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 2020, CHANGE IN USE OF PROCEEDS FROM THE GLOBAL OFFERING AND UPDATES REGARDING A SHARE OFFERING AND LISTING

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 2020 (the "**Reporting Period**"), prepared under International Financial Reporting Standards ("**IFRSs**").

FINANCIAL SUMMARY:

1. The Group's total revenue was approximately RMB587.6 million for the year ended 31 December 2020, representing an increase of approximately RMB496.7 million, or approximately 546% compared to approximately RMB90.9 million for the year ended 31 December 2019. 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 2020, the Group recognised R&D expenditure of approximately RMB1,710.9 million, representing an increase of approximately RMB304.1 million or approximately 21.6% as compared with approximately RMB1,406.8 million for the year ended 31 December 2019.

3. The Group's total loss increased by approximately RMB118.0 million to approximately RMB993.5 million for the year ended 31 December 2020, compared to approximately RMB875.5 million for the year ended 31 December 2019, mainly due to the expansion of R&D clinical activities.

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

BUSINESS HIGHLIGHTS:

1. **漢利康®(rituximab injection):**

   - 漢利康®: Applications for the addition of 2,000L drug substance production scale and 2,000L production equipment, and the addition of the specification of 500mg/50ml/vial were approved by the NMPA in April 2020. The supplemental new drug application (sNDA) for the two new indications was approved by the NMPA in July 2020.

   - Innovative indication rheumatoid arthritis of rituximab injection: In December 2020, the new drug application (NDA) for the innovative indication of rheumatoid arthritis (RA) was accepted by the NMPA.

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

   - 漢曲優®: 漢曲優® (150mg) successfully went to market in August 2020. The supplemental new drug application (sNDA) of 漢曲優® (60mg) was accepted by the NMPA in October 2020.

   - Zercepac®: In July 2020, the marketing authorization application (MAA) for Zercepac® was officially approved by the European Commission (EC), becoming the first "Chinese" mAb biosimilar approved for marketing in the EU. In June 2020, the Company and Accord entered into an agreement in relation to new specifications for Zercepac®, the adjustment in royalties, etc.

3. **漢達遠®(adalimumab):** The new drug application (NDA) for 漢達遠® was approved by the NMPA in December 2020, becoming the Group's third product for sale on the market in mainland China. The supplemental new drug application (sNDA) for a new indication of 漢達遠® was accepted by the NMPA in January 2021.

4. **Layout of International Market Commercialization:**

- In September 2020, the Company entered into a binding term sheet with Accord Healthcare Inc., pursuant to which the Company agreed to grant a license to Accord Healthcare Inc. (or Intas, its parent company) to develop and commercialise 漢曲優® (trastuzumab injection, EU brand name: Zercepac®) in the USA and Canada. The cooperation agreement was officially signed by the Company and Intas in January 2021.

- In October 2020, the Company agreed to co-develop HLX04-O (recombinant humanized anti-VEGF monoclonal antibody injection) as a therapy for eye diseases such as wet age-related macular degeneration (wAMD) with Essex, and to grant an exclusive license to Essex to develop, manufacture and commercialize the Licensed Product in ophthalmic therapeutic use and/or therapies globally.

- During the Reporting Period, the Company also signed an exclusive license agreement with Mabxience and Binacea for 漢曲優® (trastuzumab injection, EU brand name: Zercepac®) and HLX35 bispecific antibodies against EGFR and 4-1BB, respectively.

5. **Efficient Advancement of the International Multi-Center Clinical Research Projects:**

- In April 2020, the first patient dosing in Turkey was completed in a phase 3 clinical trial to compare HLX10(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); in March 2021, the international multi-center clinical trials completed the enrollment of subjects.

- In April 2020, the first patient dosing in Turkey was completed in a phase 3 clinical trial of HLX10(PD-1) or placebo in combination with chemotherapy (Carboplatin-Etoposide) in previously untreated patients with extensive-stage small cell lung cancer (ES-SCLC).

- In January 2021, the filing for a clinical trial for HLX04-O (recombinant humanized anti-VEGF monoclonal antibody injection) for the treatment of wet age-related macular degeneration (wAMD) was approved by the Therapeutic Goods Administration, Australia, and the phase 3 clinical trial were given permission to commence in Australia; its investigational new drug application (IND) was also approved by the U.S. Food and Drug Administration (FDA) in March 2021.

6. **Significant Progress of Domestic Clinical Research Projects:** In July 2020, the first patient dosing was completed in a phase 2 clinical trial of HLX10(PD-1) in combination with recombinant anti-EGFR humanised monoclonal antibody injection (HLX07) for the treatment of recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) in mainland China. In September 2020, the enrollment of subjects was completed in a phase 1 clinical trial of HLX10(PD-1) in combination with HLX04. In January 2021, the enrollment of subjects was completed in a phase 2 clinical trial of HLX10(PD-1) in combination with HLX04 against advanced hepatocellular carcinoma (HCC). In March 2021, the first patient dosing was completed in a phase 2/3 clinical trial of HLX10(PD-1) in combination with HLX04 and chemotherapy(XELOX) as a first-line treatment for metastatic colorectal cancer (mCRC) in mainland China.

7. **Efficient Advancement of the IND Application for Pre-Clinical Development Projects:** During the Reporting Period, the Group also continuously placed importance on the pre-clinical project reserves, speeding up the investigational new drug application (IND) of 7 pre-clinical research projects covering targets, such as CTLA-4, RANKL, DR4, S1 Protein of SARS-CoV-2, CD38, LAG-3.

8. **Biopharmaceutical Industrialization Base Layout with International Standards and High Cost-Efficiency:** During the Reporting Period, Xuhui Facility obtained the GMP certification by China and the EU, completing the relevant filings for four additional 2,000L bioreactors. The Group's overall commercial production capacity was increased to 20,000L. The Songjiang First Plant which has a planned production capacity of 24,000L completed the construction of twelve 2,000L bioreactors, and the construction, debugging and verification of continuous production pilot workshop has also been finished. The structure of the main production building for the phase I project of the Songjiang Second Plant was completed, with the tenders for the main equipment and engineering project being satisfied.

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 (Reference Drug)		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 and chronic lymphocytic leukemia								FOSUN PHARMA 复星医药 BIOSIDUS FARMA
	漢曲優® (trastuzumab)(2)		HER2	Breast cancer and metastatic gastric cancer								accord Jacobson Cipla mAbxience
	漢達遠® (adalimumab)(3)		TNF-α	Rheumatoid arthritis, ankylosing spondylitis and psoriasis								万邦医药 FOSUN PHARMA 复星医药
				Uveitis								
With near-term commercial visibility	HLX01 (rituximab)		CD20	Rheumatoid arthritis(4)								FOSUN PHARMA 复星医药
	HLX04 (bevacizumab)		VEGF	Metastatic colorectal cancer and non-squamous non-small cell lung cancer								
Under clinical research	HLX10	Monotherapy	PD-1	MSI-H solid tumours(5)								KGbio
				Chronic hepatitis B								
		+Chemo	PD-1	Metastatic esophageal squamous-cell carcinoma								
				Squamous non-small cell lung cancer								
				Extensive-stage small cell lung cancer								
				Gastric cancer								
		+HLX04	PD-1+VEGF	Non-squamous non-small cell lung cancer								
				Hepatocellular carcinoma								
				Metastatic colorectal cancer								
		+HLX07	PD-1+EGFR	Squamous-cell carcinoma of the head and neck								
	HLX07(5)		EGFR	Solid tumours								
	HLX05 (cetuximab)(6)		EGFR	Metastatic colorectal cancer and squamous-cell carcinoma of the head and neck								Bingze
	HLX12 (ramucirumab)		VEGFR2	Gastric cancer, metastatic non-small cell lung cancer and metastatic colorectal cancer								
	HLX20(7)		PD-L1	Solid tumours								
	HLX22		HER2	Breast cancer and gastric cancer								
	HLX55(8)		c-MET	Solid tumours								
	HLX11 (pertuzumab)		HER2	Breast cancer								
	HLX14 (denosumab)		RANKL	Osteoporosis								
	HLX04-O(9)		VEGF	Wet age-related macular degeneration								ESSEX 亿胜
	HLX13 (ipilimumab)		CTLA-4	Melanoma, renal cell carcinoma and metastatic colorectal cancer								
	HLX56(10)		DR4	Solid tumours								
	HLX71(11)		S1 Protein of SARS-CoV-2	COVID-19								
	HLX70(11)		S1 Protein of SARS-CoV-2	COVID-19								
	HLX15 (daratumumab)		CD38	Multiple myeloma								

The first Chinese mAb biosimilar launched in both China and the EU

The NDA is expected to be submitted by the end of March or early April in China.

International Multi-Center Clinical Research

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(1) Approved by the NMPA in February 2019, being the first domestic biosimilar
(2) Approved in the EU in July 2020 (EU brand name: Zercepac®); approved in China in August 2020
(3) Approved by the NMPA in December 2020; in January 2021, the supplemental new drug application (sNDA) for the treatment of non-infectious intermediate uveitis, posterior uveitis and panuveitis in adults were accepted by the NMPA
(4) Considered as biologic medicine since the reference product has not yet been approved for the relevant indications
(5) IND approved in China and the United States
(6) Commercialisation rights in China have been granted to Shanghai Jingze
(7) IND approved in China and Australia
(8) Commercialisation rights in China and certain countries in Southeast, Central and South Asia were obtained
(9) IND approved in Australia and the United States
(10) Commercialisation rights in China were obtained
(11) IND approved in the United States

Core Products

MANAGEMENT DISCUSSION AND ANALYSIS

I. BUSINESS REVIEW

Committed to "Affordable Innovation", the Group continued to promote the efficient development of the global commercialization of product pipelines during the Reporting Period, and further implemented production capacity deployment for the biomedicines with high economic benefit based on international standards. Great achievements have been made in clinical development and drug administration registration of the products in the pipeline. As at 19 March 2021, being the latest practicable date for the publication of this announcement (the "**Latest Practicable Date**"), 3 products of the Group have been successfully marketed in mainland China, 1 product has been successfully marketed in the European Union, 2 products' new drug applications have been accepted in China, more than 30 clinical trials have been approved worldwide, and more than a total of 20 clinical trials have been carried out in various countries/regions, including China, the European Union ("**EU**"), Australia, Ukraine, the Philippines and Turkey.

(I) Strong global product commercialization capability

During the Reporting Period, the Group actively implemented the concept of excellent commercialization, in order to create a complete value chain covering R&D, production and traditional commercialization. Based on the needs of patients and beginning with the end in mind, we have achieved a commercialization strategy of "focusing on product portfolio, manufacturing capacity and commercial operations to become the leader in biological medicine in China". The Group's commercialization team is divided into five sections: market promotion, channel management, pricing and market access, domestic sales, and strategic planning, covering the whole process of commercialization, and realized steady growth of product sales. After the launch of 漢利康®, China's first monoclonal antibody approved in accordance with the Guidelines for Biosimilar Drugs in 2019, the Group's two core products, 漢曲優® (trastuzumab injection, EU brand name: Zercepac®) and 漢達遠®, were successively approved and marketed during the Reporting Period and achieved commercial sales. In addition, the Group cooperated with international partners for the sale of three products of the Group (including 漢曲優® (trastuzumab injection, EU brand name: Zercepac®), HLX04-O（recombinant humanized anti-VEGF monoclonal antibody injection）for innovative eye disease treatment indications, HLX35 EGFR and 4-1BB bi-specific antibody) in international markets during the Reporting Period.

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

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

As the first domestic biosimilar drug in the strict sense, 漢利康® was successfully approved for marketing in 2019. Since the beginning of 2020, important progress has been made in the registration and the approval of 漢利康®, providing strong support for the commercialization of the product after launch:

- In April 2020, applications for a 2,000L increase in drug production capacity, and for 2,000L in production equipment and new 500mg/50ml/vial specifications were successively approved by the National Medical Products Administration of the PRC (the "**NMPA**").

- In July 2020, the supplemental new drug applications (sNDA) for two new indications, including (1) the monotherapy maintenance therapy after complete or partial response under rituximab in combination with chemotherapy for patients with initially-treated follicular lymphoma; and (2) fludarabine and cyclophosphamide (FC) combination therapy for patients with previously untreated or relapsed/refractory chronic lymphocytic leukaemia (CLL), were approved by the NMPA.

- In December 2020, the new drug application (NDA) of new indication of rituximab injection rheumatoid arthritis (RA) was accepted by the NMPA, which was developed by the Group with a differentiated strategy.

The increase in production scale and the installation of new production equipment will provide a strong guarantee for the production capacity of 漢利康®, more dosage forms will help ensure more economical use of drugs, and the approval of new indications will benefit a wider range of patient groups.

The domestic commercial sales of 漢利康® were handled by 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. In 2020, progress was made in the inclusion of 漢利康® into medical insurance procurement platforms and admission into hospitals in all provinces of mainland China. By the end of 2020, 30 provinces and municipalities had approved 漢利康®'s inclusion into the medical insurance procurement platform, 28 provinces and municipalities had completed official platform/filed procurement, and nearly 70% of the core hospitals had admitted the drug, providing a foundation for the sales of 漢利康®.

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

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

Being committed to providing high quality and affordable innovative biopharmaceuticals to patients worldwide, the Group mainly focuses on the products on the field of oncotherapy. The commercialization team of the Group is responsible for the sale and promotion of these products in mainland China.

漢曲優® (150mg) is the core product of the Group in the field of anti-tumor therapy, which has been successfully marketed since August 2020, and it is the first product sold and promoted by the Group's commercialization team in mainland China. The supplemental new drug application (sNDA) for 漢曲優®(60mg) was also accepted by the NMPA in October 2020.

The Group has an experienced commercialization core management team, with a commercialization team of about 400 people, covering five sectors including market promotion, channel management, pricing and market access, domestic sales and strategic planning (including a sales team composed of nearly 350 professionals). We made full efforts to develop and penetrate the market in mainland China. As at January 2021, 漢曲優® was approved to be included into the medical insurance procurement platform for China and all provinces and municipalities in mainland China. As at the Latest Practicable Date, 漢曲優® has been included into the medical insurance procurement platform for 28 provinces and municipalities, providing strong foundation for the improvement in sales of 漢曲優®.

– Commercial sales of Zercepac® (trastuzumab injection) in EU (a breast cancer and gastric cancer treatment product)

In July 2020, the marketing authorization application (MAA) submitted by the wholly-owned subsidiary of Accord Healthcare Limited ("**Accord**"), a business partner of Henlius for Zercepac® used for the treatment of HER2-positive early breast cancer, HER2-positive metastatic breast cancer, and untreated HER2-positive metastatic gastric cancer or gastric/esophageal junction adenocarcinoma was officially approved by the European Commission (EC). It is the first "Chinese" monoclonal antibody biosimilar drug approved for sale in the EU.

Since launching the licensing collaboration in June 2018, the Group has worked with its business partner Accord to actively promote the commercialization of Zercepac® in the EU. In June 2020, the two parties further concluded the Amendment to the License Agreement, which, on the basis of the agreement signed in June 2018, set out the agreement of the two parties on additional specifications of Zercepac® (addition of 60mg and 420mg licensing specifications on top of the original 150mg specification) and the corresponding milestone payment arrangements not exceeding $3.08 million, as well as the royalty adjustment (increased from 13.5%-25% as agreed in the original agreement to 15%-26.5% of the profit from net sales). The signing of this amendment also further reflected the international market's confidence in and recognition of the Group's products.

By the end of the Reporting Period, Zercepac® (150mg) had successfully entered a number of top hospitals in the UK (including Chelsea Hospital, Westminster and Kings College Hospital in London, etc.). In addition to the UK, Zercepac® (150mg) has been successfully marketed in nearly 20 EU countries and regions including Germany, Spain, France, Italy, Ireland, and Hungary. Meanwhile, the approval application for Zercepac® (60mg and 420mg specifications) was submitted in 2020 and it is expected to be approved for marketing in the EU in 2021. This will provide patients with more dosage forms and will facilitate the development of combination drug regimens to benefit more patients around the world.

Commercial sale of 漢達遠® (Adamumab) (an autoimmune disease treatment product)

In December 2020, the new drug application (NDA) of 漢達遠® was approved by the NMPA for the treatment of rheumatoid arthritis, ankylosing spondylitis and psoriasis. It is the third product of the Group marketed in mainland China. In January 2021, the supplemental new drug application (sNDA) of 漢達遠® for the new indication of uveitis was accepted by the NMPA .

According to the cooperation agreement between the Company and Jiangsu Wanbang (Group) Biopharmaceutical Co., Ltd.,* ("**Jiangsu Wanbang**"), subsidiary of Fosun Pharma, Jiangsu Wanbang will be responsible for the domestic commercial sales of 漢達遠® after its launch. Jiangsu Wanbang has a sizeable Department of Rheumatology and Immunization and a mixed-line sales team serving the broad market. The marketing team has a high level of professional communication skills and medical knowledge, and boasts successful experience in the commercialization of the rheumatoid treatment product Yolitong (Febuxostat Tablet). As at the Latest Practicable Date, 漢達遠® had been successfully included into the medical insurance procurement platform for 22 provinces and municipalities. In order to improve the standardized diagnosis and treatment services for Chinese patients with rheumatism, Jiangsu Wanbang established the first whole-course care platform "Dayuan Home" for autoimmune patients in China, which fully integrates the functions of an Internet hospital, popular science education, public assistance, medical insurance, patient management system, drug purchase map, and community care, with an aim to realize the whole course management of patients from medical treatment to rehabilitation.

2. Products to be commercialized in the near future

- ***HLX04 (recombinant humanized anti-VEGF monoclonal antibody injection) biosimilar of bevacizumab***

  HLX04 biosimilar of bevacizumab is independently developed by the Group. Its phase 3 clinical trial for the treatment of metastatic colorectal cancer (mCRC) was completed in August 2020 and the trial has met the pre-defined primary endpoint. In September 2020, the Company released the latest clinical trial data for HLX04 biosimilar of bevacizumab at the 23rd National Congress of Clinical Oncology and the 2020 CSCO Annual Conference. The results of the phase 3 study demonstrated the equivalence in efficacy between HLX04 biosimilar of bevacizumab and reference bevacizumab with similar safety and immunogenicity profiles as first-line treatment for metastatic colorectal cancer patients.

  In September 2020, the new drug application (NDA) for HLX04 biosimilar of bevacizumab for the treatment of metastatic colorectal cancer (mCRC) and advanced, metastatic or recurrent non-small cell lung cancer was accepted by the NMPA.

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

  In order to benefit a wider patient population, the Group has adopted a differentiated development strategy for rituximab injection. In addition to the rituximab injection for all the indications in China, including the original drug for non-Hodgkin's lymphoma that has been approved for the market, we also conducted clinical studies on the rheumatoid arthritis indication for which the original drug has not been approved in mainland China. In November 2020, the Company completed a phase 3 clinical trial of the rituximab injection for the treatment of rheumatoid arthritis (RA), which has reached its predefined primary study endpoint.

  In December 2020, the new drug application (NDA) of new indication of rituximab injection rheumatoid arthritis (RA) was accepted by the NMPA.

- ***Progress in the approval of HLX10 (anti-PD-1 monoclonal antibody)***

  HLX10(anti-PD-1 monoclonal antibody) is the core innovative mAb product in the Group's product pipeline, which has been successively approved for clinical trials in China, the United States, Poland and other EU countries as at the end of the Reporting Period. Steady progress has been made in the clinical trials of HLX10(PD-1) monotherapy and combination therapy with HLX10(PD-1) as the core for the treatment of unresectable or metastatic microsatellite instability-high (MSI-H) solid tumors that fail to respond to the standard therapy and major cancers such as lung, hepatocellular, esophageal, head and neck, and gastric cancer.

  The phase 2 clinical trial of HLX10(PD-1) for indications of unresectable or metastatic microsatellite instability-high (MSI-H) solid tumors that fail to respond to the standard therapy completed enrollment of subjects during the Reporting Period, and it was expected to reach the primary endpoint for phase 2 clinical trial in the near future, and the Group is expected to submit the new drug application (NDA) of HLX10(PD-1) in mainland China by the end of March or beginning of April 2021.

  In addition, a global multi-center phase 3 clinical trial to compare HLX10(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. It is expected to submit the new drug application (NDA) in mainland China in the second half of 2021.

3. Commercialization deployment in international markets during the Reporting Period

During the Reporting Period, the Group adhered to the internationalization strategy and continued to promote the global commercialization deployment. As at the Latest Practicable Date, the Group has signed business cooperation agreements for several products with various international pharmaceutical companies including Accord, Cipla Limited, Biosidus S.A., Jacobson Medical (Hong Kong) Limited, PT Kalbe Genexine Biologics ("**KG Bio**"), Farma De Colombia S.A.S, Mabxience Research, S.L.("**Mabxience**"), Intas Pharmaceuticals Limited ("**Intas**"), Essex and Binacea pharma Inc.("**Binacea**"), in order to actively promote the global commercialization deployment through strategic commercialization cooperation with the world's leading pharmaceutical companies.

Cooperating with Accord again for 漢曲優® (trastuzumab injection, EU brand name: Zercepac®) in the United States and Canada

In September 2020, the Company and Accord Healthcare Inc. signed a binding summary of terms, based on which the Company agreed to grant a license to Accord Healthcare Inc. (or Intas, its parent company) for the development and commercialization of 漢曲優® (trastuzumab injection, EU brand name: Zercepac®) in the United States and Canada, with the Company to receive a down payment of $27 million, a regulatory milestone payment of up to $13 million, a commercial sales milestone payment of $25 million for each $500 million in cumulative net sales of the Licensed Product in the Territory, and a tiered royalty of 18% to 50% of the net profit of the Licensed Product. The formal agreement for the cooperation was duly entered into by the Company and Intas in January 2021.

Reaching global cooperation with Essex for HLX04-O (recombinant humanized anti-VEGF monoclonal antibody injection) for innovative eye indications

In October 2020, the Company signed a joint development and exclusive licensing agreement with Essex Bio-Investment Limited ("**Essex Bio-Investment**"), and Zhuhai Essex Bio-Pharmaceutical Co, Ltd ("**Zhuhai Essex**", together with Essex Bio-Investment, "**Essex**"), based on which the Company agreed to co-develop HLX04-O (recombinant humanized anti-VEGF monoclonal antibody injection) with Essex for the treatment of wet age-related macular degeneration (wAMD) and other eye diseases, and grant Essex an exclusive license to develop, manufacture and commercialize the Licensed Product under regulatory scope for worldwide ophthalmic therapeutic uses and/or therapies, and the Company will be entitled to a contract payment of $10 million, a regulatory milestone payment of up to $15 million, a commercial sales milestone payment and a royalty of 6% to 10% of annual net sales based on the fulfillment of net sales.

At present, the incidence of ophthalmic diseases in China is increasing year by year, especially among the middle-aged and elderly patients. About 5 million people in China and as many as 30 million people worldwide suffer from wet age-related macular degeneration. However, drugs to treat wet age-related macular degeneration are not widely available. The launch of HLX04-O (recombinant humanized anti-VEGF monoclonal antibody injection) eye disease treatment product is expected to provide a solution and improve the quality of life for many patients.

In addition, during the Reporting Period, the Company also signed an exclusive license agreement with Mabxience and Binacea for 漢曲優®(trastuzumab injection, EU brand name: Zercepac®) and HLX35 (bispecific antibodies against EGFR and 4-1BB dual targets independently developed by the Company), respectively, based on which the Company will receive a down payment of $5.25 million, a regulatory milestone payment of up to $93.25 million, a commercial sales milestone payment of up to $670.25 million in total, and the corresponding royalty.

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

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

The commercial production capacity of Xuhui Facility has been increased to 20,000 liters, and it has passed the dual GMP certification of China and EU

As at the end of the Reporting Period, the Group has built a biological drug production base in Xuhui District, Shanghai (the "**Xuhui Facility**"), covering a total area of approximately 11,000 square meters, which has been certified with Chinese and EU GMP and is able to meet the short-term production needs of the Group. In July 2020, the filing for a newly added key production equipment license for four 2,000L bioreactors in the Xuhui Facility with Shanghai Municipal Drug Administrative Bureau was completed, and the overall commercial production capacity of the Group was increased to 20,000L. In addition, the Xuhui Facility also improved production efficiency through a series of lean management and process optimization measures during the Reporting Period, which effectively reduced the production costs.

The production capacity construction of 24,000 litres, and the verification of the continuous production pilot plant were completed for the Songjiang First Plant.

In order to further improve medium and long-term capacity planning, the Group has completed production capacity construction of 24,000L for the Songjiang First Plant in Songjiang District, Shanghai, including the formulation filling line, to prepare for meeting the production demand before the Songjiang Second Plant is put into operation. The drug substance production workshop of the Songjiang First Plant started GMP production of clinical samples in May 2020. At present, the four 2,000L bioreactors that passed the commissioning and verification have been used for GMP production of clinical samples. During the Reporting Period, the Group continued to promote the development and industrialization of continuous flow technology in Songjiang First Plant. The construction, commissioning and verification of the continuous production pilot workshop have been completed by the end of the Reporting Period.

The structure of the main production building for the Phase I project of the Songjiang Second Plant, as well as the bidding for major equipment and engineering projects was completed

In order to realize the long-term commercial production capacity planning, the construction of the Phase I project of the Songjiang Second Plant, with a total planned land area of 200 mu, was started in 2019 and is currently under construction. As at the Latest Practicable Date, for the Phase I project of the Songjiang Second Plant, the foundation works and structure of the main production buildings have been completed, the main structure of the main production building has been checked and accepted, and the bidding for major equipment and engineering projects has been completed. The subsequent construction of the Songjiang Second Plant will be gradually implemented in accordance with the Group's strategy.

(III) Sustainable global product development capability

The Group established the product development strategy of "combination of imitation and innovation" when it was founded, and took the lead in launching three monoclonal antibody biosimilar drugs – 漢利康®, 漢曲優® (trastuzumab injection, EU brand name: Zercepac®), and 漢達遠®. On this basis, the Group actively promoted transformation to innovation, accelerated the transformation from biosimilar drugs to innovative drugs, and gradually improved the deployment of the innovation pipeline including HLX10(PD-1). HLX10(PD-1) is the core innovative mAb in the Group's product pipeline, based on which the Group also pioneered the introduction of combined immunotherapy. As at the end of the Reporting Period, HLX10(PD-1) has been successively approved for clinical trials in China, the United States, and EU countries/regions; 10 clinical researches are in the process, including 3 internatinoal multi-center clinical trials; and a total of approximately 2,000 subjects have been enrolled in the trials in China, Turkey, Poland, Ukraine, Russia and other countries/regions.

As at the Latest Practicable Date, the Group has established a team with more than 230 highly efficient and experienced global clinical medical staff, to actively promote the clinical research of many candidate drugs across the world. In addition, the Group has the global pharmaceutical administration registration capability. As at the end of the Reporting Period, either the investigational new drug application (IND) or the new drug application (NDA) has been submitted for 23 varieties/projects in China, the United States, the EU, Australia and other countries or regions.

1. Continuous and efficient advancement on clinical research products

As at the Latest Practicable Date, the Group has obtained in total more than 30 clinical trial approvals worldwide, more than a total of 20 clinical trials for 10 products and 8 combination therapies have been carried out in various countries/regions, including China, the EU, Australia, Ukraine, the Philippines and Turkey.

Progress of international multi-center clinical research projects

- In April 2020, the first patient dosing in Turkey was completed in a phase 3 clinical trial to compare HLX10(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); in March 2021, the international multi-center clinical trials completed the enrollment of subjects.

- In April 2020, the first patient dosing in Turkey was completed in a phase 3 clinical trial of HLX10(PD-1) or placebo in combination with chemotherapy (Carboplatin- Etoposide) in previously untreated patients with extensive-stage small cell lung cancer (ES-SCLC).

- In January 2021, the filing of a clinical trial for HLX04-O（recombinant humanized anti-VEGF monoclonal antibody injection） for the treatment of wet age-related macular degeneration (wAMD) was approved by the Therapeutic Goods Administration, Australia, and the phase 3 clinical trial was given permission to commence in Australia; its investigational new drug application (IND) was also approved by the U.S. Food and Drug Administration (FDA) in March 2021. The phase 3 international multi-center clinical trial is intended to be launched soon.

The deployment of international multi-center clinical research is not only conducive to the global market coverage of the Group's products in the future, but also reflects the international market's confidence and recognition of the quality of the Group's products.

Progress of domestic clinical research projects

As at the Latest Practicable Date, smooth progress has been made in all clinical studies of the Group in mainland China.

- In July 2020, the first patient dosing was completed in a phase 2 clinical trial of HLX10(PD-1) in combination with recombinant anti-EGFR humanized monoclonal antibody injection (HLX07) for the treatment of recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) in mainland China.

- In September 2020, the enrollment of patients was completed in a phase 1 clinical trial of HLX10(PD-1) in combination with HLX04.

- In January 2021, the enrollment of subjects was completed in a phase 2 clinical trial of HLX10(PD-1) in combination with HLX04 against advanced hepatocellular carcinoma (HCC).

- In March 2021, the first patient dosing was completed in a Phase 2/3 clinical trial of HLX10(PD – 1) in combination with HLX04 and chemotherapy(XELOX) as first-line treatment for metastatic colorectal cancer (mCRC) in mainland China.

- In March 2020, the first patient dosing was completed in a phase 1 clinical trial of HLX55 monoclonal antibody for injection for the treatment of advanced solid tumors refractory to standard therapy in Taiwan, China.

- In March 2020, HLX07 (recombinant humanized anti-EGFR monoclonal antibody injection) has demonstrated its good safety and tolerability in a prospective, open-labeled, dose-escalation phase 1 clinical trial designed to assess it in the treatment for metastatic or recurrent epithelial tumors refractory to standard therapy, and the relevant clinical trial report was finished.

- In September 2020, the first patient dosing was completed in the phase 1 clinical trial of recombinant anti-HER2 domain II HLX11 (humanized monoclonal antibody injection) for the treatment of metastatic breast cancer and early breast cancer in mainland China.

- In November 2020, the first patient dosing was completed in the phase 1 clinical trial of recombinant HLX14 (recombinant anti-RANKL human monoclonal antibody injection) for the treatment of postmenopausal osteoporosis in women with high fracture risk in mainland China.

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

During the Reporting Period, the Group continued to increase the pre-clinical project pipeline, and accelerated the submission of investigational new drug application (IND) of 7 pre-clinical research projects covering targets such as CTLA-4, RANKL, DR4, S1 Protein of SARS-CoV-2, CD38, and LAG-3.

- In January 2020, the investigational new drug application (IND) of recombinant anti-CTLA-4 fully human monoclonal antibody injection ("HLX13") for the treatment of unresectable or metastatic melanoma, advanced renal cell carcinoma, microsatellite instability-high or mismatch repair-deficient metastatic colorectal cancer and adjuvant therapy of melanoma was accepted by the NMPA. The application was approved by the NMPA in April 2020.

- In May 2020, the investigational new drug application (IND) of anti-death receptor 4 mAb injection ("HLX56") for the treatment of advanced solid tumors without other standard treatments was approved by the Ministry of Health and Welfare of Taiwan.

- In October 2020, the investigational new drug application (IND) of anti-S1 fully human monoclonal neutralizing antibody ("HLX70") for the treatment of COVID-19 and acute respiratory distress syndrome (ARDS) or multiple organ failure caused by COVID-19 was approved by the U.S. Food and Drug Administration (FDA).

- In November 2020, the investigational new drug application (IND) of ACE2-Fc receptor fusion protein ("HLX71") for the treatment of COVID-19 was approved by the U.S. Food and Drug Administration (FDA).

- In November 2020, the investigational new drug application (IND) of recombinant anti-CD38 human monoclonal antibody injection ("HLX15") for the treatment of multiple myeloma (MM) was accepted by the NMPA. The application was approved by the NMPA in January 2021.

- In January 2021, the investigational new drug application (IND) of recombinant anti-LAG-3 human monoclonal antibody injection ("HLX26") for the treatment of solid tumors and lymphomas was accepted by the NMPA.

The clinical and pre-clinical application results of the Group from the beginning of 2020 to the Latest Practicable Date:

Product name (reference drugs/targets)	Indications	Progress as at the Latest Practicable Date
Efficient advancement on international multi-center clinical research projects		
HLX10(PD-1) in combination with chemotherapy (carboplatin-albumin paclitaxel)	squamous non-small cell lung cancer (sqNSCLC)	In April 2020, the first patient dosing in Turkey was completed in a phase 3 clinical trial In March 2021, the enrollment of global subjects was completed in a phase 3 clinical trial
HLX10(PD-1) in combination with with chemotherapy (carboplatin-etoposide)	Extensive stage small cell lung cancer (ES-SCLC)	In April 2020, the first patient dosing in Turkey was completed in a phase 3 clinical trial
HLX04-O（recombinant humanized anti-VEGF monoclonal antibody injection）	wet age-related macular degeneration (wAMD)	In January 2021, the investigational new drug application (IND) was approved by Therapeutic Goods Administration In March 2021, the investigational new drug application (IND) was approved by the U.S. Food and Drug Administration (FDA)

Product name (reference drugs/targets)	Indications	Progress as at the Latest Practicable Date
Smooth progress of domestic clinical projects		
HLX10+ HLX07	head and neck squamous cell carcinoma (HNSCC)	In July 2020, the first patient dosing was completed in a phase 2 clinical trial in mainland China
HLX10+ HLX04	Solid tumor	In September 2020, the enrollment of subjects was completed in a phase 1 clinical trial
HLX10+ HLX04	Hepatocellular Carcinoma (HCC)	In January 2021, the enrollment of subjects was completed in a phase 2 clinical trial
HLX10+HLX04	Metastatic colorectal cancer (mCRC)	In March 2021, the first patient dosing was completed in a Phase 2/3 clinical trial in mainland China
HLX55 (innovative anti-c-Met monoclonal antibody)	Solid tumor	In March 2020, the first patient dosing was completed in a phase 1 clinical trial in Taiwan, China
HLX07 (modified innovative anti-EGFR monoclonal antibody)	Solid tumor	In March 2020, the relevant clinical research report was completed for the phase 1 clinical trial
HLX11 (pertuzumab)	Breast cancer (BC)	In September 2020, the first patient dosing was completed in a phase 1 clinical trial in mainland China
HLX14 (desumumab)	Osteoporosis (OP)	In November 2020, the first patient dosing was completed in a phase 1 clinical trial in mainland China

Product name (reference drugs/targets)	Indications	Progress as at the Latest Practicable Date
Efficient advancement on IND application for pre-clinical development projects		
HLX13 (ipilimumab)	Melanoma, Renal Cell Carcinoma (RCC), Metastatic Colorectal Cancer (mCRC)	In January 2020, the investigational new drug application (IND) was accepted by the NMPA In April 2020, the investigational new drug application (IND) was approved by the NMPA
HLX56 (anti-DR4 monoclonal antibody)	Solid tumor	In May 2020, the investigational new drug application (IND) was approved by the Ministry of Health and Welfare of Taiwan.
HLX70 (anti-S1 fully human monoclonal neutralizing antibody)	COVID-19	In October 2020, the investigational new drug application (IND) was approved by the U.S. Food and Drug Administration (FDA)
HLX71 (ACE2-Fc receptor fusion protein)	COVID-19	In November 2020, the investigational new drug application (IND) was approved by the U.S. Food and Drug Administration (FDA)
HLX15 (daratumumab)	Multiple myeloma (MM)	In November 2020, the investigational new drug application (IND) was accepted by the NMPA In January 2021, the investigational new drug application (IND) was approved by the NMPA
HLX26 (Recombinant anti-LAG-3 human monoclonal antibody injection)	Solid tumor, lymphoma	In January 2021, the investigational new drug application (IND) was accepted by the NMPA

(IV) Social responsibility, environmental policies and performance

Always adhering to the philosophy of "Reliable Quality, Affordable Innovation", the Group actively fulfills its responsibilities to stakeholders such as patients, employees, partners, and communities, committed to providing more affordable biopharmaceuticals to global patients. In terms of social public welfare, the Group and Shanghai Fosun Foundation established the Fosun Foundation Henlius Special Public Welfare Fund to give full play to its industrial advantages and focus on public welfare projects in areas such as health education, patient care and rural doctors. During COVID-19, the Group has successively made donations of materials equivalent to more than RMB1 million to the affected areas, and led a number of units to carry out scientific and research projects against the epidemic. At the same time, the Group is committed to the sustainable development of the environment and society. While focusing on the development of the enterprise, the Group regards the realisation of a harmonious win-win situation with the environment and society as a vital part of fulfilling its social responsibilities. During the Reporting Period, the Group continuously improved its environmental management system to reduce the impact of its own operations on the environment, and there were no incidents of punishment by relevant departments for environmental issues.

Further information on the Group's social responsibility, environmental policies and performance will be set out in the social responsibility report that the Company will issue 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 not be able to ultimately develop and market our core products.

II. OUTLOOK FOR 2021

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

(I) Capitalize on first-entrant advantages and increase the global market coverage of products

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

漢曲優® is the anti-cancer core product sold and promoted by the Group's commercialization team in mainland China. Following the launch of 漢曲優® with the dosage form of 150mg in August 2020, supplemental new drug application (sNDA) for the product with the dosage form of 60mg was accepted by the NMPA in October 2020 and it is expected to be approved in the third quarter of 2021. With the launch of 150mg and 60mg dosage forms, we can flexibly meet the clinical medication needs of breast cancer patients with different body weight through more dosage forms, and provide patients with personalized and more economical treatment plans. In 2021, Henlius will continue to actively cooperate with relevant enterprises in terms of medical big data, HER2 testing, innovation payment, patient management and education, doctor education and other aspects, with an aim to consolidate the construction of the diagnosis and treatment ecosystem for HER2-positive patients. On this basis, the Group will constantly strengthen market access, accelerate commercialization and promotion in the domestic market, and drive the market expansion of its products. In 2021, the sales network of 漢曲優® will be further enhanced. The sales team is expected to further expand and reach approximately 320 cities across the country, covering nearly 4,000 DTP pharmacies/hospitals.

In 2021, the Group will continue to strengthen the sales of 漢利康®, capitalize on their first-entrant advantage, maintain close cooperation with Jiangsu Fosun, and focus on the continuous growth of 漢利康® in the field of blood tumors. The release of capacity resulting from the approval of a production capacity of 2,000L during the Reporting Period, as well as the approval of two additional indications, is expected to drive the continued sales growth of 漢利康® and the gradual reduction of production costs, thereby enhancing our market competitiveness. The Group will also promote the approval of the new drug application (NDA) for the rituximab injection for rheumatoid arthritis (RA), so as to improve the market share and penetration of the rituximab injection.

In addition, the Group will continue to cooperate with Jiangsu Wanbang to prepare for the sales of 漢達遠®, and enhance promotion in both the field of rheumatism (for indications of ankylosing spondylitis and rheumatoid arthritis (RA)) and the field of skin (for indications of psoriasis). It is planned to extend the coverage of 漢達遠® to 4,000 specialists and over 5,000 DTP pharmacies/hospitals in 2021, so as to ensure the economic accessibility and channel accessibility of 漢達遠® and achieve the target that patients can purchase the drugs without leaving their own county. On this basis, we will further cooperate with academic organizations and social groups to complete the standardized training for Chinese specialists, and improve patients' self-awareness of the disease, so as to fulfill the mission of 漢達遠® to treat every autoimmune disease patient in China as much as possible.

While actively deploying the domestic market, the Group will continue to promote the business cooperation of self-developed products in the international market. Based on the continuous R&D and registration progress of the Group's product pipeline, as well as the gradual understanding and full recognition of its products in the international market, the Group will continue to actively explore the global market and seek strategic cooperation with more leading international pharmaceutical companies in 2021, with an aim to jointly promote the global registration and clinical research of projects and extend the coverage of its products to a broader international market, especially the emerging markets where there is a huge unmet demand for affordable drugs, through the influence of the international strategic partners, thus benefiting overseas patients.

(II) Continue to commercialize more products

HLX04（recombinant humanized anti-VEGF monoclonal antibody injection）biosimilar of bevacizumab

HLX04 biosimilar of bevacizumab is indenpendently developed by the Group. Different from the biosimilar drugs of bevacizumab currently on the market in China, metastatic colorectal cancer (mCRC) was selected in the design of a phase 3 comparative study on the clinical efficacy and safety of HLX04 biosimilar of bevacizumab. It is the only biosimilar drug of bevacizumab with clinical data of metastatic colorectal cancer in China, and more the clinical data and experience can be accumulated for the application of bevacizumab in colorectal cancer patients in China. It is expected that the new drug application (NDA) of HLX04 biosimilar of bevacizumab will be approved in the fourth quarter of 2021. Given the fact that a new indication of glioma (GBM) was added for the original drug Bevacizu monoantigen in China in 2020, the Group also plans to start the supplemental new drug application (sNDA) after the launch of HLX04 biosimilar of bevacizumab.

Rituximab for rheumatoid arthritis (RA) indications

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

Progress on the approval of HLX10(PD-1)

HLX10(PD-1) is the core innovative monoclonal antibody product in the Group's product pipeline, and the related production and R&D are in strict compliance with international quality standards. As at the end of the Reporting Period, clinical trials of two HLX10(PD-1) monotherapies and 8 combination therapies with HLX10(PD-1) at their core have been carried out in many countries and regions around the world. In addition, the business cooperation for HLX10(PD-1) in 10 countries in Southeast Asia based on the cooperation agreement entered into with KG Bio in 2019 will be further carried out following the approval of the product. The Group will make best efforts to promote the new drug application (NDA) of HLX10(PD-1) for indications of unresectable or metastatic microsatellite instability-high (MSI-H) solid tumors that fail to respond to the standard therapy. It is expected that application submission will be completed by the end of March or in the beginning of April 2021. In addition, the Group is expecting to submit the new drug application (NDA) of indication of HLX10(PD-1) combining chemotherapy (carboplatin-albumin paclitaxel) in first-line treatment of locally advanced or metastatic squamous non-small cell lung cancer (sqNSCLC) in mainland China in the second half of 2021. The commercialization strategy formulation and market deployment in various therapeutic fields of HLX10(PD-1) will be promoted simultaneously.

(III) Continue to build innovative product pipeline through independent R&D and introduction of external licenses

1. Continuous independent innovation research and development based on its own rich pipelines

In 2021, the Group will, by making full use of international resources and advantages and following the international frontier trend, expand and enrich the product targets, optimize the development platform of dual specific antibodies, and continue to create a high-quality, affordable and differentiated innovative product pipeline, in order to promote innovative drug R&D, achieve commercialization excellence, and truly meet the needs of patients and the market. It is planned that the new drug application (NDA) for the indication of unresectable or metastatic microsatellite instability-high (MSI-H) solid tumors that fail to respond to the standard therapy will be submitted to the NMPA by the end of March or in the beginning of April 2021. It is expected that the new drug application (NDA) of the indication of HLX10(PD-1) combining chemotherapy as first-line therapy for locally advanced or metastatic squamous non-small cell lung cancer (sqNSCLC) will be submitted in the second half of 2021. In addition, it is expected that the HLX10(PD-1) based clinical trial of tumor immunocombination therapy for indications of squamous non-small cell lung cancer, non-squamous non-small cell lung cancer, extensive stage small cell lung cancer, esophageal squamous cell carcinoma, gastric cancer, hepatocellular carcinoma, and squamous cell carcinoma will be further promoted in 2021. Among them: five indications are currently in phase 3 clinical studies (four of which are expected to have the subjects enrolled for the phase 3 clinical trials in 2021); three indications are currently in phase 2 clinical studies (the application for the phase 3 clinical trials of one of the indications is expected to be submitted this year). The Group will continue to promote the further development of the research, the release of relevant clinical trial data at important international industry conferences (including ESMO, ASCO, etc.) and the subsequent application for product marketing.

While rapidly advancing the clinical trials of drug candidates in the pipeline, the Group will continue to efficiently advance the pre-clinical development process of products under research, promote the global registration and approval of products in the pipeline, including several innovative monoclonal antibody, dual clonal antibody and antibody-drug conjugates (ADC) products, and carry out the corresponding clinical research plans. During the Reporting Period, HLX71, the Group's self-developed ACE2-Fc fusion proteins product against COVID-19 was approved as a COVID-19 Emergency Response Project under the "Public Safety Risk Prevention and Control and Emergency Response Technology and Equipment" of the key R&D program of China, and was approved for a new drug clinical trial by by the U.S. Food and Drug Administration (FDA). The Group intends to promote the implementation of the relevant clinical trials for HLX71 in the United States as soon as possible, with an aim to contribute Chinese efforts to the global fight against the pandemic.

2. License introduction and cooperative development

In order to actively deploy the pipeline of innovative products, the Group plans to accelerate the expansion of innovative potential targets, antibody-drug conjugates (ADC) products and oncolytic virus products through the introduction of licensing projects. Relying on the Group's rich experience in target development and integrated R&D platforms, we will actively develop more innovative products for the market based on the introduction of projects, and seek synergies between them and the existing pipeline of innovative products. In January 2021, the Company signed an exclusive license agreement with Chiome Bioscience, Inc. to introduce antibodies against human TROP2 (Trophoblast cell-surface antigen 2) and the relevant intellectual property in the research, development, production and commercialization in China (including Hong Kong, Macau and Taiwan). TROP2, expressed in triple negative breast cancer, non-small cell lung cancer, urothelial carcinoma and many types of solid tumors, is expected to be a therapeutic target with broad spectrum anti-tumor effects, and has the potential of development in the direction of antibody conjugated drugs (ADC), bispecific antibodies and combination therapy. In addition, the Group also plans to share costs and risks with partners through cooperative development, and explore more innovative possibilities based on clinical needs by leveraging the strengths and expertise of their respective fields of expertise.

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

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

As at the Latest Practicable Date, production capacity construction of 24,000L at the Songjiang First Plant has been completed, and the four 2,000L bioreactors that passed the commissioning and verification have been used for GMP production of clinical samples. The remaining eight 2,000L bioreactors are scheduled to complete process validation for commercial production in the first half of 2021. In addition to production capacity construction, it is planned that the continuous production pilot workshop of the Songjiang First Plant shall complete the continuous production of at least two products within 2021, in order to ensure the production efficiency and quality for the future large-scale commercial production.

To achieve the long-term capacity planning, we will continue to promote the construction of the Songjiang Second Plant, in order to enhance the overall production capacity of the Group. As at the Latest Practicable Date, for the Phase I project of the Songjiang Second Plant, the main production buildings are expected to be completed and put into trial production and subject to relevant verifications in 2021. 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 biosimilar and bioinnovative pharmaceutical products.

III. FINANCIAL REVIEW

(I) Revenue

In 2020, COVID-19 brought certain challenges to the overall operation of the Group. The Group promptly took epidemic prevention measures to protect the safety of employees, and tried its best to coordinate various departments to take flexible arrangements to maintain normal operation, in order to ensure the on-time achievements of all work targets and the normal supply of medication for patients.

During the Reporting Period, despite the impact of COVID-19, the Group successfully marketed two independently developed monoclonal antibody biosimilar drugs with great market potential: 漢曲優® and Zercepac®, 漢達遠®. Zercepac® and 漢曲優® were approved for marketing by the European Commission and the NMPA in July and August 2020 respectively, becoming the first China-developed monoclonal antibody biosimilar medicine approved in both China and the EU. As at the end of the Reporting Period, the Group had successfully marketed three independently developed monoclonal antibody biosimilar drugs to serve patients, including the first domestic biosimilar drug 漢利康® marketed by the Group in 2019.

At the same time, the Group made active deployment in the domestic and international markets, in order to maximize overall business marketing growth through multiple channels of cooperation with a number of business partners. We plan to work with business partners to promote our product brand awareness and open technology platform, communicate with the market on the Group's key technology, operational and business improvement strategies to further develop existing and potential customers, and develop them into active two-way communication customers with the Group. In addition, the Group actively explored the multi-dimensional business marketing model, further developed the marketing potential and increased sales revenue through cooperative development with business partners and technology transfer/licensing.

During the Reporting Period, the Group realized an operating income of RMB587.6 million, representing an increase of 546% compared to last year, and the main revenue components are as follows:

1) Revenue from Chinese market:

漢利康®, the first domestic biosimilar drug independently developed by the Group, was commercialized in 2019. In order to further consolidate and strengthen the first-mover advantage of 漢利康® in the domestic market, we actively promoted the commercial development of 漢利康® through the strong market access and sales network of Fosun Pharma. According to the cooperation agreement with Fosun Pharma, Fosun Pharma will reimburse all the expenses related to the clinical trials of 漢利康® incurred by the Group after the relevant cooperation agreement is signed, while the Group is responsible for the production of 漢利康® in China and the supply of 漢利康® to Fosun Pharma, and shall share the profits from the sales of 漢利康® in China. For the year ended 31 December 2020, the shipment volume of 漢利康® amounted to approximately 720,000 (among which, the shipment volume in the second half of the year amounted to approximately 520,000). The retail price is RMB1,398 per article. Meanwhile, the Group realized sales revenue of approximately RMB288.2 million and licensing revenue of approximately RMB10.4 million for the 漢利康® during the Reporting Period under the aforementioned profit sharing arrangement with its partners.

漢達遠®, a biosimilar drug independently developed by the Group, was approved by the NMPA for market in December 2020. The Group has reached a commercialization agreement with Fosun Pharma to promote the commercial development of 漢達遠® by fully relying on the successful experience of Fosun Pharma, which has been deeply engaged in the field of rheumatic immunity for many years. According to the cooperation agreement with Fosun Pharma, Fosun Pharma will reimburse all the expenses related to the clinical trials of 漢達遠® incurred by the Group after the relevant cooperation agreement is signed. After the commercialization of 漢達遠®, the Group will be responsible for the production of 漢達遠® in China and the supply of 漢達遠® to Fosun Pharma, and shall share the profits from the sales of 漢達遠® in China. In December 2020, the Group realized sales revenue of approximately RMB1.2 million and licensing revenue of approximately RMB0.4 million for the 漢達遠® under the aforementioned profit sharing arrangement with its partners.

漢曲優®, a biosimilar drug of monoclonal antibody independently developed by the Group, which has great market potential, began to be commercialized in the domestic market in August 2020. Based on the long-term development strategy of the Group, we mainly commercialized 漢曲優® through our own team. By the end of December 2020, a highly efficient and experienced commercialization team consisting of nearly 400 professionals has been established to effectively promote the commercialization process of 漢曲優®, realizing steady sales growth of the product. As at the end of the Reporting Period, the Group has realized sales revenue of approximately RMB109.5 million for 漢曲優®.

2) Revenue from international market

In order to better develop the international market and bring high-quality and low-cost treatment solutions to patients around the world, the Group actively practiced a comprehensive international research and development and operation strategy, and promoted the commercialization of its products in the international market by entering into strategic commercialization cooperation with international leading pharmaceutical companies. In July 2020, the marketing authorization application (MAA) of Zercepac® submitted by a wholly-owned subsidiary of Accord was approved. Since then, 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 the centralized marketing license. From the beginning of its commercialization in the international market in 2020 to 31 December 2020, the Group realized revenue of approximately RMB26.6 million for Zercepac®.

3) Joint development and technology transfer/commercialization licensing revenue

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

In June 2018, the Group entered into a license agreement with Accord in relation to Zercepac®, granting Accord exclusive commercial rights in special territories as agreed therein. In July 2020, the marketing authorization application (MAA) of Zercepac® submitted by a wholly-owned subsidiary of Accord was approved. Since then, 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. For the year ended 31 December 2020, the Group realized licensing revenue and revenue from R&D services of approximately RMB85.6 million.

In September 2019, the Group entered into a collaborative research, development and commercialization agreement with KG Bio for HLX10, a biologically innovative anti-PD-1 mAb in which the Group has exclusive patent and technical expertise. With the continued performance of R&D services, the Group has recognized revenue from R&D services of approximately RMB19.3 million for the year ended 31 December 2020.

In September 2020, the Group entered into a co-development and exclusive license agreement with Essex in relation to HLX04-O（recombinant humanized anti-VEGF monoclonal antibody injection） independently developed by the Group. The Group has recognized licensing revenue and revenue from R&D services of approximately RMB45.0 million for the 12 months ended 31 December 2020.

(II) Cost of Sales

The Group's cost of sales primarily represents reagents and consumables, employee compensation, outsourcing expenses, utilities expenses and depreciation and amortisation, etc. During the Reporting Period, the Group recorded cost of sales of RMB182.1 million, representing an increase of approximately RMB110.3 million as compared with that for the year ended 31 December 2019, which was due to the increase of the production cost of the key commercial products.

(III) Gross profit

During the Reporting Period, the Group recorded a gross profit of RMB405.5 million, representing an increase of approximately RMB386.4 million, or 2,022% as compared with that for the year ended 31 December 2019, mainly due to the gross profit contribution of the Company's key commercial products.

(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 promulgated by the government).

During the Reporting Period, the Group recognised other income and gains of approximately RMB43.7 million.

	Year ended 31 December	
	2020	2019
	RMB'000	*RMB'000*
Government grants	**35,393**	7,448
Interest income	**7,404**	16,062
Others	**940**	1,164
Total	**43,737**	24,674

(V) R&D expenditure

	Year ended 31 December	
	2020	2019
	RMB'000	*RMB'000*
Expensed R&D expenses		
Share-based compensation	**11,147**	68,333
R&D employee salaries	**251,886**	182,910
Outsourcing fees	**138,320**	62,759
Reagents and consumables	**119,466**	83,266
Utilities expenses	**53,564**	7,308
Depreciation and amortisation	**43,334**	45,637
Consulting expense	**15,153**	16,176
Clinical trials	**154,215**	107,595
Others	**107,059**	33,843
Total expensed R&D expenses	**894,144**	607,827
Capitalised R&D expenses		
Clinical trials	**545,992**	517,194
R&D employee salaries	**131,174**	107,098
Reagents and consumables	**60,735**	30,199
Depreciation and amortisation	**10,693**	31,125
Utilities expenses	**21,302**	4,310
Outsourcing fees	**26,255**	47,427
Share-based compensation	**9,268**	26,517
Others	**11,342**	35,067
Total capitalised R&D expenses	**816,761**	798,937

During the Reporting Period, the Group recognised R&D expenditure of approximately RMB1,710.9 million, representing an increase of approximately RMB304.1 million or approximately 22% as compared with approximately RMB1,406.8 million for the year ended 31 December 2019. The increase in our research and development expenditure was mainly due to: (1) the increases in clinical trial expenses and costs of preclinical studies in line with our expanding pipeline and significant progress of R&D activities; (2) the increases in the number of R&D employees.

(VI) Administrative Expenses

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

During the Reporting Period, the Group recognised administrative expenses of approximately RMB192.6 million, representing an increase of 10% as compared to that of approximately RMB174.8 million for the year ended 31 December 2019. The increase in administrative expenses of the Group was mainly due to: (1) the increase in the number of administrative employees in line with the expansion of the Company's operations and development; (2) the increase in office administrative expenses in conjunction with business development; and (3) the increase in other consultation fees.

(VII) Selling and distribution expenses

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

During the Reporting Period, the Group recognised selling and distribution expenses of approximately RMB243.6 million, which were mainly the marketing expenses incurred in the marketing and commercialization of 漢曲優® products.

(VIII) Other expenses

During the Reporting Period, the Group incurred other expenses of RMB68.6 million, representing an increase of RMB32.0 million from RMB36.6 million for the year ended 31 December 2019. Such other expenses comprised exchange loss of RMB59.8 million due to the fluctuation of the foreign-currency exchange rates and RMB7.6 million mainly related to donations to various charitable organisations and provisions of RMB1.2 million for inventory impairment.

(IX) Income tax expenses

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

(X) Loss for the year

In view of the above, the Group's loss increased by approximately RMB118.0 million from approximately RMB875.5 million for the year ended 31 December 2019 to approximately RMB993.5 million for the year ended 31 December 2020.

(XI) Liquidity and capital resources

As at 31 December 2020, the cash and cash equivalents of the Group were approximately RMB1,114.3 million, mainly denominated in Renminbi ("RMB"), United States Dollars ("USD"), New Taiwan Dollars ("NTD"), Hong Kong Dollars ("HKD") and Euro, where such decrease was mainly due to the daily R&D and manufacturing overhead. As of 31 December 2020, the current assets of the Group were approximately RMB1,910.0 million, including cash and cash equivalents of approximately RMB1,114.3 million. There is no pledged deposits.

The inventories were approximately RMB305.2 million, trade receivables were approximately RMB196.2 million, prepayments, deposits and other receivables were approximately RMB294.2 million. As at 31 December 2020, the current liabilities of the Group were approximately RMB1,979.5 million, including trade and bills payables of approximately RMB299.0 million, other payables and accruals of approximately RMB439.8 million and interest-bearing bank borrowings and other borrowings of approximately RMB1,188.5 million.

As at 31 December 2020, the foreign exchange bank balances of the Group are as follows:

	RMB'000
RMB	251,058
HKD	1,254
USD	857,336
Euro	1,507
NTD	3,154

	Original amount
RMB	251,058
HKD	1,490
USD	131,333
Euro	188
NTD	13,590

(XII) Inventories

Inventories of the Group increased from approximately RMB129.9 million as at 31 December 2019 to approximately RMB305.2 million as at 31 December 2020, mainly due to the increased purchases of raw materials and consumables in order to facilitate the clinical trial and commercialised production.

(XIII) Trade receivables

As at 31 December 2019 and 31 December 2020, trade receivables from customer contracts were approximately RMB29.8 million and RMB196.2 million, respectively. There are no changes in accounting estimates or material assumptions made in both years.

	As at 31 December	
	2020	2019
	RMB'000	*RMB'000*
Within 3 months	**196,213**	29,830
3 to 6 months	**–**	–
6 to 9 months	**–**	–
9 to 12 months	**–**	–
1 to 2 years	**–**	–
Total	**196,213**	29,830

(XIV) Interest-bearing bank and other borrowings

As at 31 December 2020, borrowings from bank and other institutions (exclusive of lease liabilities) of the Group were approximately RMB1,540.6 million. The Group incurred new borrowings for the following reasons: ongoing clinical research trials and preclinical research for drug candidates, commercialisation 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.

(XV) Maturity structure of outstanding debts

The following table sets forth the maturity structure of outstanding debts as at 31 December 2020 and 31 December 2019, of which lease liabilities were initially recognised upon the adoption of IFRS 16 – Leases on 1 January 2017.

	31 December 2020	31 December 2019
	RMB'000	*RMB'000*
Within one year	**1,188,486**	278,241
In the second year	**82,089**	206,418
In the third to fifth year (inclusive)	**320,792**	96,153
Over five years	**242,250**	28,577
Total	**1,833,617**	609,389

(XVI) Collateral and pledged assets

As at 31 December 2020, the Group's pledged assets in relation to borrowings included trade receivables and other receivables of approximately RMB9.6 million and land use right of approximately RMB205.3 million.

(XVII) Key financial ratios

	31 December 2020	31 December 2019
Current ratio[(1)]:	**96.5%**	277.3%
Quick ratio[(2)]:	**81.1%**	263.7%
Gearing ratio[(3)]:	**18.4%**	N/A[(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.

(4) The Group did not have a gearing ratio as at 31 December 2019 as the Group's balance of cash and cash equivalents exceeded the Group's total indebtedness on that date.

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

Save as disclosed in this report, as at 31 December 2020, the Group did not make other significant investments.

(XIX) Capital commitments and capital expenditures

	31 December 2020	31 December 2019
	RMB'000	*RMB'000*
Plant and machinery	**170,240**	146,439
Construction in progress	**274,769**	36,143
Electronic equipment	**15,822**	15,990
Leasehold improvements	**106,058**	32,686
Others	**473**	–
Total	**567,362**	231,258

We had capital commitments for plant and machinery contracted but not provided for of RMB697.8 million as at 31 December 2020. These capital commitments primarily relate to expenditures expected to be incurred for the purchase of machinery, renovation of our existing laboratories and buildings and the R&D cost to be capitalised.

(XX) Contingent liabilities

As at 31 December 2020, the Group did not have any material contingent liabilities.

(XXI) Material acquisitions and disposals

As at 31 December 2020, the Group did not have any material acquisitions and disposals.

(XXII) Dividends

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

IV. RISK MANAGEMENT

(I) Foreign exchange risk

Up until 31 December 2020, the Group was principally engaged in business in the PRC, in which most of the transactions were settled in RMB with no significant foreign exchange risk. No financial instrument for hedging foreign exchange risk or other hedging purposes was employed.

(II) Exchange rate risk

Currently, the major business operation of the Group is in the PRC and most of the revenue and expenses are settled in RMB, which is the Group's reporting currency. With the acceleration of the Group's development in overseas markets, it is expected that the sales revenue denominated in USD and Euro 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 treatment indication, 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: 漢利康®，漢曲優® (trastuzumab injection, EU brand name: Zercepac®) and 漢達遠®. Most of the Group's drug candidates are still under development and are in the clinical development stages, and the course of clinical development involves a lengthy and expensive process with uncertainties in various aspects, as there can be no assurance from the Group of the development and clinical results. Furthermore, if the clinical development and regulatory approval process of the drug candidates are delayed or terminated, the successful development and commercialisation of the Group's drug candidates in a timely manner may be adversely affected.

3. Potential Risks of 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 2020, 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.

V. EMPLOYEES AND REMUNERATION POLICIES

The following table sets forth the breakdown of our employees by function as at 31 December 2020:

Function	Number of employees
Management and administrative	203
R&D	351
Quality and technical support	256
Manufacturing	437
Clinical medical affairs	231
Commercial Operation	395
Total	1,873

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.

USE OF PROCEEDS FROM THE GLOBAL OFFERING

Use of Proceeds during the Reporting Period

References are made to the prospectus (the "**Prospectus**") of the Company dated 12 September 2019 relating to the global offering (the "**Global Offering**"). After deduction of listing expenses, the total net proceeds from the Global Offering (including the net proceeds from the partial exercise of the over-allotment option) (the "**Net Proceeds**") was approximately HK$3,147.1 million (approximately RMB2,800.9 million). During the Reporting Period, the Company had utilised Net Proceeds of RMB1,201.8 million in accordance with the plan disclosed in the Prospectus of the Company.

Change in Use of Proceeds from the Global Offering

As at the date of this announcement, the Company has not yet utilised the Net Proceeds of approximately RMB716.5 million (the "**Unutilised Net Proceeds**"). The Board, having considered the reasons set out in "Reasons for the Change in Use of Proceeds" below, resolved to change in use of the Unutilised Net Proceeds. The change and the revised allocation of the Net Proceeds and Unutilised Net Proceeds are set out in the table below.

Intended use of proceeds as set out in the Prospectus		Allocation proportion of the Net Proceeds as set out in the Prospectus (approximately)	Amounts of Unutilised Net Proceeds as at the date of this announcement (RMB million)	Change (RMB million)	Revised allocation of the Net Proceeds (approximately)	Revised amounts of Unutilised Net Proceeds as at the date of this announcement (RMB million)
(a)	**Fund the on-going clinical trials, regulatory filing and registration for Core Products**	**40.0% (RMB1,120.4 million)**	**502.7**	**(200.0)**	**32.9% (RMB920.4 million)**	**302.7**
	Fund the ongoing clinical trials, regulatory filing and registration for HLX02	6.0% (RMB168.1 million)	0.5	–	6.0% (RMB168.1 million)	0.5
	Fund the ongoing clinical trials, regulatory filing and registration for HLX04 for the mCRC indication	8.0% (RMB224.1 million)	65.3	–	8.0% (RMB224.1 million)	65.3
	Develop immuno-oncology combination therapy comprised of HLX04 and HLX10 for the treatment of advanced solid tumours	26.0% (RMB728.2 million)	436.9	(200.0)	18.9% (RMB528.2 million)	236.9
(b)	**Fund the ongoing clinical trials, regulatory filing and registration for other biosimilar candidates, including HLX12, HLX11 and HLX14**	**15.0% (RMB420.1 million)**	**176.0**	**(176.0)**	**8.7% (RMB244.1 million)**	**–**
(c)	**Fund the ongoing clinical trials, regulatory filing and registration for bio-innovative drugs and the development of immuno-oncology combination therapy**	**35.0% (RMB980.3 million)**	**36.5**	**376.0**	**48.4% (RMB1,356.3 million)**	**412.5**
	HLX06	0.2% (RMB5.6 million)	5.6	(5.6)	–	–
	HLX07	4.3% (RMB120.4 million)	27.6	(27.6)	3.3% (RMB92.8 million)	–
	HLX20	0.2% (RMB5.6 million)	1.4	–	0.2% (RMB5.6 million)	1.4
	HLX10 and immuno-oncology combination therapies involving HLX10 (including HLX10+HLX07)	30.3% (RMB848.7 million)	1.9	409.2	44.9% (RMB1,257.9) million	411.1

Intended use of proceeds as set out in the Prospectus	Allocation proportion of the Net Proceeds as set out in the Prospectus (approximately)	Amounts of Unutilised Net Proceeds as at the date of this announcement (RMB million)	Change (RMB million)	Revised allocation of the Net Proceeds (approximately)	Revised amounts of Unutilised Net Proceeds as at the date of this announcement (RMB million)
(d) Working capital and general corporate purposes	10.0% (RMB280.1 million)	1.3	–	10.0% (RMB280.1 million)	1.3
TOTAL	100% (RMB2,800.9 million)	716.5	–	100% (RMB2,800.9 million)	716.5

Reasons for the Change in Use of Proceeds

The Board considered the research and development progress of HLX10 and immuno-oncology therapies and is of the view that the clinical trials, regulatory filing and registration for HLX10 and immuno-oncology therapies require additional investments. Please refer to "Management Discussion and Analysis – 1. Business Review" above for the development progress of HLX10 and immuno-oncology therapies. The Board considers the change in the use of the Net Proceeds as set out above is in the interest of the Company and its shareholders (the "**Shareholders**") as a whole. Save for the above, there is no other change in the use of Net Proceeds from the Global Offering.

THE A SHARE OFFERING AND LISTING

References are made to the Company's circular to the Shareholders dated 26 April 2020 (the "**A Share Offering Circular**") in relation to the Company's proposed initial public offering of A Shares and listing of such Shares (the "**A Share Offering and Listing**") on the Science and Technology Innovation Board of the Shanghai Stock Exchange (the "**SSE STAR Market**"), as well as the 2020 second extraordinary general meeting (the "**2020 Second EGM**"), the 2020 first class meeting of domestic shareholders and the 2020 first class meeting of H shareholders (together, the "**2020 Class Meetings**"), each held on Friday, 12 June 2020.

As set out in the A Share Offering Circular, the resolutions in relation to the A Share Offering and Listing as well as the authorization granted to the Board to fully handle the matters in connection with the A Share Offering and Listing shall be valid for a term of 12 months from the date they were considered and approved. As such, these resolutions are due to expire on 11 June 2021, and the Board has resolved to renew the validity period of these resolutions.

In addition, taking into account the operational and development needs of the Group, the Board has also resolved to revise the original name of "Biosimilar drugs and innovative drugs R&D project" to "Drug development and clinical research project". There has been no change to the expected investment amount from the proceeds for each project. The updated plan for use of proceeds to be raised by the Company from the A Share Offering and Listing is as follows:

No.	Revised Project Name	Proposed investment amount from proceeds raised from the A Share Offering and Listing *(RMB '000)*
1.	Drug development and clinical research project	2,400,000
2.	Biotech industrialization site project	700,000
3.	Replenishment of working capital	900,000
	Total	4,000,000

The relevant resolutions will be subject to the approval of the Shareholders by way of special resolution at a general meeting and at the respective class meetings. Relevant details will be set out in a circular to be despatched to the Shareholders in due course.

The A Share Offering and Listing may or may not proceed to completion. Shareholders and potential investors are advised to exercise caution in dealing in the H Shares.

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 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 subsequent events have occurred since the end of the Reporting Period and up to the date of this announcement.

PURCHASE, SALE AND REDEMPTION OF LISTED SECURITIES

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

COMPLIANCE WITH CORPORATE GOVERNANCE CODE

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

During the Reporting Period, the Company has complied with all principles and code provisions of 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 2020 annual results and the financial statements for the year ended 31 December 2020 prepared in accordance with the IFRSs.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS

Year ended 31 December 2020

	Notes	**2020** ***RMB'000***	2019 *RMB'000*
REVENUE	*3*	**587,586**	90,929
Cost of sales		**(182,119)**	(71,821)
Gross profit		**405,467**	19,108
Other income and gains	*4*	**43,737**	24,674
Selling and distribution expenses		**(243,648)**	(45,689)
Administrative expenses		**(192,640)**	(174,834)
Impairment losses on financial assets, net		**14**	(5,300)
Research and development expenses		**(894,144)**	(607,827)
Other expenses		**(68,622)**	(36,635)
Finance costs	*6*	**(43,705)**	(48,307)
LOSS BEFORE TAX	*5*	**(993,541)**	(874,810)
Income tax expense	*7*	**–**	(655)
LOSS FOR THE YEAR		**(993,541)**	(875,465)
Attributable to:			
Owners of the parent		**(993,541)**	(875,465)
Non-controlling interests		**–**	–
		(993,541)	(875,465)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted (RMB)	*9*	**(1.88)**	(1.76)

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

Year ended 31 December 2020

	2020	2019
	RMB'000	*RMB'000*
LOSS FOR THE YEAR	**(993,541)**	(875,465)
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	**(1,770)**	(1,180)
Reclassification adjustments for a foreign operation disposed of during the year	**–**	1,024
OTHER COMPREHENSIVE LOSS FOR THE YEAR, NET OF TAX	**(1,770)**	(156)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	**(995,311)**	(875,621)
Attributable to:		
Owners of the parent	**(995,311)**	(875,621)
Non-controlling interests	**–**	–
	(995,311)	(875,621)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

31 December 2020

	Notes	2020 ***RMB'000***	2019 *RMB'000*
NON-CURRENT ASSETS			
Property, plant and equipment		**984,909**	500,713
Intangible assets		**2,942,454**	2,175,149
Right-of-use assets		**452,279**	356,678
Other non-current assets		**149,540**	206,578
Total non-current assets		**4,529,182**	3,239,118
CURRENT ASSETS			
Inventories		**305,224**	129,871
Trade receivables	*10*	**196,213**	29,830
Prepayments, deposits and other receivables		**294,248**	196,347
Pledged deposits		**–**	3,559
Cash and cash equivalents		**1,114,309**	2,301,092
Total current assets		**1,909,994**	2,660,699
CURRENT LIABILITIES			
Trade and bills payables	*11*	**298,952**	240,158
Other payables and accruals		**439,845**	409,199
Contract liabilities		**52,225**	32,039
Interest-bearing bank and other borrowings		**1,188,486**	278,241
Total current liabilities		**1,979,508**	959,637
NET CURRENT LIABILITIES/ASSETS		**(69,514)**	1,701,062
TOTAL ASSETS LESS CURRENT LIABILITIES		**4,459,668**	4,940,180

	2020 *RMB'000*	2019 *RMB'000*
NON-CURRENT LIABILITIES		
Interest-bearing bank and other borrowings	**645,131**	331,148
Contract liabilities	**520,870**	572,515
Deferred income	**94,895**	36,102
Total non-current liabilities	**1,260,896**	939,765
Net assets	**3,198,772**	4,000,415
EQUITY		
Share capital	**543,495**	543,495
Reserves	**2,655,277**	3,456,920
Equity attributable to owners of the parent and total equity	**3,198,772**	4,000,415

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 RMB69,514,000 as at 31 December 2020. 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 2020. 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 or not 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 *Conceptual Framework for Financial Reporting 2018* and the following revised IFRSs for the first time for the current year's financial statements.

Amendments to IFRS 3	*Definition of a Business*
Amendments to IFRS 9, IAS 39 and IFRS 7	*Interest Rate Benchmark Reform*
Amendment to IFRS 16	*Covid-19-Related Rent Concessions* (early adopted)
Amendments to IAS 1 and IAS 8	*Definition of Material*

The nature and the impact of the *Conceptual Framework for Financial Reporting 2018* and the revised IFRSs are described below:

(a) *Conceptual Framework for Financial Reporting 2018* (the "**Conceptual Framework**") sets out a comprehensive set of concepts for financial reporting and standard setting, and provides guidance for preparers of financial statements in developing consistent accounting policies and assistance to all parties to understand and interpret the standards. The Conceptual Framework includes new chapters on measurement and reporting financial performance, new guidance on the derecognition of assets and liabilities, and updated definitions and recognition criteria for assets and liabilities. It also clarifies the roles of stewardship, prudence and measurement uncertainty in financial reporting. The Conceptual Framework is not a standard, and none of the concepts contained therein override the concepts or requirements in any standard. The Conceptual Framework did not have any significant impact on the financial position and performance of the Group.

(b) Amendments to IFRS 3 clarify and provide additional guidance on the definition of a business. The amendments clarify that for an integrated set of activities and assets to be considered a business, it must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output. A business can exist without including all of the inputs and processes needed to create outputs. The amendments remove the assessment of whether market participants are capable of acquiring the business and continue to produce outputs. Instead, the focus is on whether acquired inputs and acquired substantive processes together significantly contribute to the ability to create outputs. The amendments have also narrowed the definition of outputs to focus on goods or services provided to customers, investment income or other income from ordinary activities. Furthermore, the amendments provide guidance to assess whether an acquired process is substantive and introduce an optional fair value concentration test to permit a simplified assessment of whether an acquired set of activities and assets is not a business. The Group has applied the amendments prospectively to transactions or other events that occurred on or after 1 January 2020. The amendments did not have any impact on the financial position and performance of the Group.

(c) Amendments to IFRS 9, IAS 39 and IFRS 7 address issues affecting financial reporting in the period before the replacement of an existing interest rate benchmark with an alternative risk-free rate ("**RFR**"). The amendments provide temporary reliefs which enable hedge accounting to continue during the period of uncertainty before the introduction of the alternative RFR. In addition, the amendments require companies to provide additional information to investors about their hedging relationships which are directly affected by these uncertainties. The amendments did not have any impact on the financial position and performance of the Group as the Group does not have any interest rate hedging relationships.

(d) Amendment to IFRS 16 provides a 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. The practical expedient applies only to rent concessions occurring as a direct consequence of the pandemic and only if (i) the change in lease payments results in revised consideration for the lease that is substantially the same as, or less than, the consideration for the lease immediately preceding the change; (ii) any reduction in lease payments affects only payments originally due on or before 30 June 2021; and (iii) there is no substantive change to other terms and conditions of the lease. The amendment is effective for annual periods beginning on or after 1 June 2020 with earlier application permitted and shall be applied retrospectively.

During the year ended 31 December 2020, certain monthly lease payments for the leases of the Group's office buildings have been reduced by the lessors as a result of the pandemic and there are no other changes to the terms of the leases. The Group has early adopted the amendment on 1 January 2020 and elected not to apply lease modification accounting for all rent concessions granted by the lessors as a result of the pandemic during the year ended 31 December 2020. Accordingly, a reduction in the lease payments arising from the rent concessions of RMB81,000 has been accounted for as a variable lease payment by derecognising part of the lease liabilities and crediting to profit or loss for the year ended 31 December 2020.

(e) Amendments to IAS 1 and IAS 8 provide a new definition of material. The new definition states that information is material if omitting, misstating or obscuring it could reasonably be expected to influence decisions that the primary users of general purpose financial statements make on the basis of those financial statements. The amendments clarify that materiality will depend on the nature or magnitude of information, or both. The amendments did not have any significant impact on the financial position and performance of the Group.

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*[2]
Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16	*Interest Rate Benchmark Reform – Phase 2*[1]
Amendments to IFRS 10 and IAS 28	*Sale or Contribution of Assets Between an Investor and its Associate or Joint Venture*[4]
IFRS 17	*Insurance Contracts*[3]
Amendments to IFRS 17	*Insurance Contracts*[3, 5]
Amendments to IAS 1	*Classification of Liabilities as Current or Non-current*[3]
Amendments to IAS 16	*Property, Plant and Equipment: Proceeds before Intended Use*[2]
Amendments to IAS 37	*Onerous Contracts – Cost of Fulfilling a Contract*[2]
Amendments to IAS 1	*Disclosure of Accounting Policies*[3]
Amendments to IAS 8	*Definition of Accounting Estimates*[3]
Annual Improvements to IFRS Standards 2018-2020	Amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41[2]

1 Effective for annual periods beginning on or after 1 January 2021
2 Effective for annual periods beginning on or after 1 January 2022
3 Effective for annual periods beginning on or after 1 January 2023
4 No mandatory effective date yet determined but available for adoption
5 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 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 RFR. The Phase 2 amendments provide a practical expedient to allow the effective interest rate to be updated without adjusting the carrying amount 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 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 amendments are effective for annual periods beginning on or after 1 January 2021 and shall be applied retrospectively, but entities are not required to restate the comparative information. The amendments are not expected to have any significant impact on the Group's financial statements.

Amendments to IFRS 10 and IAS 28 address an inconsistency between the requirements in IFRS 10 and in IAS 28 in dealing with the sale or contribution of assets between an investor and its associate or joint venture. The amendments require a full recognition of a gain or loss 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 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 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.

Amendments to IAS 1 provide guidance and examples to help entities apply materiality judgements to accounting policy disclosures. The amendments replace the requirement to disclose "significant" accounting policies with a requirement to disclose "material" accounting policies. In assessing the materiality of accounting policy information, both quantitative and qualitative aspects need to be considered. Entity-specific accounting policy information is more useful for users of financial statements than the standardised information. The amendments also add guidance on how entities apply the concept of materiality in making decisions about accounting policy disclosures. 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 8 are designed to clarify the distinction between changes in accounting estimates and changes in accounting policies and the correction of errors. The amendments explain how entities use measurement techniques and inputs to develop accounting estimates and state that these can include estimation and valuation techniques. The amendments clarify that not all estimates will meet the definition of an accounting estimate, but rather may refer to inputs used in developing accounting estimates. 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.

Annual Improvements to IFRS Standards 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

	2020	2019
	RMB'000	*RMB'000*
Mainland China	**455,470**	88,312
Europe	**112,196**	–
Asia Pacific (excluding Mainland China)	**19,908**	2,617
Other regions	**12**	–
	587,586	90,929

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

(b) Non-current assets

	2020	2019
	RMB'000	*RMB'000*
Mainland China	**4,412,807**	3,223,215
Overseas	**116,375**	15,903
	4,529,182	3,239,118

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 of approximately RMB273,079,000 (2019: RMB75,418,000) was derived from sales of biopharmaceutical products to a single customer. Revenue of approximately RMB112,196,000 (2019: Nil) was derived from sales of biopharmaceutical products, licensing and research and development services to a single customer.

3. REVENUE

An analysis of revenue is as follows:

	2020	2019
	RMB'000	*RMB'000*
Revenue from contracts with customers	**587,574**	90,929
Revenue from other sources		
Gross rental income from operating leases	**12**	–
	587,586	90,929

Revenue from contracts with customers

(a) Revenue information

	2020	2019
	RMB'000	*RMB'000*
Types of goods or service		
Sales of biopharmaceutical products	**425,451**	78,951
Research and development services	**118,388**	3,400
The License	**42,294**	8,578
Others	**1,441**	–
Total revenue from contracts with customers	**587,574**	90,929
Timing of revenue recognition		
Transferred at a point in time	**456,749**	79,734
Transferred over time	**130,825**	11,195
Total revenue from contracts with customers	**587,574**	90,929

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:

	2020	2019
	RMB'000	*RMB'000*
Revenue recognised that was included in contract liabilities at the beginning of the Reporting Period:		
Research and development services	**78,915**	–
License	**11,951**	8,578
	90,866	8,578

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 delivery of the products and payment is generally due within 90 days from the delivery.

The License

The performance obligation of commercialisation licenses is satisfied overtime during the expected commercialisation period after the Group obtains the commercialisation authorisation from the local authorities and payment in advance is normally required. The performance obligation of intellectual property licenses is satisfied at a point of 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:

	2020	2019
	RMB'000	*RMB'000*
Amounts expected to be recognised as revenue:		
Within one year	**147,161**	32,039
After one year	**685,267**	652,276
	832,428	684,315

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 commercialised 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

	2020	2019
	RMB'000	*RMB'000*
Interest income	**7,404**	16,062
Government grants	**35,393**	7,448
Reclassification adjustments for a foreign operation disposed of during the year	**–**	1,024
Others	**940**	140
	43,737	24,674

5. LOSS BEFORE TAX

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

	2020	2019
	RMB'000	*RMB'000*
Cost of inventories sold	**168,526**	71,821
Cost of services provided	**13,593**	–
Depreciation of property, plant and equipment*	**62,172**	38,858
Depreciation of right-of-use assets*	**39,949**	27,704
Amortisation of intangible assets*	**33,655**	15,937
Research and development expenses:		
Current year expenditure	**894,144**	607,827
Lease payments not included in the measurement of lease liabilities	**3,774**	249
Listing expenses	**3,444**	18,443
Auditor's remuneration	**2,350**	1,750
Employee benefit expense (including directors' and chief executive's remuneration):		
Wages and salaries	**346,273**	206,754
Staff welfare expenses	**49,598**	39,159
Share-based payment expense*	**35,731**	97,117
Foreign exchange loss	**59,773**	32,283
Impairment of financial assets, net	**(14)**	5,300
Write-down of inventories to net realisable value	**1,188**	–
Bank interest income	**(7,404)**	(16,062)
Loss on disposal of items of property plants and equipment	**96**	11
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:

	2020	2019
	RMB'000	*RMB'000*
Interest expense on bank and other borrowings	**30,119**	36,208
Interest expense on lease liabilities	**16,230**	12,099
Less: Interest capitalised	**(2,644)**	–
	43,705	48,307

7. INCOME TAX

The provision for Chinese Mainland current income tax is based on the statutory rate of 25% (2019: 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 preferential rates 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 (2019: 19% and 29.84%, respectively), for the year ended 31 December 2020.

	2020	2019
	RMB'000	*RMB'000*
Current – Mainland China	**–**	655
Total tax charged for the year	**–**	655

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 529,574,066 (2019: 497,157,841) in issue during the year, as adjusted to reflect the rights 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:

	2020	2019
	RMB'000	*RMB'000*
Loss		
Loss attributable to ordinary equity holders of the parent, used in the basic loss per share calculation	**(993,541)**	(875,465)

	Number of shares	
	2020	2019
Shares		
Weighted average number of ordinary shares in issue during the year used in the basic loss per share calculation	**529,574,066**	497,157,841
Effect of dilution – weighted average number of ordinary shares:		
Restricted shares under share award scheme	**–**	–
	529,574,066	497,157,841

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

	2020	2019
	RMB'000	*RMB'000*
Trade receivables	**201,499**	35,130
Impairment	**(5,286)**	(5,300)
	196,213	29,830

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 and bills receivables are non-interest-bearing.

At 31 December 2020, the Group's trade receivables with a carrying amount of RMB4,300,000 (2019: RMB5,305,000) were pledged as security for the Group's interest-bearing bank and other borrowings.

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

	2020	2019
	RMB'000	*RMB'000*
Within 3 months	**196,213**	29,830

11. TRADE AND BILLS PAYABLES

	2020	2019
	RMB'000	*RMB'000*
Trade payables	**298,952**	236,599
Bills payable	**–**	3,559
	298,952	240,158

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

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

	2020	2019
	RMB'000	*RMB'000*
Within 1 year	**298,148**	239,957
1 to 2 years	**804**	201
	298,952	240,158

12. EVENTS AFTER THE REPORTING PERIOD

There have been no significant events since the end of the Reporting Period.

PUBLICATION OF ANNUAL RESULTS AND ANNUAL REPORT

This results announcement is published on the website of the Stock Exchange at http://www.hkexnews.hk and on the website of the Company at http://www.henlius.com. The 2020 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.
Qiyu CHEN
Chairman

Hong Kong, 26 March 2021

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