, representing a decrease of approximately RMB9.4 million compared to approximately RMB993.5 million for the year ended 31 December 2020.

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

BUSINESS HIGHLIGHTS:

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

   - HANQUYOU (150mg): completed the tendering process on the procurement platform and was included into the medical insurance procurement platform for all provinces in Mainland China in the first half of 2021.

   - HANQUYOU (60mg): completed the tendering process on the procurement platform in 23 provinces and was included into the medical insurance procurement platform in 30 provinces in Mainland China.

   - Zercepac®: following 150mg obtaining marketing approval in the EU in July 2020, Zercepac® 60mg and 420mg were approved for marketing in the EU in April 2021 and June 2021 respectively; in July 2021, the Swissmedic approved the new drug application of Zercepac® (150mg).

2. **HANLIKANG (rituximab injection):**

   - HANLIKANG (100mg/10ml): included into the medical insurance procurement platform in 30 provinces in Mainland China, and completed the tendering process on the procurement platform in 28 provinces, and procured by more than 70% of major hospitals.

   - HANLIKANG (500mg/50ml): completed the tendering process on the procurement platform in 19 provinces and has been included into the medical insurance procurement platform in 14 provinces in Mainland China.

3. **HANDAYUAN (adamumab injection):** completed the tendering process on the procurement platform in 27 provinces and has been included into the medical insurance procurement platform in 30 provinces in Mainland China as at the end of the Reporting Period.

4. **HANBEITAI (bevacizumab injection):** was approved for marketing in Mainland China in November 2021.

5. Business Expansion:

- After the signing of 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 Group agreed to grant a license to Intas for the development and commercialization of HANQUYOU (trastuzumab injection, EU brand name: Zercepac®) in the United States and Canada.

- In January 2021, the Company entered into an exclusive license agreement with Chiome Bioscience, Inc., pursuant to which, the Company licensed in an exclusive right for antibodies targeting human TROP2 (trophoblast cell surface antigen 2) and to research, develop, manufacture and commercialize the related intellectual property rights in China (including Hong Kong, Macau and Taiwan regions of China).

- In March 2021, the Company entered into a binding term sheet with Suzhou NeuPharma Co., Ltd., pursuant to which the Company licensed in an exclusive right for HLX208, a small-molecule inhibitor targeting V600E mutation in human BRAF protein to develop, manufacture, commercialize and sublicense in China (including Hong Kong, Macau and Taiwan regions of China). Relevant cooperation agreement was formally entered into in May 2021.

- In February 2022, the Group entered into an agreement with Getz Pharma, pursuant to which, the Group agreed to grant a license to Getz Pharma to commercialize HANDAYUAN in Pakistan, Philippines, Vietnam and other regions.

6. Efficient Advancement on Clinical Research Projects both Domestically and Internationally

- In January 2021, the enrollment of subjects was completed in a phase 2 clinical study of serplulimab injection (PD-1) in combination with HANBEITAI for the treatment of advanced hepatocellular carcinoma (HCC).

- In March 2021, the first patient has been dosed in a phase 2/3 clinical study of serplulimab injection (PD-1) in combination with HANBEITAI and chemotherapy (XELOX) for first-line treatment of metastatic colorectal cancer (mCRC) in Mainland China.

- In March 2021, a single-arm, open-label, multi-center phase 2 clinical study of serplulimab injection (PD-1) 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 study endpoint.

- In December 2021, the phase 2 investigational new drug application (IND) of serplulimab injection (PD-1) in combination with HLX07 (recombinant anti-EGFR humanized monoclonal antibody injection) for the treatment of solid tumors was approved by the NMPA.

- In December 2021, the enrollment of subjects was completed in a phase 3 clinical study of serplulimab injection (PD-1) in combination with chemotherapy (cisplatin + 5-FU) for first-line treatment of patients with locally advanced/metastatic esophageal squamous cell carcinoma (ESCC).

- In December 2021, a randomized, double-blind, international multi-center phase 3 clinical trial of serplulimab injection (PD-1) or placebo in combination with chemotherapy (carboplatin-etoposide) in previously untreated patients with extensive-stage small cell lung cancer (ES-SCLC) has met the primary study endpoint of the overall survival (OS) in the first interim analysis after the assessment of the Independent Data Monitoring Committee (IDMC).

- In January 2022, the phase 3 investigational new drug application (IND) of serplulimab injection (PD-1) in combination with chemotherapy concurrent radiotherapy for the treatment of limited-stage small cell lung cancer (LS-SCLC) was accepted by the NMPA.

- In February 2022, the phase 2 investigational new drug application (IND) of serplulimab injection (PD-1) in combination with HLX07 (recombinant anti-EGFR humanized monoclonal antibody injection) and HANBEITAI for first-line treatment of unresectable or metastatic hepatocellular carcinoma (HCC) was accepted by the NMPA.

- From January 2021 to the Latest Practicable Date, the application for 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, Latvia, Singapore and some EU countries such as Spain, Czech Republic and Poland. The international multi-center phase 3 clinical trial of this subject is intended to be launched soon. In July 2021, the first patient has been dosed in a phase 1 clinical trial of HLX04-O for the treatment of wet age-related macular degeneration (wAMD) in Mainland China, and the first patient has been dosed in the related phase 3 clinical study in November 2021.

- In January 2022, a phase 1b/2 investigational new drug application (IND) of HLX208 (BRAF V600E inhibitor) monotherapy or in combined therapy for the treatment of BRAF V600E or BRAF V600 mutation-positive advanced solid tumors was approved by the NMPA. In January 2022, the first patient has been dosed in the phase 2 clinical trial of HLX208 (BRAF V600E inhibitor) for the treatment of adult Langerhans Cell Histiocytosis (LCH) and Erdheim-Chester disease (ECD) with BRAF V600E mutation in Mainland China.

7. **Efficient Advancement for Pre-Clinical Development Projects:** During the Reporting Period, the Group accelerated the submission of investigational new drug application (IND) of pre-clinical research projects covering targets such as CD38, CD73, LAG-3, EGFR×4-1BB and PD-L1×TIGIT.

8. **Biopharmaceutical Industrialization Base Layout with International Standards and High Cost-Efficiency:** During the Reporting Period, Xuhui Facility which had obtained GMP certificates both in China and EU, kept on improving its production efficiency through a series of lean management and process optimization initiatives. Two 2,000L bioreactors were newly constructed in Xuhui Facility, increasing the commercial production capacity from 20,000L to 24,000L. As at the Latest Practicable Date, the Group has completed production capacity construction of 24,000L for the Songjiang First Plant in Songjiang District, Shanghai. The Group received the Drug Manufacturing Certificate(《藥品生產許可證》) issued by the Shanghai Medical Products Administration and agreed to add the Songjiang First Plant for the production of HANQUYOU. The supplemental new drug application (sNDA) for second-generation process of HANQUYOU was also accepted. As at the Latest Practicable Date, the designed production capacity for Phase I project of Songjiang Second Plant increased from 36,000L to 96,000L. The construction of the main structure and secondary structure of the two main production buildings and the supporting public works and warehouses has been completed for the first and second stage for the Phase I of Songjiang Second Plant. The main structure of the auxiliary production buildings was completed and accepted, and most of the main production facilities such as the drug substance lines and the drug product lines has been completed the factory acceptance testing and installed in place.

For details of the above, please refer to this announcement and (if applicable) the Company's previous announcements on the Stock Exchange and the Company's websites.

OUR PRODUCT PIPELINE

	Product		Target	Indication	Pre-clinical	IND	Phase 1	Phase 2	Phase 3	NDA	Launched	Global business partners
Marketed products	漢利康®(rituximab)[1]		CD20	Non-Hodgkin lymphoma, chronic lymphocytic leukemia and rheumatoid arthritis[2]								FOSUN PHARMA, FARMA DE COLOMBIA
	漢曲優®(trastuzumab)[3]		HER2	Breast cancer and metastatic gastric cancer								accord, Cipla, Jacobson, mAbxience
	漢達遠®(adalimumab)[4]		TNF-α	Rheumatoid arthritis, ankylosing spondylitis, psoriasis and uveitis								万邦医药, FOSUN PHARMA, Getz pharma
	漢貝泰®(bevacizumab)[5]		VEGF	Metastatic colorectal cancer and locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer								
With near-term commercial visibility	HLX10 (serplulimab)[6]	Monotherapy	PD-1	MSI-H solid tumours						Under NDA priority review		KGbio
		+Chemo		Squamous non-small cell lung cancer				Global multi-centre clinical trial				
Under clinical research	HLX10 (serplulimab)[6]	+Chemo	PD-1	Extensive-stage small cell lung cancer				Global multi-centre clinical trial				
				Metastatic esophageal squamous-cell carcinoma								
				Neo-/adjuvant treatment of gastric cancer								
		+漢貝泰®	PD-1+VEGF	Non-squamous non-small cell lung cancer								
				Hepatocellular carcinoma								
				Metastatic colorectal cancer								
		+HLX07	PD-1+EGFR	Squamous-cell carcinoma of the head and neck								
				Squamous non-small cell lung cancer								
	HLX04-O[7]		VEGF	Wet age-related macular degeneration								ESSEX 亿胜
	HLX22	+漢曲優®	HER2+HER2	Gastric cancer								
	HLX07[8]		EGFR	Solid tumours (non-small cell lung cancer, esophageal carcinoma, etc.)								
	HLX208[9]		BRAF V600E	Solid tumours (metastatic colorectal cancer, non-small cell lung cancer, etc.) , Langerhans cell histiocytosis and Erdheim-Chester disease								
	HLX11 (pertuzumab)		HER2	Breast cancer								
	HLX05 (cetuximab)[10]		EGFR	Metastatic colorectal cancer and squamous-cell carcinoma of the head and neck								Jingze
	HLX12 (ramucirumab)		VEGFR2	Gastric cancer, metastatic non-small cell lung cancer and metastatic colorectal cancer								
	HLX20[11]		PD-L1	Solid tumours								
	HLX14 (denosumab)		RANKL	Osteoporosis								
	HLX26		LAG-3	Solid tumours and lymphomas								
	HLX35[12]		EGFR x 4-1BB	Solid tumours								BINACEA
	HLX301[13]		PD-L1 x TIGIT	Solid tumours								
	HLX13 (ipilimumab)		CTLA-4	Melanoma, renal cell carcinoma and metastatic colorectal cancer								
	HLX15 (daratumumab)		CD38	Multiple myeloma								
	HLX23[14]		CD73	Solid tumours								

(1) Approved by the NMPA in February 2019, being the first domestic biosimilar.
(2) Considered as innovative biologic medicine since the reference product has not yet been approved for the relevant indications.
(3) Approved in the EU in July 2020 (EU brand name: Zercepac ®); Approved in China in August 2020.
(4) Approved by the NMPA in December 2020.
(5) Approved by the NMPA in November 2021.
(6) IND approved in China, the United States, the EU etc.
(7) IND approved in Mainland China, Australia, the United States, Singapore, and the EU countries.
(8) IND approved in China and the United States.
(9) Commercialisation rights in China including Hong Kong, Macao and Taiwan China were obtained.
(10) Commercialisation rights in Mainland China have been granted to Shanghai Jingze.
(11) IND approved in China and Australia.
(12) Global commercialisation rights in Mainland China excluding Hong Kong, Macau and Taiwan regions have been granted to Binacea.
(13) Clinical Trial Notification has been acknowledged in Australia.
(14) IND approved in the United States.

Core Products

MANAGEMENT DISCUSSION AND ANALYSIS

I. BUSINESS REVIEW

As part of our commitment to provide affordable and high-quality biomedicines for patients worldwide, the Group has been dedicated to the innovation and layout of the three major segments of R&D, production and commercialization. During the Reporting Period, we have worked to promote the efficient development of the global commercialization of product pipeline and implement production capacity deployment for the biomedicines with high economic benefit based on international standards. With great achievements in clinical development and drug registration of pipeline products, the Group was gradually evolving from Biotech model to Biopharma model that is more scaled up and highly competitive in the market. From the beginning of 2021 to 11 March 2022, being the latest practicable date for the issuance of this announcement (the "**Latest Practicable Date**"), HANBETAI and HANLIKANG for the treatment of the innovative indication of rheumatoid arthritis (RA) were approved for marketing, while other marketed products achieved steady progress in sales. During the Reporting Period, the Group made significant progress in 12 clinical trials, and received approvals for multiple clinical trials worldwide for 6 products and 1 combined therapy.

As at the Latest Practicable Date, 4 products (12 indications) of the Group have been successfully marketed in Mainland China (excluding Hong Kong, Macau and Taiwan regions) ("**Mainland China**"), 1 product has been successfully marketed in Europe, new drug application of 2 indications of 1 new drug have been accepted in Mainland China, and more than 20 clinical trials are being carried out around the world.

(I) Strong global product commercialization capability

During the Reporting Period, the Group actively implemented the concept of excellent commercialization bearing patients' needs in mind. Our commercialization team comprises of five major segments, namely market promotion, channel management, pricing and market access, domestic sales and strategic planning, covering the whole process of commercialization, in order to achieve continuous growth in sales scale of products. Following the launch of HANLIKANG, the first monoclonal antibody approved in China in accordance with the Guidelines for the R&D and Evaluation of Biosimilars (Trial) (the "**Guidelines for Biosimilars**") in 2019, several core products of the Group such as HANQUYOU (trastuzumab injection, EU brand name: Zercepac®), HANDAYUAN and HANBEITAI, were successively approved for marketing. From the beginning of 2021 to the Latest Practicable Date, we have reached sales cooperation with international partners in the United States, Canada, Pakistan, Philippines, Vietnam and other regions for HANQUYOU (trastuzumab injection, EU brand name: Zercepac®) and HANDAYUAN.

1. Commercialization process of marketed core products

Commercialization process of HANQUYOU (trastuzumab injection, EU brand name: Zercepac®) in Mainland China and EU (a therapeutic product for breast cancer and gastric cancer)

– Commercial sales of HANQUYOU in Mainland China

HANQUYOU is the core product of the Group in the field of anti-tumor therapy, and also the first product sold and promoted by the Group's in-house commercialization team in Mainland China. HANQUYOU (150mg) was launched for commercial sales since August 2020, and completed the tendering process on the procurement platform and was included into the medical insurance procurement platform for all provinces in Mainland China in the first half of 2021. Meanwhile, since its approval for marketing in August 2021, HANQUYOU (60mg) has completed the tendering process on the procurement platform in 23 provinces and was included into the medical insurance procurement platform in 30 provinces in Mainland China. In addition to the efficient market layout providing a strong foundation for the overall sales growth of HANQUYOU, the flexible dose portfolio of 150mg and 60mg also brings personalized and more economical treatment options for patients with different weight ranges. During the Reporting Period, the Group also actively cooperated with relevant enterprises in respect of physician education, medical big data, HER2 testing, innovative payment, patient management and education and has harvested a good market reputation in the construction of diagnosis and treatment ecosystem for HER2-positive breast cancer and gastric cancer patients. In addition, biosimilars were added to the new Chinese Society of Clinical Oncology (CSCO) Guidelines for Diagnosis and Treatment of Breast Cancer in 2021, and HANQUYOU was added to the new Chinese Society of Clinical Oncology (CSCO) Guidelines for Diagnosis and Treatment of Gastric Cancer in 2021.

The Group has an experienced commercialization core management team, the total member of which increased from approximately 400 at the end of 2020 to over 500 at the end of the Reporting Period, including a sales team of HANQUYOU composed of more than 400 professionals. We made full efforts to develop and further tap into other markets in Mainland China.

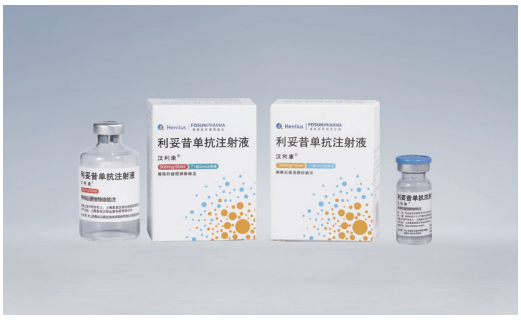
In September 2021, the Group received the Drug Manufacturing Certificate(《藥品生產許可證》) issued by the Shanghai Medical Products Administration ("**Shanghai Medical Products Administration**"). The supplemental new drug application (sNDA) for Second Generation Process of HANQUYOU has also been accepted during the Reporting Period.

– Commercial sales of Zercepac® in the international market

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

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

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



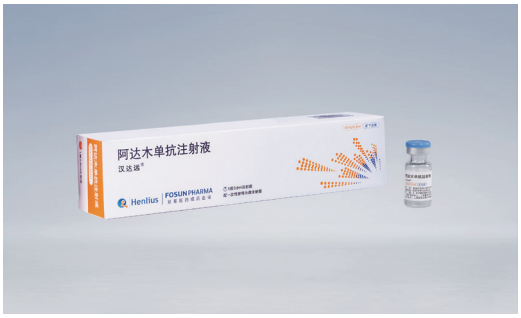
In February 2022, HANLIKANG for the treatment of the innovative indication of rheumatoid arthritis (RA) was approved for marketing, which is used in combination with methotrexate to treat moderate to severe active rheumatoid arthritis (RA) in adult patients who have responded inadequately to one or more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

As at the Latest Practicable Date, HANLIKANG (100mg/10ml) has been included into the medical insurance procurement platform in 30 provinces in Mainland China, and has completed the tendering process on the procurement platform in 28 provinces, and was procured by more than 70% of major hospitals, laying a base for the sales of HANLIKANG. HANLIKANG (500mg/50ml) has been launched and supplied since May 2021, and has completed the tendering process on the procurement platform in 19 provinces and was included into the medical insurance procurement platform in 14 provinces in Mainland China.

In August 2021, the production base at Yishan Road, Xuhui District, Shanghai ("**Xuhui Facility**") of the Group successfully passed the on-site inspection conducted by the Shanghai Medical Products Administration at drug product no.2 line for the production of HANLIKANG. In September 2021, the supplemental new drug application (sNDA) in respect of additional production site for Drug product of HANLIKANG (100mg/10ml) was approved by the National Medical Products Administration ("**NMPA**").

Jiangsu Fosun Pharmaceutical Sales Co., Ltd. ("**Jiangsu Fosun**"), a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd. ("**Fosun Pharma**"), the controlling shareholder of the Company, was responsible for the domestic commercial sale of HANLIKANG. As at the Latest Practicable Date, the specifications of HANLIKANG covered 100mg/10ml and 500mg/50ml, and its indications were further expanded to the field of autoimmune diseases on the basis of covering all the indications of the original drug approved in Mainland China in the field of hematology oncology. The implementation of both types of indications will cover more patient groups, which is expected to further increase the market influence of HANLIKANG.

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



HANDAYUAN is the third product of the Group marketed in Mainland China, which was granted marketing approval in December 2020. And it has been approved for the indications of rheumatoid arthritis, ankylosing spondylitis, psoriasis and uveitis in Mainland China until now. As at the end of the Reporting Period, HANDAYUAN has completed the tendering process on the procurement platform in 27 provinces and was included into the medical insurance procurement platform in 30 provinces in Mainland China.

Jiangsu Wanbang Biopharmaceutical (Group) Co., Ltd. ("**Jiangsu Wanbang**"), a subsidiary of Fosun Pharma, the controlling shareholder of the Company, was responsible for the domestic commercial sale of HANDAYUAN. 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. In order to improve the standardized diagnosis and treatment services for Chinese patients with rheumatism, Jiangsu Wanbang established the first whole-course care platform "Da'en Home" (formally known as Dayuan Home) for autoimmune patients in China, which integrates the functions of Internet hospital, popular science education, public assistance, medical insurance, patient management, drug purchase map, and community care, with an aim to realize the whole-course management of patients from medical treatment to rehabilitation, and benefit more patients with convenient and standardized medical experience. During the Reporting Period, Da'en Home provided a total of more than 5,000 patients with one-to-one exclusive services, covering consultation, diagnosis, treatment and prognosis. 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 HANDAYUAN. Through a four-tier medical consortium network, we are working together to help standardize the treatment of ankylosing spondylitis in China. In 2021, the project was implemented in more than 10 provinces in China, which benefited more than 14,000 patients by providing standardized diagnosis and treatment.

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

In November 2021, HANBEITAI, the fourth biosimilar product of the Group, was approved for marketing in Mainland China for the treatment of metastatic colorectal cancer (mCRC), advanced, metastatic or recurrent non-small cell lung cancer, and was the only biosimilar of bevacizumab with phase 3 clinical data of patients with metastatic colorectal cancer in China. In 2022, the Group will actively promote the inclusion into the medical insurance procurement platform, tendering process on the procurement platform and hospital access of HANBEITAI, and gradually achieve sales growth for provinces and municipalities adopting dual-channel medical insurance payment, with a view to providing new high-quality drug options for patients with high incidence of lung cancer and colorectal cancer in China. In April 2021, Xuhui Facility of the Group has successfully passed the on-site inspection of the drug substance south line and drug product no.1 line for the production of HANBEITAI by the Shanghai Medical Products Administration. Based on the indications for the original product approved for marketing in Mainland China, the Group also plans to submit the supplemental new drug application (sNDA) for new indications of HANBEITAI to treat recurrent glioblastoma, hepatocellular carcinoma, epithelial ovarian, fallopian tube or primary peritoneal cancer and cervical cancer in 2022.

2. Products to be commercialized in the near future

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

Serplulimab injection (PD-1) is the core innovative monoclonal antibody product in the product pipeline of the Group. The phase 2 clinical research for indications to treat unresectable or metastatic microsatellite instability-high (MSI-H) solid tumors that fail to respond to the standard therapy met the primary study 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 had been formally included in the priority assessment process. This indication is screened by specific MSI-H tumor markers rather than by cancer type, covering a wide range of patient groups. In October 2021, Xuhui Facility successfully passed the GMP compliance on-site inspection conducted by Shanghai Medical Products Administration at drug south line, drug product no.2 line and the packaging area of drug product no.1 line for the production of serplulimab injection (PD-1). The Group has established a professional and experienced team in advance for the sale of serplulimab injection (PD-1) after its launch. As at the end of the Reporting Period, the recruitment of sales management personnel for serplulimab injection (PD-1) has been completed. The Group is expected to build a sales team of approximately 200 members for serplulimab injection (PD-1) within the first quarter of 2022, and after the formal launch of serplulimab injection (PD-1), we will implement differentiated layout and fully expand into the markets in Mainland China.

During the Reported Period, an international multi-center phase 3 clinical trial to compare serplulimab injection (PD-1) 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 and met the predefined primary study endpoint. Study data showed that the combined therapy significantly prolongs the progression-free survival (PFS) of patients. The new drug application (NDA) of this indication, which is the second indication for serplulimab injection (PD-1) submitted by the Company in Mainland China, has been accepted by the Center for Drug Evaluation of the NMPA in September 2021.

In addition, a randomized, double-blind, international multi-center phase 3 clinical trial of serplulimab injection (PD-1) or placebo in combination with chemotherapy (carboplatin-etoposide) in previously untreated patients with extensive-stage small cell lung cancer (ES-SCLC) has completed enrollment during the Reporting Period. In December 2021, such combined therapy met the primary study endpoint of the overall survival (OS) in the first interim analysis after the assessment of the Independent Data Monitoring Committee (IDMC).

3. Commercialization deployment in international markets during the Reporting Period

From the beginning of 2021 to the Latest Practicable Date, the Group adhered to the internationalization strategy by adding HANQUYOU (trastuzumab injection, EU brand name: Zercepac®) and HANDAYUAN to its commercialization portfolio in the United States, Canada, Pakistan, the Philippines, Vietnam and other regions. After the signing of the binding term sheet with Accord Healthcare Inc., in September 2020, the Group entered into a formal agreement with Intas Pharmaceuticals Limited ("**Intas**"), the parent company of Accord Healthcare Inc. in January 2021, pursuant to which, the Group agreed to grant a license to Intas for the development and commercialization of HANQUYOU (trastuzumab injection, EU brand name: Zercepac®) in the United States and Canada. According to the agreement, the Company is entitled 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 ranging from 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 America market of HANQUYOU, but also a sign of its commercialization to cover the mainstream biologics market in Europe and the United States. The new drug application for HANQUYOU in the United States is expected to be filed in 2022. In February 2022, the Group has entered into an agreement with Getz Pharma (Private) Limited and its affiliated company, Getz Pharma International FZ-LLC (together, "**Getz Pharma**"), pursuant to which, the Group agreed to grant a license to Getz Pharma to commercialize HANDAYUAN in Pakistan, Philippines, Vietnam, Myanmar, Cambodia, Nigeria, Kenya, Sri Lanka, Ukraine, Kazakhstan and Uzbekistan and other regions. According to the agreement, the Company is entitled to receive a down payment of $500,000, and a milestone payment of up to $7.5 million.

In the meantime, given the slow implementation of the collaboration on HANLIKANG in the licensed territories (including Argentina, Paraguay, Uruguay and Bolivia) 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 HANLIKANG 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 Biologics ("**KG Bio**"), Farma De Colombia S.A.S, Mabxience Research, S.L., Intas, Essex Bio-Investment Limited and Zhuhai Essex Bio-Pharmaceutical Co., Ltd. ("**Essex**"), Binacea pharma Inc.("**Binacea**") and Getz Pharma. The Group will continue to actively promote the global commercialization deployment through strategic commercialization cooperation with the leading pharmaceutical companies in the world.

(II) Layout of industrialization base 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 system, so that it can expand capacity and improve economic cost-effectiveness while maintaining high quality standards. In addition, we have optimized the deployment of production technology, production cost control and other aspects in advance, which laid a solid foundation for the commercialization of the Group's products in multiple jurisdictions.

Xuhui Facility (granted with dual GMP certification of China and EU, with commercial production capacity increasing from 20,000L to 24,000L)

As at the end of the Reporting Period, the Group has established Xuhui Facility, a biopharmaceutical production base in Shanghai Caohejing Hi-Tech Park, covering a total area of approximately 11,000 square meters, which has been granted with Chinese and EU GMP certificates and achieved normalized supply in China and the EU markets. During the Reporting Period, two 2,000L bioreactors were newly constructed in Xuhui Facility. As at the Latest Practicable Date, the commercial production capacity of Xuhui Facility has been increased from 20,000L to 24,000L, which can meet the Group's production needs in the near term. During the Reporting Period, Xuhui Facility continuously improved production efficiency through a series of lean management and process optimization measures. Furthermore, the Group promoted research and change on the localization of critical supplies, consumable materials and equipments for production, so as to minimize the risk related to material supply and equipment procurement against the prevailing international situation.

Songjiang First Plant (with production capacity construction of 24,000 L and equipment verification completed, manufacturing certificate granted)

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 Songjiang First Plant has started GMP production of clinical samples since May 2020. The verification of all twelve 2,000L bioreactors was completed on schedule in the first half of 2021, and the construction of packaging lines were also completed on time during the Reporting Period. In September 2021, the Group received the Drug Manufacturing Certificate (《藥品生產許可證》) issued by the Shanghai Medical Products Administration and agreed to add the Songjiang First Plant for the production of HANQUYOU. The supplemental new drug application (sNDA) for second-generation process of HANQUYOU was also accepted during the Reporting Period. In addition, during the Reporting Period, the Songjiang First Plant further promoted the development of continuous flow technology and successfully completed the pilot magnification of continuous production process for two products, including the end-to-end continuous production process of one product, i.e. upstream perfusion technology, downstream intelligent continuous production.

Songjiang Second Plant (with total planned land area of 200 mu and designed production capacity for Phase I project increasing from 36,000L to 96,000L)

In order to meet the long-term demand on commercial production capacity, the construction of the Phase I of Songjiang Second Plant, with a total planned land area of 200 mu was started in 2019. The designed production capacity for the first and second stages of this project is totaled 36,000L. The construction of the main structure and secondary structure of the two main production buildings and the supporting public works and warehouses has been completed. The main structure of the auxiliary production buildings was completed and accepted, and most of the main production facilities such as the drug substance lines and the drug product lines has been completed the factory acceptance testing and installed in place. In addition, other ancillary projects are progressing steadily. In November 2021, the Board of the Company further approved the third stage construction plan for the Phase I of Songjiang Second Plant. The designed production capacity of the third stage was 60,000L, covering a drug substance line consisting of four 15,000L stainless steel reactors. The Phase I of Songjiang Second Plant expanded its capacity to 96,000L. The construction of the subsequent stage of Songjiang Second Plant will also be gradually implemented in accordance with the Group's strategy.

(III) Sustainable global clinical development capability on medical products

During the Reporting Period, based on clinical needs, the Group gradually improved the innovation pipeline including serplulimab injection (PD-1) and related combined therapy (including serplulimab injection (PD-1) in combination with HANBEITAI, serplulimab injection (PD-1) in combination with HLX07 (recombinant anti-EGFR humanized monoclonal antibody injection)), HLX208 (BRAF V600E inhibitor), HLX301 (recombinant human anti-PD-L1 and anti-TIGIT bispecific antibody injection), HLX22 (anti-human epidermal growth factor receptor-2 (HER2) humanized monoclonal antibody injection) in combination with HANQUYOU, HLX26 (recombinant anti-LAG-3 humanized monoclonal antibody injection). The Company has orderly organized the development of innovative products indicated for the treatment of solid tumors, adult Langerhans cell histiocytosis (LCH) and Erdheim-Chester disease (ECD), gastric cancer, lymphomas, hepatocellular carcinoma, intestinal cancer, lung cancer and others.

Serplulimab injection (PD-1) is the core innovative monoclonal antibody product 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 (PD-1) has been successively approved for clinical trials in China, the United States, the EU and other countries/regions; 10 clinical researches are in the process in an orderly manner, including 2 international multi-center clinical trials; and as at the end of the Reporting Period, a total of over 2,800 subjects have been enrolled in the trials in China, Turkey, Poland and other countries/regions, representing an increase of over 800 subjects for trials as compared with the end of 2020. HLX208 (BRAF V600E inhibitor), an innovative product in-licensed by the Group during the Reporting Period, is currently in phase 2 clinical study and early clinical data have also demonstrated preliminary efficacy and minimal side effects. This target-focused product may have synergy with the Group's EGFR or PD-1-targeted monoclonal antibody products 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 for the treatment of Langerhans cell histiocytosis (LCH) and Erdheim-Chester disease (ECD), metastatic colorectal cancer, non-small cell lung cancer are also progressing forward positively.

As at the end of the Reporting Period, the Group has established a global product development team with more than 350 staff for advancing the clinical research and drug registration of many candidate drugs across the world, and achieved significant progress in 12 clinical trials and multiple global clinical trial approvals for 6 products and 1 combined therapy during the Reporting Period.

1. Continuous and efficient advancement on clinical research products

As at the Latest Practicable Date, the Group is carrying out a total of more than 20 clinical trials for 12 products and 10 combined therapies in an orderly manner in various countries/regions.

Progress of international clinical research projects

- In January 2021, HLX04-O (recombinant humanized anti-VEGF monoclonal antibody injection) for the treatment of wet age-related macular degeneration (wAMD) was acknowledged by the Therapeutic Goods Administration, Australia, and the phase 3 clinical trial was given permission to commence in Australia. The application for phase 3 clinical trial was also approved by the United States Food and Drug Administration (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 Singapore and some EU countries such as Spain, Czech Republic and Poland. The international multi-center phase 3 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 for clinical study was completed during the Reporting Period.

- In November 2021, HLX301 (recombinant humanised anti-PD-L1 and anti-TIGIT bispecific antibody injection) for the treatment of locally advanced or metastatic solid tumors was acknowledged by Therapeutic Goods Administration, Australia, and the Phase 1 clinical trial is permitted to commence in Australia, and the first subject had been dosed in such clinical trial in Australia in February 2022.

- In December 2021, a randomized, double-blind, international multi-center phase 3 clinical trial of serplulimab injection (PD-1) or placebo in combination with chemotherapy (carboplatin-etoposide) in previously untreated patients with extensive-stage small cell lung cancer (ES-SCLC) has met the primary study endpoint of the overall survival (OS) in the first interim analysis after the assessment of the Independent Data Monitoring Committee (IDMC).

Progress of domestic clinical study projects

– Progress of serplulimab injection (PD-1)

- In January 2021, the enrollment of subjects was completed in a phase 2 clinical study of serplulimab injection (PD-1) in combination with HANBEITAI for the treatment of advanced hepatocellular carcinoma (HCC).

- In March 2021, the first patient has been dosed in a phase 2/3 clinical study of serplulimab injection (PD-1) in combination with HANBEITAI and chemotherapy (XELOX) for first-line treatment of metastatic colorectal cancer (mCRC) in Mainland China.

- In March 2021, a single-arm, open-label, multi-center phase 2 clinical study 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 study endpoint.

- In December 2021, the phase 2 investigational new drug application (IND) of serplulimab injection (PD-1) in combination with HLX07 (recombinant anti-EGFR humanized monoclonal antibody injection) for the treatment of solid tumors was approved by the NMPA.

- In December 2021, the enrollment of subjects was completed in a phase 3 clinical study of serplulimab injection (PD-1) in combination with chemotherapy (cisplatin + 5-FU) for first-line treatment of patients with locally advanced/metastatic esophageal squamous cell carcinoma (ESCC).

- In January 2022, the phase 3 investigational new drug application (IND) of serplulimab injection (PD-1) in combination with chemotherapy concurrent radiotherapy for the treatment of limited-stage small cell lung cancer (LS-SCLC) was accepted by the NMPA.

- In February 2022, the phase 2 investigational new drug application (IND) of serplulimab injection (PD-1) in combination with HLX07 (recombinant anti-EGFR humanized monoclonal antibody injection) and HANBEITAI for first-line treatment of unresectable or metastatic hepatocellular carcinoma (HCC) was accepted by the NMPA.

– Progress of other products

- In July 2021, the first patient has been dosed 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, and the first patient has been dosed in the related phase 3 clinical study in November 2021.

- In September 2021, the first patient has been dosed in a phase 2 clinical trial of HLX22 (anti-human epidermal growth factor receptor-2 (HER2) humanized monoclonal antibody injection) in combination with HANQUYOU and chemotherapy (XELOX) versus placebo in combination with HANQUYOU and chemotherapy (XELOX) for first-line treatment of patients with HER2-positive locally advanced or metastatic gastric cancer in Mainland China.

- In January 2021, the investigational new drug application (IND) of HLX26 (recombinant anti-LAG-3 human monoclonal antibody injection) for the treatment of solid tumors and lymphomas was accepted by the NMPA. Such application was approved by the NMPA in April 2021. In October 2021, the first subject has been dosed in a phase 1 clinical trial of HLX26 (recombinant anti-LAG-3 humanized monoclonal antibody injection) for the treatment of solid tumors and lymphomas in Mainland China.

- In November 2021, a phase 1 clinical trial of HLX11(recombinant anti-HER2 domain II humanised monoclonal antibody injection) reached primary study endpoint and was successfully completed. HLX11 is intended for the treatment of metastatic/early breast cancer.

- In December 2021, HLX55 (recombinant humanised IgG2 anti-c-MET monoclonal antibody for injection) has demonstrated its good safety and tolerability in a phase 1 clinical trial for subjects with advanced solid tumors refractory to standard therapy, and the relevant clinical study report has been finished.

- In January 2022, a phase 1b/2 investigational new drug application (IND) of HLX208 (BRAF V600E inhibitor) monotherapy or in combined therapy for the treatment of BRAF V600E or BRAF V600 mutation-positive advanced solid tumors was approved by the NMPA. In January 2022, the first patient has been dosed in the phase 2 clinical trial of HLX208 (BRAF V600E inhibitor) for the treatment of adult Langerhans Cell Histiocytosis (LCH) and Erdheim-Chester disease (ECD) with BRAF V600E mutation in Mainland China.

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, CD73, LAG-3, EGFR×4-1BB and PD-L1×TIGIT.

- In January 2021, the investigational new drug application (IND) of HLX15 (recombinant anti-CD38 human monoclonal antibody injection) for the treatment of multiple myeloma (MM) was approved by the NMPA.

- In May 2021, the investigational new drug application of HLX23 (recombinant anti-CD73 fully human monoclonal antibody injection) for the treatment of advanced solid tumors was approved by the United States Food and Drug Administration (FDA).

- In January 2022, the investigational new drug application (IND) of HLX35 (recombinant humanised anti-EGFR and anti-4-1BB bispecific antibody injection) for the treatment of advanced malignant solid tumors was approved by the NMPA. The global commercialization rights for HLX35 outside of China were granted to Binacea in November 2020, and phase 1 clinical study for the relevant indications in Australia have also been approved and progressed.

- In January 2022, the investigational new drug application (IND) of HLX301(recombinant humanised anti-PD-L1 and anti-TIGIT bispecific antibody injection) for the treatment of locally advanced/metastatic solid tumors or lymphomas was accepted by the NMPA.

- In February 2022, the investigational new drug application (IND) of HLX26 (recombinant anti-LAG-3 human monoclonal antibody injection) in combination with serplulimab injection (PD-1) for the treatment of advanced/metastatic solid tumors or lymphomas was accepted by the NMPA.

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

Product name (targets)	Indications	Progress as at the Latest Practicable Date
Efficient advancement on international clinical research projects		
HLX04-O (VEGF)	Wet age-related macular degeneration (wAMD)	In January 2021, the phase 3 investigational new drug application was approved by Therapeutic Goods Administration, Australia In March 2021, the phase 3 investigational new drug application was approved by FDA In April 2021, the phase 3 investigational new drug application was approved by the State Agency of Medicines of Latvia
HLX71 (S1 Protein of SARS-CoV-2)	COVID-19	In April 2021, the first subject dosing was completed in a phase 1 clinical study in the United States. The enrollment of subjects was completed during the Reporting Period
HLX301 (PD-L1×TIGIT)	Solid tumor	In November 2021, the phase 1 investigational new drug application was approved by Therapeutic Goods Administration, Australia In February 2022, the first subject dosing in Australia was completed in a phase 1 clinical study
Serplulimab injection in combination with chemotherapy (PD-1)	Extensive stage small cell lung cancer (ES-SCLC)	In December 2021, the international multi-center phase 3 clinical study reached the primary study endpoint

Product name (targets)	Indications	Progress as at the Latest Practicable Date
Smooth progress of domestic clinical projects		
Serplulimab injection in combination with HANBEITAI (PD-1+VEGF)	Hepatocellular Carcinoma (HCC)	In January 2021, the enrollment of subjects was completed in a phase 2 clinical study
Serplulimab injection in combination with HANBEITAI and chemotherapy (PD-1+VEGF)	Metastatic Colorectal Cancer (mCRC)	In March 2021, the first patient dosing was completed in a phase 2/3 clinical study
Serplulimab injection(PD-1)	Solid tumor (MSI-H/ dMMR)	In March 2021, the phase 2 clinical study reached the primary study endpoint
Serplulimab injection in combination with HLX07 (PD-1+EGFR)	Solid tumor	In December 2021, the phase 2 investigational new drug application was approved by the NMPA
Serplulimab injection in combination with chemotherapy (PD-1)	Esophageal squamous cell carcinoma (ESCC)	In December 2021, the enrollment of subjects was completed in a phase 3 clinical study
Serplulimab injection in combination with chemotherapy (PD-1)	Limited-stage small cell lung cancer (LS-SCLC)	In January 2022, the phase 3 investigational new drug application was accepted by the NMPA
Serplulimab injection in combination with HLX07 and HANBEITAI (PD-1+EGFR+VEGF)	Hepatocellular carcinoma (HCC)	In February 2022, the phase 2 investigational new drug application was accepted by the NMPA

Product name (targets)	Indications	Progress as at the Latest Practicable Date
HLX04-O (VEGF)	Wet age-related macular degeneration (wAMD)	In July 2021, the first patient dosing was completed in a phase 1 clinical study In November 2021, the first patient dosing was completed in a phase 3 clinical study
HLX22 in combination with HANQUYOU and in combination with chemotherapy (HER2+HER2)	Gastric cancer (GC)	In September 2021, the first patient dosing was completed in a phase 2 clinical study
HLX26 (LAG-3)	Solid tumor, lymphomas	In January 2021, the investigational new drug application was accepted by the NMPA In April 2021, the investigational new drug application was approved by the NMPA In October 2021, the first patient dosing was completed in a phase 1 clinical study
HLX11 (HER2)	Breast cancer (BC)	In November 2021, the phase 1 clinical study reached the primary study endpoint
HLX55 (c-MET)	Solid tumor	In December 2021, the relevant clinical research report was completed for the phase 1 clinical study
HLX208 (BRAF V600E)	Solid tumor, Adult Langerhans Cell Histiocytosis (LCH) and Erdheim-Chester disease (ECD)	In January 2022, the investigational new drug application of monotherapy or combined therapy was approved by the NMPA In January 2022, the first patient dosing was completed in a phase 2 clinical study

Product name (targets)	Indications	Progress as at the Latest Practicable Date
Efficient advancement on IND application for pre-clinical development projects		
HLX15 (CD38)	Myeloma (MM)	In January 2021, the investigational new drug application was approved by the NMPA
HLX23 (CD73)	Solid tumor	In May 2021, the investigational new drug application was approved by FDA
HLX35 (EGFR × 4-1BB)	Solid tumor	In January 2022, the investigational new drug application was approved by the NMPA
HLX301 (PD-L1 × TIGIT)	Solid tumor, lymphomas	In January 2022, the investigational new drug application was accepted by the NMPA
HLX26 in combination with serplulimab injection (LAG-3+PD-1)	Solid tumor, lymphomas	In February 2022, the investigational new drug application was accepted by the NMPA

(IV) Social responsibility, environmental policies and performance

Adhering to the philosophy of "Affordable Innovation, Reliable Quality" and staying true to its mission, the Group has actively fulfilled its responsibilities toward stakeholders such as patients, employees, partners, and communities, and committed to providing more affordable but higher quality biopharmaceuticals for global patients. The Group has placed the legality and compliance as its core operating principle by strictly abiding by the relevant laws and regulations in the regions where it operates and restricting its own behavior. Also, the Group attaches great importance to the establishment and maintenance of relationships with its stakeholders, focusing on its ability to build an employment relationship of mutual facilitation with its employees, to establish a supply and demand relationship of mutual trust with the market, and to establish a cooperation relationship of mutual win-win with its cooperative partners. The Group actively assumes corporate social responsibilities by giving full play to its own advantages and cooperating with all walks of the society to jointly promote the development of social welfare undertakings. During the Year, the Group continued to promote its public welfare project of "Leaving No HER2-positive Patient Behind" and built a diversified ecosystem around patient health education, patient care, testing and screening, rural medical care, and other aspects. The Group also kept a close eye on rural revitalization, fighting floods and providing disaster relief, and exert material assistance by investing resources. In terms of environmental management, the Group greatly values the impact of the corporate value chain on the environment. The Group has been continuously improving the environmental management system, and also formulated environmental goals, strengthened the environmental governance, in order to strengthen the ability to respond to climate change risks. During the Reporting Period, the Group did not have any events that made us subject to any major penalties from relevant departments due to environmental issues.

Further information on the Group's social responsibility, corporate governance, environmental policies and performance will be set out in the Corporate Social Responsibility Report to be published by the Company in due course.

WARNING STATEMENT REQUIRED BY RULE 18A.05 OF THE RULES GOVERNING THE LISTING OF SECURITIES ON THE STOCK EXCHANGE OF HONG KONG LIMITED: We may be unable to finally succeed in development and commercialization of our core products.

II. OUTLOOK FOR 2022

In 2022, the Group will further expand its biopharmaceutical product pipeline covering oncology, auto-immune diseases and other fields, capitalise on the achieved first-entrant advantages to consolidate the internationalised capability of "integrating research, production and marketing". Adhering to independent research and development, the Group keeps accelerating innovation progress in the fields of monoclonal antibody, bispecific antibody, ADC, small molecules, and other fields, quickly implementing production capacity construction to meet strong market demand, and actively improving the commercialization layout to build a powerful commercial organization with predominant strength, we will gradually evolve ourselves into a Biopharma with larger scale and stronger market competitiveness.

(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 medical insurance reform, and provides patients with biological drugs of affordable price and high-quality. Also, based on the patient-oriented principle, the Group has established a comprehensive and efficient business operation model to continuously promote the successful commercialization of more products.

Serplulimab injection (PD-1) is one of the Group's core innovative monoclonal antibody products for the treatment of indications of unresectable or metastatic microsatellite instability-high (MSI-H) solid tumors that have failed to respond to the standard therapy. It is expected to be approved for marketing in the near future. The Group has established a professional and experienced team in advance for the sales of serplulimab injection (PD-1) after its launch. While actively implementing the marketing and sales layout, the Group also plans to establish in-depth cooperation with genetic testing companies to jointly explore innovative solutions in the field of oncology, build a new patient service model, improve the standards and accessibility of MSI testing, and gradually establish diagnosis and treatment ecosystem for patients with gastrointestinal tumors and gynecological tumors. On this basis, with successive approvals for other indications (including advanced or metastatic squamous non-small cell lung cancer (sqNSCLC), extensive stage small cell lung cancer (ES-SCLC), etc.) of serplulimab injection (PD-1) obtained, the Group will further consolidate the market sales layout in lung cancer and other fields, and build a complete diagnosis and treatment ecosystem for oncology patients in an orderly manner.

HANQUYOU is the Group's first core anti-tumor product promoted and sold within Mainland China as led by its self-built commercialization team. In 2022, the Group will take further actions to promote the inclusion of HANQUYOU (both 150mg and 60mg) into medical insurance procurement platforms and admission into hospitals. Also, the Group will rely on its exclusive advantages in HANQUYOU (both 150mg and 60mg) in terms of personalized dosage and cost to continue to promote the products into lower-tier cities. In 2022, the Group will continue to optimize the diagnosis and treatment ecosystem for HER2-positive patients by focusing on improving patient management and education platform construction and building a public welfare platform for primary medical care. The Group is planning to invite domestic experts in oncology and relevant teams from professional hospitals to go deep into the grassroots to conduct public welfare trainings on the prevention and treatment of breast

cancer and other oncology diseases, and carry out exchange activities such as large-scale free diagnosis, ward rounds, case discussions, etc., to effectively implement cancer prevention, diagnosis and treatment projects, contributing to the standardization of cancer diagnosis and treatment in grassroots areas. In 2022, the sales network of HANQUYOU will continue to be strengthened, which plans to cover approximately 450 cities and nearly 5,500 DTP pharmacies/hospitals across China.

In February 2022, HANLIKANG was approved for marketing and sales of its innovative rheumatoid arthritis (RA) indication, which will add additional bargaining advantages to the marketing and sales of HANLIKANG. As the first monoclonal antibody drug approved for marketing under the Guidelines for Biosimilars in China, HANLIKANG is currently available in two dosage forms (100mg/10ml and 500mg/50ml) in the market, and its applicable indications include not only the indications of the original drug in the field of hematology oncology approved in Mainland China, but also the field of autoimmunity, providing high-quality and flexible treatment options for a larger patient population. The Group will maintain close cooperation with Jiangsu Fosun to seize the first-entrant advantages and promote the continuous growth of sales of HANLIKANG. In 2022, HANLIKANG will continue to cooperate with academic groups to promote the standardized diagnosis and treatment of lymphomas through academic exchanges and other means, and enter into the field of rheumatism to benefit patients with rheumatoid arthritis.

At the same time, the Group will continue to cooperate with Jiangsu Wanbang to carry out sales promotion of HANDAYUAN, focusing on the fields of rheumatism (ankylosing spondylitis, rheumatoid arthritis (RA)), dermatology (psoriasis), and ophthalmology (uveitis). In 2022, focusing on the four major indications, HANDAYUAN will continue to help patients stay away from the pains and suffering by relying on the platforms such as "ASSC Ankylosing Spondylitis Standardized Treatment Project" and "Da'en Home". It is intended that HANDAYUAN will be available to 4,500 specialists and approximately 3,500 DTP pharmacies/hospitals by 2022, which will gradually ensure the "channel accessibility" of HANDAYUAN on the basis of "economic accessibility".

While actively expanding the domestic market, the Group will constantly promote the business cooperation of its self-developed products in the international market. With the continuous advancement of the R&D and registration of pipeline products of the Group and the increasing understanding and full recognition of the Group's products of the international market, the Group will continue to seek business cooperation with more international leading pharmaceutical companies in 2022 to jointly promote the expansion of our products into broader international markets, especially emerging markets with huge unmet medical needs for affordable drugs, which, in our expectation, will benefit patients overseas.

(II) Continue to drive approval for more products indications

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

Serplulimab injection (PD-1) is the core innovative monoclonal antibody product of the Group, and the related R&D and production thereof strictly follow international quality standards. As of the Latest Practicable Date, 1 serplulimab injection (PD-1) monotherapy and 9 combined therapies with serplulimab injection (PD-1) as the core were undergoing clinical trials in multiple countries and regions around the world.

- The application for marketing of serplulimab injection (PD-1) in Mainland China for its second indication, and the new drug application (NDA) of first-line treatment of locally advanced or metastatic squamous non-small cell lung cancer (sqNSCLC) in Mainland China is expected to be approved in 2022.

- The new drug applications of serplulimab injection (PD-1) or placebo in combination with chemotherapy (Carboplatin-Etoposide) for indication of extensive-stage small cell lung cancer (ES-SCLC) in Mainland China and EU are expected to be submitted in 2022.

- The new drug application (NDA) of serplulimab injection (PD-1) or placebo in combination with chemotherapy (cisplatin+5-FU) for first-line treatment of locally advanced/metastatic esophageal squamous cell carcinoma (ESCC) in Mainland China is expected to be submitted in 2022.

In 2022, the Group will also proactively cooperate with international partners to facilitate the submission of new drug applications in terms of HANQUYOU, HANLIKANG and Serplulimab injection (PD-1) in the United States, Colombia, Venezuela, Peru, Ecuador and other places.

(III) Continue to build innovative product pipeline through iterate R&D capabilities

In 2022, the Group, by making continuous use of international resources and advantages as well as advancing the internal innovation capacity building, will continue to create innovative product pipelines of high-quality, with affordable price and differentiated advantages. In terms of early research and development, the Group plans to closely focus on antibody technology that combined with new type of conjugation technology in order to vigorously expand various forms of antibody conjugated molecules, and to build a comprehensive AXC platform, which covered small molecules (ADC), functional enzymes (AEC), isotope (ARC), cell (ACC), PROTAC (APC) and nucleic acid (AOC), etc. The Group will also provide solutions for unmet clinical needs through innovative drug formats. The Group has spent more than one decade taking solid steps in the field of oncology, but still, it will proactively expand into the field of non-oncology diseases (including metabolism, cardiovascular, inflammation and other diseases). At the same time, the Group will also develop innovative products based on tumor metabolism, immune metabolism and other R&D concepts through continuous introduction of new scientific concepts. By doing so, the Group will build up its

momentum in the process of developing and commercializing its innovative products, thereby truly meet the needs from the patients and demand from the market. Certain innovative monoclonal antibody/bispecific antibody products that independently developed by the Group are expected to make further advancement in 2022:

- A phase 3 clinical study to compare serplulimab injection (PD-1) in combination with chemotherapy (carboplatin-pemetrexed), serplulimab injection (PD-1) in combination with HANBEITAI in combination with chemotherapy (carboplatin-pemetrexed) with chemotherapy (carboplatin-pemetrexed) in the first-line treatment for metastatic non-squamous, non-small cell lung cancer (nsNSCLC), is expected to complete its enrollment of subjects by mid-2022.

- HLX301 (recombinant humanised anti-PD-L1 and anti-TIGIT bispecific antibody injection), an innovative bispecific antibody product, is used for the treatment of locally advanced/metastatic solid tumors or lymphomas, and its phase 1/2 investigational new drug application (IND) in Mainland China is expected to be approved in the first half of 2022, and clinical studies will be launched soon.

- HLX35 (recombinant humanised anti-EGFR and anti-4-1BB bispecific antibody injection), an innovative bispecific antibody product, which is used for the treatment of advanced malignant solid tumor, is expected complete the first patient dosing in a phase 1 clinical trial in Mainland China in the first half of 2022.

On the basis of self-research and development, the Group also actively expanded the innovative potential targets through the introduction of licensing projects. During the Reporting Period, the Group introduced the antibodies against human TROP2 target and HLX208 (BRAF V600E inhibitor). The first patient has been dosed in the phase 2 clinical trial of HLX208 (BRAF V600E inhibitor), for the treatment of adult Langerhans Cell Histiocytosis (LCH) and Erdheim-Chester disease (ECD) with BRAF V600E mutation in Mainland China. Also, in 2022, the Group plans to work hard in order to lead advancement on clinical trial in respect of HLX208 (BRAF V600E inhibitor) for solid tumors including metastatic colorectal cancer, non-small cell lung cancer, and indications including adult Langerhans Cell Histiocytosis (LCH) and Erdheim-Chester disease (ECD).

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

The Group will plan in advance the construction of production base and the expansion of production capacity according to the product R&D and marketing process, in order to provide a strong guarantee for the continuous commercial sales of products and realize the efficient utilization of production capacity. The Group's Xuhui Facility has achieved stable and efficient commercial production after 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 be further enhanced in 2022. In addition, the production materials and consumables, key production equipments will also go through further localization in 2022.

As of the Latest Practicable Date, Songjiang First Plant had completed the engineering construction and verification of facilities with production capacity of 24,000L. Also, The Drug Manufacturing Certificate (《藥品生產許可證》) was approved for the production of HANQUYOU, and the supplemental new drug application (sNDA) for the second-generation process of HANQUYOU has also been accepted during the Reporting Period. The Group anticipates that the supplemental new drug application (sNDA) and GMP compliance on-site inspection of the second-generation process of HANQUYOU are likely to be approved and passed in mid-2022, while Songjiang First Plant is expected to be officially put into commercial production for HANQUYOU in mid-2022. In addition, Songjiang First Plant will also continue to improve its international standard quality system and plan to complete the GMP inspection by the United States Food and Drug Administration (FDA) in the first half of 2023.

To achieve the long-term capacity planning, the Group will continue to promote the construction of the Songjiang Second Plant, in order to enhance the overall production capacity. The construction, installation of process equipments for the two main production buildings in the first and second stage of the Songjiang Second Plant Phase I Project are expected to be completed in the first half of 2022 and will enter into the joint commissioning and verification stage. Also, the verification work of facilities and equipment is expected to be completed in the second half of 2022 and will enter into the stage of trial production and process verification. The first batch production of the Songjiang Second Plant project is expected to be completed by the end of 2022. The concept and fundamental design of the third stage of the Songjiang Second Plant Phase I project has been completed and is scheduled to enter the full-scale construction phase in 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, the Group has built a first-class commercialization team in the industry by virtue of innovative market access, business strategy and efficient executive capability in sales, through which the Group rapidly established a foothold in the broad domestic market and continued to penetrate into every corner of the market, laying a solid groundwork for the subsequent transformation of the Company. With the commercialization of four core products in the recent three years, the Group witnessed an increase in the sales of its major products during the Reporting Period with the help of its first-class self-built commercialization team and its close cooperation with its partners, making gratifying achievements.

As an international innovative biopharmaceutical company, the Group seeks to cooperate with global well-known biopharmaceutical companies by capitalizing on its own enhancing R&D capability and unique domestic clinical resources to establish presence in multiple global markets while making overall plans for the domestic market, covering European and American mainstream markets and many other emerging markets. Strategically, through the commercialization right of out-licensed products, the Group introduced its cost-effective products to a broader global market, bringing considerable R&D service revenue and licensing revenue for the Group while benefiting more patients around the world.

During the Reporting Period, the Group registered an operating income of approximately RMB1,682.5 million, an increase of 186.3% over the last year, mainly including the following:

1) Revenue from Chinese market:

HANQUYOU: the first domestic trastuzumab approved for marketing, was independently developed by the Group and also the first product of the Group to adopt its own team to conduct commercialization promotion. It was commercialized in the domestic market in August 2020. During the Reporting Period, HANQUYOU recorded a sales revenue of approximately RMB868.0 million, an increase of approximately RMB758.5 million or 692.7% over 2020.

HANLIKANG: according to the cooperation agreement with Fosun Pharma, Fosun Pharma will reimburse all the expenses related to the clinical trials of HANLIKANG incurred by the Group after the relevant cooperation agreement is signed, while the Group is responsible for the production of HANLIKANG in China and the supply of HANLIKANG to Fosun Pharma after the commercialization of HANLIKANG, and shall share the profits from the sales of HANLIKANG in China. During the Reporting Period, the Group realized sales revenue of approximately RMB542.5 million and licensing revenue of approximately RMB10.4 million under the aforementioned profit-sharing arrangement with its partners.

HANDAYUAN: according to the cooperation agreement with Fosun Pharma, Fosun Pharma will reimburse all the expenses related to the clinical trials of HANDAYUAN incurred by the Group after the relevant cooperation agreement is signed, while the Group is responsible for the production of HANDAYUAN in China and the supply of HANDAYUAN to Fosun Pharma after the commercialization of HANDAYUAN, and

shall share the profits from the sales of HANDAYUAN in China. During the Reporting Period, HANDAYUAN realized sales revenue of approximately RMB21.8 million and licensing revenue of approximately RMB1.0 million under the aforementioned profit-sharing arrangement with its partners.

2) Revenue from international market

As at the end of the Reporting Period, the Group realized revenue of approximately RMB40.6 million for Zercepac®, while realizing sales revenue of drug substance of trastuzumab of approximately RMB21.6 million.

3) Revenue from joint development and technology transfer/commercialization licensing

With the continuous improvement of the R&D system and innovation capabilities of the Group, our influence in the international market is growing, at the same time, the number and overall amount of licensed-out projects are constantly expanding. 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, etc..

In June 2018, the Group entered into a license agreement with Accord in relation to HANQUYOU (trastuzumab injection, EU brand name: Zercepac®), granting Accord exclusive commercial rights in special territories as agreed therein. In July 2020, the marketing authorization application of HANQUYOU (Zercepac®) submitted by a wholly-owned subsidiary of Accord was approved. Since then, HANQUYOU (Zercepac®) 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. The Group has recognised licensing revenue and revenue from R&D services of approximately RMB11.0 million for the 12 months ended 31 December 2021.

In September 2019, the Group entered into a co-development and commercialization agreement with KG Bio in relation to Serplulimab Injection (PD-1). With the continuous advancement of research and development services, the Group has recognised revenue from R&D services of approximately RMB16.3 million for the 12 months ended 31 December 2021.

In September 2020, the Group entered into a co-development and exclusive license agreement with Essex in relation to the HLX04-O (recombinant humanized anti-VEGF monoclonal antibody injection independently developed by the Group). The Group has recognised revenue from R&D services of approximately RMB71.4 million for the 12 months ended 31 December 2021.

In November 2020, the Group entered into a license and co-development agreement with Binacea in relation to HLX35 (recombinant humanized anti-EGFR and anti-4-1BB bispecific antibody injection independently developed by the Group). The Group has recognised licensing revenue of approximately RMB57.8 million for the 12 months ended 31 December 2021.

In January 2021, the Group entered into a license agreement with Intas in relation to HANQUYOU (trastuzumab injection, EU brand name: Zercepac®), granting Intas exclusive developing and commercial rights in special territories as agreed therein. The Group has recognised revenue from R&D services of approximately RMB19.2 million for the 12 months ended 31 December 2021.

(II) Cost of sales

Cost of sales of the Group primarily represents reagents and consumables, employee compensation, outsourcing expenses, utilities expenses and depreciation and amortisation. For the 12 months ended 31 December 2021, the Group recorded cost of sales of approximately RMB522.7 million, representing an increase of approximately RMB340.6 million as compared with that for the 12 months ended 31 December 2020, due to the increase of the sales volume of the key commercial products in the market.

(III) Gross profit

For the 12 months ended 31 December 2021, the Group recorded a gross profit of approximately RMB1,159.7 million, representing an increase of approximately RMB754.2 million, as compared with that for the twelve months ended 31 December 2020, mainly due to the gross profit contribution from the key commercial products of the Company.

(IV) Other income and gains

Other income and gains 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 imposed by the government).

During the Reporting Period, the Group recognised other income and gains of approximately RMB45.1 million.

	Year ended 31 December	
	2021	2020
	RMB'000	*RMB'000*
Government grants	**41,896**	35,393
Interest income	**2,686**	7,404
Others	**509**	940
Total	**45,091**	43,737

(V) R&D expenditure

	Year ended 31 December	
	2021	2020
	RMB'000	*RMB'000*
Expensed R&D expenses		
Share-based compensation	**13,188**	11,147
R&D employee salaries	**338,988**	251,886
Outsourcing fees	**152,730**	138,320
Reagents and consumables	**92,712**	119,466
Utilities expenses	**15,822**	53,564
Depreciation and amortisation	**87,171**	43,334
Consulting expense	**24,709**	15,153
Technology expense	**136,808**	9,339
Clinical trials	**90,850**	154,215
Others	**70,953**	97,720
Total expensed R&D expenses	**1,023,930**	894,144
Capitalised R&D expenses		
Clinical trials	**420,143**	545,992
R&D employee salaries	**195,413**	131,174
Reagents and consumables	**36,849**	60,735
Depreciation and amortisation	**37,669**	10,693
Utilities expenses	**28,650**	21,302
Outsourcing fees	**4,593**	26,255
Consulting expense	**2,858**	7,008
Share-based compensation	**4,519**	9,268
Others	**9,100**	4,334
Total capitalised R&D expenses	**739,793**	816,761

For the 12 months ended 31 December 2021, the Group recognised R&D expenses of approximately RMB1,763.7 million, representing an increase of approximately RMB52.8 million as compared with that of approximately RMB1,710.9 million for the twelve months ended 31 December 2020. The increase in R&D expenses was mainly due to the increase of investment in innovative R&D projects to accelerate the Company's innovation and transformation.

(VI) Administrative expenses

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

For the 12 months ended 31 December 2021, the Group recognised administrative expenses of approximately RMB280.6 million as compared with that of approximately RMB192.6 million for the twelve ended 31 December 2020, representing an increase of 45.7%. The increase in administrative expenses of the Group was mainly due to: (1) the increase in the headcount of the administrative staff and the higher compensation resulted from the expansion of the operations and development of the Company; (2) the increase in office administrative expenses, lease expenses and promoting expenses; and (3) the corresponding increase in consulting expenses incurred from meetings to improve the Company's operational efficiency.

(VII) Selling and distribution expenses

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

For the 12 months ended 31 December 2021, the Group recognised selling and distribution expenses of approximately RMB520.3 million, which were mainly the marketing expenses incurred in the marketing and commercialization of the product of HANQUYOU.

(VIII) Loss for the year

In view of the above, loss of the Group decreased by approximately RMB9.4 million from approximately RMB993.5 million for the year ended 31 December 2020 to approximately RMB984.1 million for the year ended 31 December 2021.

(IX) Liquidity and capital resources

As of 31 December 2021, cash and bank balances of the Group were approximately RMB707.3 million, mainly denominated in Renminbi ("**RMB**"), United States Dollars ("**USD**"), New Taiwan Dollars ("**NTD**"), Hong Kong Dollars ("**HKD**") and Euro ("**EUR**"). Such decrease was mainly due to the daily R&D and manufacturing overhead of the Group. As of 31 December 2021, the current assets of the Group were approximately RMB1,647.2 million, including cash and cash equivalents of approximately RMB155.0 million, pledged deposits of approximately RMB1.7 million and the restricted cash for investments of approximately RMB550.6 million.

Inventories were approximately RMB420.1 million, trade receivables were approximately RMB295.7 million, prepayments, deposits and other receivables were approximately RMB224.0 million. As at 31 December 2021, the current liabilities of the Group were approximately RMB2,959.7 million, including trade payables of approximately RMB383.5 million, other payables and accruals of approximately RMB867.3 million, contract liabilities of RMB138.3 million and interest-bearing bank and other borrowings of approximately RMB1,570.7 million.

As at 31 December 2021, the bank balances in foreign exchange were as follows:

	RMB'000
RMB	116,978
HKD	7,297
USD	580,571
EUR	217
NTD	2,270

	Original amount
RMB	116,978
HKD	8,925
USD	91,061
EUR	30
NTD	9,862

(X) Inventories

Inventories of the Group increased from approximately RMB305.2 million as at 31 December 2020 to approximately RMB420.1 million as at 31 December 2021, mainly due to (1) the increased purchases of raw materials and consumables in line with the clinical trial progress and preparation for commercialized production; (2) safety stock is prepared to meet the increasing demand for key commercial products.

(XI) Trade receivables

As at 31 December 2020 and 31 December 2021, trade receivables from customer contracts were approximately RMB196.2 million and RMB295.7 million, respectively. There were no changes in accounting estimates or key assumptions made in both years.

	As at 31 December	
	2021	2020
	RMB'000	*RMB'000*
Within 3 months	**295,741**	196,213
3 to 6 months	**–**	–
6 to 9 months	**–**	–
9 to 12 months	**–**	–
1 to 2 years	**–**	–
Total	**295,741**	196,213

(XII) Interest-bearing bank and other borrowings

As of 31 December 2021, borrowings from bank and other institutions (exclusive of lease liabilities) of the Group were approximately RMB2,330.2 million. The Group incurred new borrowings for the following reasons: ongoing clinical research trials and preclinical research for drug candidates, commercialization of products 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.

(XIII) Maturity structure of outstanding debts

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

	As at 31 December	
	2021	2020
	RMB'000	*RMB'000*
Within one year	**1,570,674**	1,188,486
In the second year	**318,790**	82,089
In the third to fifth year (inclusive)	**177,956**	320,792
Over five years	**555,517**	242,250
Total	**2,622,937**	1,833,617

(XIV) Collateral and pledged assets

As at 31 December 2021, the Group's pledged assets in relation to borrowings included trade receivables of approximately RMB69.4 million, prepayments, deposits and other receivables of approximately RMB8.3 million, property, plant and equipment of approximately RMB364.1 million and land use right of approximately RMB201.1 million. The Group had a deposit of approximately RMB1.7 million due to issuance of letter of credit.

(XV) Key financial ratios

	31 December 2021	31 December 2020
Current ratio [(1)]:	**55.7%**	96.5%
Quick ratio [(2)]:	**41.5%**	81.1%
Gearing ratio [(3)]:	**51.8%**	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 then divided by current liabilities as of the same day.

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

(XVI) Material 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 RMB2.54 billion for the construction of the Phase I project of the Songjiang Second Plant (first stage, second stage and third stage). As at the end of the Reporting Period, the facility is under construction and the subsequent stages of construction will be gradually carried out based on the strategy of the Group. The capital expenditure of the construction of the Songjiang Second Plant will be mainly funded through debt financing.

Save as disclosed in this announcement, as at 31 December 2021, the Group did not make other significant investments.

(XVII) Capital commitments and capital expenditures

	As at 31 December	
	2021	2020
	RMB'000	*RMB'000*
Plant and machinery	**55,745**	170,240
Construction in progress	**250,773**	274,769
Electronic equipment	**14,096**	15,822
Leasehold improvements	**45,706**	106,058
Others	**378**	473
Total	**366,698**	567,362

We had capital commitments for plant and machinery contracted but not provided for of approximately RMB463.1 million as at 31 December 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 expenditure to be capitalised.

(XVIII) Contingent liabilities

As of 31 December 2021, the Group did not have any material contingent liabilities.

(XIX) Material acquisitions and disposals

As of 31 December 2021, the Group did not have any material acquisitions and disposals.

(XX) Dividends

The Company did not pay or declare any dividend for the year ended 31 December 2021.

IV. RISK MANAGEMENT

(I) Foreign exchange risk

Up until 31 December 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 EUR will increase in the future. Fluctuations in exchange rates may adversely affect the Group's cash flows, revenues, earnings and financial position.

(III) Potential risks

1. Market Risk

The biologics market is highly competitive, and the Group's existing 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 indication treatment, drug novelty, drug quality and reputation, breadth of drug portfolio, manufacturing and distribution capacity, drug price, coverage and depth of customer, consumer behaviour and supply chain relationships. The Group's ability to remain competitive depends to a large extent on our ability to innovate, develop and promote new products and technologies that meet market needs in a manner to capture market share. At the same time, in October 2020, in the "Response to the Recommendation of No. 6450 of the Third Session of the 13th NPC", the National Healthcare Security Administration stated that 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 for R&D, to develop, enhance or acquire technologies that will allow the Group to expand the scope and improve the quality of the services. The currently available products of the Group include: HANLIKANG , HANQUYOU (trastuzumab injection, EU brand name: Zercepac®), HANDAYUAN and HANBEITAI. Most of the Group's drug candidates are still under development and are in the clinical development stages, and the course of clinical development involves a lengthy and expensive process with uncertainties in various aspects, as there can be no assurance from the Group of the development and clinical results. Furthermore, if the clinical development and regulatory approval process of the drug candidates are delayed or terminated, the successful development and 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 second 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 of staff for clinical trials and staff's involvement, approval of regulatory registration, procurement of raw materials, and construction progress of production base. The Group will continue to observe the epidemic situation and make all preparations in advance.

4. Force Majeure Risk

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

V. EMPLOYEES AND REMUNERATION POLICIES

The following table sets forth the breakdown of our employees by function as at 31 December 2021:

Function	Number of employees
Management and administrative	203
R&D	335
Quality and technical support	255
Manufacturing	610
Clinical medical affairs	304
Commercial Operation	527
Total	2,234

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 are 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.

COMMUNICATION WITH SHAREHOLDERS AND INVESTORS

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

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

FINAL DIVIDEND

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

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

The Company will arrange the time of convening the forthcoming annual general meeting (the"**AGM**") as soon as practicable, and the notice of the AGM will be published and dispatched to the Shareholders in a timely manner in accordance with the requirements of the Rules Governing the Listing of Securities on the Stock Exchange (the "**Listing Rules**") and the articles of association of the Company. Once the date of the AGM is finalised, the Company will publish the period of closure of the register of members of H shares of the Company in a separate announcement and in the notice of the AGM.

EVENTS AFTER THE END OF THE REPORTING PERIOD

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

PURCHASE, SALE AND REDEMPTION OF LISTED SECURITIES

During the Reporting Period, neither the Company nor any of its subsidiaries have purchased, sold or redeemed any of the Company's listed securities.

COMPLIANCE WITH CORPORATE GOVERNANCE CODE

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

Code provision C.2.1 of the CG Code provides that the roles of chairman and chief executive should be separate and should not be performed by the same individual. From 30 November 2021, Mr. Zhang Wenjie assumed the roles of both chairman and chief executive officer, the Company deviated from the requirements set out in code provision C.2.1 of the CG Code. Mr. Zhang Wenjie joined the Company in March 2019 and has successively served in various key positions in the Company, including the chief commercial operation officer and chief strategy officer of the Company, his familiarity with the business operation of the Company and his roles as the Chairman of the Board and the Chief Executive Officer of the Company can facilitate the formulation and implementation of business strategies of the Company. The Board considered that the current structure will not impair the balance of power and authority between the Board and the management of the Company. The Board will make decisions on important matters of the Company within the authority granted by the articles of association of the Company and its shareholders at the general meetings. In addition, the Board, which currently comprises one executive Director, five non-executive Director and four independent non-executive Directors, is appropriately structured with a balance of power to provide sufficient checks to protect the interests of the Company and the shareholders as a whole.

Save as disclosed above, during the Reporting Period, the Company has complied with all the 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.

AUDIT COMMITTEE

The audit committee of the Company has reviewed the Group's 2021 annual results and the financial statements for the year ended 31 December 2021 prepared in accordance with the IFRSs.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS

Year ended 31 December 2021

	Notes	**2021**	2020
		RMB'000	*RMB'000*
REVENUE	*3*	**1,682,472**	587,586
Cost of sales		**(522,748)**	(182,119)
Gross profit		**1,159,724**	405,467
Other income and gains	*4*	**45,091**	43,737
Selling and distribution expenses		**(520,261)**	(243,648)
Administrative expenses		**(280,606)**	(192,640)
Impairment losses on financial assets, net		**(174)**	14
Research and development expenses		**(1,023,930)**	(894,144)
Other expenses		**(251,763)**	(68,622)
Finance costs	*6*	**(84,820)**	(43,705)
LOSS BEFORE TAX	*5*	**(956,739)**	(993,541)
Income tax expense	*7*	**(27,313)**	–
LOSS FOR THE YEAR		**(984,052)**	(993,541)
Attributable to:			
Owners of the parent		**(984,052)**	(993,541)
Non-controlling interests		**–**	–
		(984,052)	(993,541)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted (RMB)	*9*	**(1.83)**	(1.88)

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

Year ended 31 December 2021

	2021	2020
	RMB'000	*RMB'000*
LOSS FOR THE YEAR	**(984,052)**	(993,541)
OTHER COMPREHENSIVE LOSS		
Other comprehensive loss that may be reclassified to profit or loss in subsequent periods:		
Exchange differences:		
Exchange differences on translation of foreign operations	**(448)**	(1,770)
OTHER COMPREHENSIVE LOSS FOR THE YEAR, NET OF TAX	**(448)**	(1,770)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	**(984,500)**	(995,311)
ATTRIBUTABLE TO:		
Owners of the parent	**(984,500)**	(995,311)
Non-controlling interests	**–**	–
	(984,500)	(995,311)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

Year ended 31 December 2021

	Notes	2021 RMB'000	2020 RMB'000
NON-CURRENT ASSETS			
Property, plant and equipment		**1,228,885**	984,909
Intangible assets		**3,634,931**	2,942,454
Right-of-use assets		**438,201**	452,279
Other non-current assets		**223,668**	149,540
Total non-current assets		**5,525,685**	4,529,182
CURRENT ASSETS			
Inventories		**420,112**	305,224
Trade receivables	*10*	**295,741**	196,213
Prepayments, deposits and other receivables		**223,973**	294,248
Cash and bank balances		**707,333**	1,114,309
Total current assets		**1,647,159**	1,909,994
CURRENT LIABILITIES			
Trade payables	*11*	**383,470**	298,952
Other payables and accruals		**867,278**	439,845
Contract liabilities		**138,303**	52,225
Interest-bearing bank and other borrowings		**1,570,674**	1,188,486
Total current liabilities		**2,959,725**	1,979,508
NET CURRENT LIABILITIES		**(1,312,566)**	(69,514)
TOTAL ASSETS LESS CURRENT LIABILITIES		**4,213,119**	4,459,668
NON-CURRENT LIABILITIES			
Interest-bearing bank and other borrowings		**1,052,263**	645,131
Other long-term payables		**54,425**	–
Contract liabilities		**653,934**	520,870
Deferred income		**155,741**	94,895
Total non-current liabilities		**1,916,363**	1,260,896
Net assets		**2,296,756**	3,198,772
EQUITY			
Share capital		**543,495**	543,495
Reserves		**1,753,261**	2,655,277
Equity attributable to owners of the parent and total equity		**2,296,756**	3,198,772

1.1 BASIS OF PREPARATION

These financial statements have been prepared in accordance with International Financial Reporting Standards ("**IFRSs**"), which comprise all standards and interpretations approved by the International Accounting Standards Board (the "**IASB**"), and International Accounting Standards ("**IASs**") and Standing Interpretations Committee interpretations approved by the International Accounting Standards Committee that remain in effect, and the disclosure requirements of the Hong Kong Companies Ordinance. They have been prepared under the historical cost convention. These financial statements are presented in Renminbi ("**RMB**"), and all values are rounded to the nearest thousand except when otherwise indicated.

The Group had net current liabilities of RMB1,312,566,000 as at 31 December 2021. Having taken into account the unused banking facilities and the expected cash flows from operating and financing activities, the Directors consider that it is appropriate to prepare the financial statements on a going concern basis.

Basis of consolidation

The consolidated financial statements include the financial statements of the Company and its subsidiaries (collectively referred to as the "**Group**") for the year ended 31 December 2021. A subsidiary is an entity (including a structured entity), directly or indirectly, controlled by the Company. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee (i.e., existing rights that give the Group the current ability to direct the relevant activities of the investee).

When the Company has, directly or indirectly, less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, including:

(a) the contractual arrangement with the other vote holders of the investee;

(b) rights arising from other contractual arrangements; and

(c) the Group's voting rights and potential voting rights.

The financial statements of the subsidiaries are prepared for the same Reporting Period as the Company, using consistent accounting policies. The results of subsidiaries are consolidated from the date on which the Group obtains control and continue to be consolidated until the date that such control ceases.

Profit or loss and each component of other comprehensive income are attributed to the owners of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. All intra-group assets and liabilities, equity, income, expenses, and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

The Group reassesses whether it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control described above. A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

If the Group loses control over a subsidiary, it derecognises (i) the assets (including goodwill) and liabilities of the subsidiary, (ii) the carrying amount of any non-controlling interest and (iii) the cumulative translation differences recorded in equity; and recognises (i) the fair value of the consideration received, (ii) the fair value of any investment retained and (iii) any resulting surplus or deficit in profit or loss. The Group's share of components previously recognised in other comprehensive income is reclassified to profit or loss or retained profits, as appropriate, on the same basis as would be required if the Group had directly disposed of the related assets or liabilities.

1.2 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The Group has adopted the following revised IFRSs for the first time for the current year's financial statements.

Amendments to IFRS 9, IAS 39, IFRS 7 IFRS 4 and IFRS 16	*Interest Rate Benchmark Reform – Phase 2*
Amendment to IFRS 16	*Covid-19-Related Rent Concessions beyond 30 June 2021* (early adopted)

The nature and the 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 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 IAS 39 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 RMB based on the Loan Prime Rate ("**LPR**") as at 31 December 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 March 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. However, the Group has not received covid-19-related rent concessions and plans to apply the practical expedient when it becomes applicable within the allowed period of application.

1.3 ISSUED BUT NOT YET EFFECTIVE INTERNATIONAL FINANCIAL REPORTING STANDARDS

The Group has not applied the following new and revised IFRSs, that have been issued but are not yet effective, in these financial statements.

Amendments to IFRS 3	*Reference to the Conceptual Framework*[1]
Amendments to IFRS 10 and IAS 28	*Sale or Contribution of Assets between an Investor and its Associate or Joint Venture*[3]
IFRS 17	*Insurance Contracts*[2]
Amendments to IFRS 17	*Insurance Contracts*[2, 4]
Amendment to IFRS 17	*Initial Application of IFRS 17 and IFRS9 – Comparative Information*[2]
Amendments to IAS 1	*Classification of Liabilities as Current or Non-current*[2]
Amendments to IAS 1 and IFRS Practice Statement 2	*Disclosure of Accounting Policies*[2]
Amendments to IAS 8	*Definition of Accounting Estimates*[2]
Amendments to IAS 12	*Deferred Tax related to Assets and Liabilities arising from a Single Transaction*[2]
Amendments to IAS 16	*Property, Plant and Equipment: Proceeds before Intended Use*[1]
Amendments to IAS 37	*Onerous Contracts – Cost of Fulfilling a Contract*[1]
Annual Improvements to IFRSs 2018-2020	Amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41[1]

1 Effective for annual periods beginning on or after 1 January 2022

2 Effective for annual periods beginning on or after 1 January 2023

3 No mandatory effective date yet determined but available for adoption

4 As a consequence of the amendments to IFRS 17 issued in June 2020, IFRS 4 was amended to extend the temporary exemption that permits insurers to apply IAS 39 rather than IFRS 9 for annual periods beginning before 1 January 2023

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

Amendments to IFRS 3 are intended to replace a reference to the previous Framework for the Preparation and Presentation of Financial Statements with a reference to the Conceptual Framework for Financial Reporting issued in March 2018 without significantly changing its requirements. The amendments also add to IFRS 3 an exception to its recognition principle for an entity to refer to the Conceptual Framework to determine what constitutes an asset or a liability. The exception specifies that, for liabilities and contingent liabilities that would be within the scope of IAS 37 or IFRIC 21 if they were incurred separately rather than assumed in a business combination, an entity applying IFRS 3 should refer to IAS 37 or IFRIC 21 respectively instead of the Conceptual Framework. Furthermore, the amendments clarify that contingent assets do not qualify for recognition at the acquisition date. The Group expects to adopt the amendments prospectively from 1 January 2022. Since the amendments apply prospectively to business combinations for which the acquisition date is on or after the date of first application, the Group will not be affected by these amendments on the date of transition.

Amendments to IFRS 10 and IAS 28 address an inconsistency between the requirements in IFRS 10 and in IAS 28 in dealing with the sale or contribution of assets between an investor and its associate or joint venture. The amendments require a full recognition of a gain or loss resulting from a downstream transaction when the sale or contribution of assets between an investor and its associate or joint venture constitutes a business. For a transaction involving assets that do not constitute a business, a gain or loss resulting from the transaction is recognised in the investor's profit or loss only to the extent of the unrelated investor's interest in that associate or joint venture. The amendments are to be applied prospectively. The previous mandatory effective date of amendments to IFRS 10 and IAS 28 was removed by the IASB in December 2015 and a new mandatory effective date will be determined after the completion of a broader review of accounting for associates and joint ventures. However, the amendments are available for adoption now.

Amendments to IAS 1 Classification of Liabilities as Current or Non-current clarify the requirements for classifying liabilities as current or non-current. The amendments specify that if an entity's right to defer settlement of a liability is subject to the entity complying with specified conditions, the entity has a right to defer settlement of the liability at the end of the Reporting Period if it complies with those conditions at that date. Classification of a liability is unaffected by the likelihood that the entity will exercise its right to defer settlement of the liability. The amendments also clarify the situations that are considered a settlement of a liability. The amendments are effective for annual periods beginning on or after 1 January 2023 and shall be applied retrospectively. Earlier application is permitted. The amendments are not expected to have any significant impact on the Group's financial statements.

Amendments to IAS 1 Disclosure of Accounting Policies require entities to disclose their material accounting policy information rather than their significant accounting policies. Accounting policy information is material if, when considered together with other information included in an entity's financial statements, it can reasonably be expected to influence decisions that the primary users of general purpose financial statements make on the basis of those financial statements. Amendments to IFRS Practice Statement 2 provide non-mandatory guidance on how to apply the concept of materiality to accounting policy disclosures. Amendments to IAS 1 are effective for annual periods beginning on or after 1 January 2023 and earlier application is permitted. Since the guidance provided in the amendments to IFRS Practice Statement 2 is non-mandatory, an effective date for these amendments is not necessary. The Group is currently assessing the impact of the amendments on the Group's accounting policy disclosures.

Amendments to IAS 8 clarify the distinction between changes in accounting estimates and changes in accounting policies. Accounting estimates are defined as monetary amounts in financial statements that are subject to measurement uncertainty. The amendments also clarify how entities use measurement techniques and inputs to develop accounting estimates. The amendments are effective for annual reporting periods beginning on or after 1 January 2023 and apply to changes in accounting policies and changes in accounting estimates that occur on or after the start of that period. Earlier application is permitted. The amendments are not expected to have any significant impact on the Group's financial statements.

Amendments to IAS 12 narrow the scope of the initial recognition exception so that it no longer applies to transactions that give rise to equal taxable and deductible temporary differences, such as leases and decommissioning obligations. Therefore, entities are required to recognise a deferred tax asset and a deferred tax liability for temporary differences arising from these transactions. The amendments are effective for annual reporting periods beginning on or after 1 January 2023 and shall be applied to transactions related to leases and decommissioning obligations at the beginning of the earliest comparative period presented, with any cumulative effect recognised as an adjustment to the opening balance of retained profits or other component of equity as appropriate at that date. In addition, the amendments shall be applied prospectively to transactions other than leases and decommissioning obligations. Earlier application is permitted. The amendments are not expected to have any significant impact on the Group's financial statements.

Amendments to IAS 16 prohibit an entity from deducting from the cost of an item of property, plant and equipment any proceeds from selling items produced while bringing that asset to the location and condition necessary for it to be capable of operating in the manner intended by management. Instead, an entity recognises the proceeds from selling any such items, and the cost of those items, in profit or loss. The amendments are effective for annual periods beginning on or after 1 January 2022 and shall be applied retrospectively only to items of property, plant and equipment made available for use on or after the beginning of the earliest period presented in the financial statements in which the entity first applies the amendments. Earlier application is permitted. The amendments are not expected to have any significant impact on the Group's financial statements.

Amendments to IAS 37 clarify that for the purpose of assessing whether a contract is onerous under IAS 37, the cost of fulfilling the contract comprises the costs that relate directly to the contract. Costs that relate directly to a contract include both the incremental costs of fulfilling that contract (e.g., direct labour and materials) and an allocation of other costs that relate directly to fulfilling that contract (e.g., an allocation of the depreciation charge for an item of property, plant and equipment used in fulfilling the contract as well as contract management and supervision costs). General and administrative costs do not relate directly to a contract and are excluded unless they are explicitly chargeable to the counterparty under the contract. The amendments are effective for annual periods beginning on or after 1 January 2022 and shall be applied to contracts for which an entity has not yet fulfilled all its obligations at the beginning of the annual reporting period in which it first applies the amendments. Earlier application is permitted. Any cumulative effect of initially applying the amendments shall be recognised as an adjustment to the opening equity at the date of initial application without restating the comparative information. The amendments are not expected to have any significant impact on the Group's financial statements.

Annual Improvements to IFRSs 2018-2020 sets out amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41. Details of the amendments that are expected to be applicable to the Group are as follows:

- IFRS 9 Financial Instruments: clarifies the fees that an entity includes when assessing whether the terms of a new or modified financial liability are substantially different from the terms of the original financial liability. These fees include only those paid or received between the borrower and the lender, including fees paid or received by either the borrower or lender on the other's behalf. An entity applies the amendment to financial liabilities that are modified or exchanged on or after the beginning of the annual reporting period in which the entity first applies the amendment. The amendment is effective for annual periods beginning on or after 1 January 2022. Earlier application is permitted. The amendment is not expected to have a significant impact on the Group's financial statements.

- IFRS 16 Leases: removes the illustration of payments from the lessor relating to leasehold improvements in Illustrative Example 13 accompanying IFRS 16. This removes potential confusion regarding the treatment of lease incentives when applying IFRS 16.

2. OPERATING SEGMENT INFORMATION

The Group is engaged in biopharmaceutical R&D, biopharmaceutical services and biopharmaceutical production, which is regarded as a single reportable segment in a manner consistent with the way in which information is reported internally to the Group's senior management for purposes of resource allocation and performance assessment. Therefore, no analysis by operating segment is presented.

Geographical information

(a) Revenue from external customers

	2021	2020
	RMB'000	*RMB'000*
Mainland China	**1,515,645**	455,470
Europe	**109,541**	112,196
Asia Pacific (excluding Mainland China)	**57,286**	19,908
Other regions	**–**	12
	1,682,472	587,586

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

(b) Non-current assets

	2021	2020
	RMB'000	*RMB'000*
Mainland China	**5,430,594**	4,412,807
Overseas	**95,091**	116,375
	5,525,685	4,529,182

The non-current asset information above is based on the locations of the assets and excludes financial instruments and deferred tax assets.

Information about major customers

Revenue from customers amounting to over 10% to the total revenue of the Group in the Reporting Period is as follows:

	2021
	RMB'000
Customer A	**534,538**
Customer B	**458,237**
	992,775

	2020
	RMB'000
Customer A	273,079
Customer B	112,196
Customer C	61,397
	446,672

3. REVENUE

An analysis of revenue is as follows:

	2021	2020
	RMB'000	RMB'000
Revenue from contracts with customers	**1,682,472**	587,574
Revenue from other sources		
Gross rental income from operating leases	**–**	12
	1,682,472	587,586

Revenue from contracts with customers

(a) Revenue information

	2021	2020
	RMB'000	RMB'000
Types of goods or service		
Sales of biopharmaceutical products	**1,494,639**	425,451
Research and development services	**112,873**	118,388
The License	**74,222**	42,294
Others	**738**	1,441
Total revenue from contracts with customers	**1,682,472**	587,574
Timing of revenue recognition		
Transferred at a point in time	**1,495,377**	456,749
Transferred over time	**187,095**	130,825
Total revenue from contracts with customers	**1,682,472**	587,574

The following table shows the amounts of revenue recognised in the current Reporting Period that were included in the contract liabilities at the beginning of the Reporting Period:

	2021	2020
	RMB'000	*RMB'000*
Revenue recognised that was included in contract liabilities at the beginning of the Reporting Period:		
Research and development services	**107,387**	78,915
License	**14,545**	11,951
	121,932	90,866

There is no revenue recognised from performance obligations satisfied in previous periods.

(b) Performance obligations

Information about the Group's performance obligations is summarised below:

Sale of biopharmaceutical products

The performance obligation is satisfied upon receipt of the products and payment is generally due within 90 days from the received date.

The License

The performance obligation of commercialization licenses is satisfied overtime during the expected commercialization period after the Group obtains the commercialization authorisation from the local authorities and payment in advance is normally required. The performance obligation of intellectual property licenses is satisfied at a point in time and payment is billed based on the milestone achieved.

Research and development services

Based on the terms of the contracts, the performance obligation is satisfied over time as services are rendered or at the point in time as the services are completed and accepted and payment is billed based on the milestone achieved.

The amounts of transaction prices allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at 31 December are as follows:

	2021	2020
	RMB'000	*RMB'000*
Amounts expected to be recognised as revenue:		
Within one year	**232,700**	147,161
After one year	**804,982**	685,267
	1,037,682	832,428

The remaining performance obligations expected to be recognised after one year mainly relate to the transaction prices allocated to the License and research and development services. The revenue from the License is expected to be recognised during the future estimated commercialization period. The revenue from research and development services is expected to be recognised during the period in which the services are being rendered. The amounts disclosed above do not include variable consideration.

4. OTHER INCOME AND GAINS

	2021	2020
	RMB'000	*RMB'000*
Interest income	**2,686**	7,404
Government grants	**41,896**	35,393
Others	**509**	940
	45,091	43,737

5. LOSS BEFORE TAX

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

	2021	2020
	RMB'000	*RMB'000*
Cost of inventories sold	**396,900**	168,526
Cost of services provided	**125,848**	13,593
Depreciation of property, plant and equipment*	**83,976**	62,172
Depreciation of right-of-use assets*	**49,607**	39,949
Amortisation of intangible assets*	**66,593**	33,655
Research and development expenses:		
Current year expenditure	**1,023,930**	894,144
Lease payments not included in the measurement of lease liabilities	**5,093**	3,774
Listing expenses	**159**	3,444
Auditor's remuneration	**2,800**	2,350
Employee benefit expense (including directors' and chief executive's remuneration):		
Wages and salaries	**709,686**	346,273
Staff welfare expenses	**144,419**	49,598
Share-based payment expense*	**48,417**	35,731
Foreign exchange loss	**16,662**	59,773
Impairment of financial assets, net:		
Impairment of trade receivables, net	**174**	(14)
Impairment of deferred development costs, net	**28,848**	–
Write-down of inventories to net realisable value	**7,566**	1,188
Provision for the contract loss	**191,271**	–
Bank interest income	**(2,686)**	(7,404)
Loss on disposal of items of property, plant and equipment	**932**	96
Gain on disposal of items of right-of-use assets	**–**	(907)

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

6. FINANCE COSTS

An analysis of finance costs is as follows:

	2021	2020
	RMB'000	*RMB'000*
Interest expense on bank and other borrowings	**78,505**	30,119
Interest expense on lease liabilities	**16,649**	16,230
Less: Interest capitalised	**(10,334)**	(2,644)
	84,820	43,705

7. INCOME TAX

The provision for Chinese Mainland current income tax is based on the statutory rate of 25% (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 Chinese Mainland, which are taxed at a preferential rate of 15%.

Taxes on profits assessable elsewhere have been calculated at the tax rates prevailing in the jurisdictions in which the Group operates. The provision for current income tax of Taiwan Henlius and Hengenix, is based on the statutory rates of 20% and 29.84%, respectively (2020: 20%, 29.84%, respectively), for the year ended 31 December 2021. The provision for current income tax of Henlius Industrial is based on the statutory rates of 8.25% for the year ended 31 December 2021.

	2021	2020
	RMB'000	*RMB'000*
Current – Mainland China	**27,313**	–
Total tax charged for the year	**27,313**	–

8. DIVIDENDS

No dividends have been paid or declared by the Company during the Reporting Period.

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

The calculation of the basic loss per share amounts is based on the loss attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 538,836,373 (2020: 529,574,066) in issue during the year.

The calculation of the diluted loss per share amounts is based on the loss for the year attributable to ordinary equity holders of the parent. The weighted average number of ordinary shares used in the calculation is the number of ordinary shares in issue during the year, as used in the basic loss per share calculation, and the weighted average number of conversion of all dilutive potential ordinary shares into ordinary shares.

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

	2021	2020
	RMB'000	*RMB'000*
Loss		
Loss attributable to ordinary equity holders of the parent, used in the basic loss per share calculation	**(984,052)**	(993,541)

	Number of shares	
	2021	2020
Shares		
Weighted average number of ordinary shares in issue during the year used in the basic loss per share calculation	**538,836,373**	529,574,066
Effect of dilution – weighted average number of ordinary shares: Restricted shares under share award scheme	**–**	–
Weighted average number of ordinary shares in issue during the year in the diluted loss per share calculation	**538,836,373**	529,574,066

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

10. TRADE RECEIVABLES

	2021	2020
	RMB'000	*RMB'000*
Trade receivables	**301,201**	201,499
Impairment	**(5,460)**	(5,286)
	295,741	196,213

The Group's trading terms with its customers are mainly on credit. The credit period is generally three months. The Group seeks to maintain strict control over its outstanding receivables and has a credit control department to minimise credit risk. Overdue balances are reviewed regularly by senior management. Trade receivables are non-interest-bearing.

At 31 December 2021, the Group's trade receivables with the amount of RMB69,444,000 (2020: RMB4,300,000) were pledged as security for the Group's interest-bearing bank and other borrowings.

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

	2021	2020
	RMB'000	*RMB'000*
Within 3 months	**295,741**	196,213

11. TRADE PAYABLES

	2021	2020
	RMB'000	*RMB'000*
Trade payables	**383,470**	298,952

Trade payables are non-interest-bearing and are normally settled on terms of three to six months.

An ageing analysis of the trade payables as at the end of each reporting period based on the invoice date, is as follows:

	2021	2020
	RMB'000	*RMB'000*
Within 1 year	**383,470**	298,148
1 to 2 years	**–**	804
	383,470	298,952

PUBLICATION OF ANNUAL RESULTS AND ANNUAL REPORT

This results announcement is published on the website of the Stock Exchange at http://www.hkexnews.hk and on the website of the Company at http://www.henlius.com. The 2021 annual report containing all the information required by the Listing Rules will be despatched to the Shareholders in due course and will be published on the websites of the Company and the Stock Exchange.

APPRECIATION

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

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

Hong Kong, 16 March 2022

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