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Shanghai Henlius Biotech, Inc.

上海復宏漢霖生物技術股份有限公司

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

(Stock Code: 2696)

ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED 31 DECEMBER 2019

The board of directors (the “**Board**”) of Shanghai Henlius Biotech, Inc. (the “**Company**”) 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 2019 (the “**Reporting Period**”), prepared under International Financial Reporting Standards (“**IFRSs**”).

FINANCIAL SUMMARY:

1. The Group’s total revenue was RMB90.9 million for the year ended 31 December 2019, as compared to RMB7.4 million for the year ended 31 December 2018. 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 2019, the Group recognised R&D expenditure of approximately RMB1,406.8 million, representing an increase of approximately RMB434.3 million or approximately 44.66% as compared with approximately RMB972.5 million for the year ended 31 December 2018.
3. The Group’s total loss increased by RMB370.7 million to RMB875.5 million for the year ended 31 December 2019, compared to RMB504.8 million for the year ended 31 December 2018, mainly due to the expansion of R&D activities.
4. The Board does not recommend a final dividend for the Reporting Period.

BUSINESS HIGHLIGHTS:

On 25 September 2019, the Company was successfully listed on The Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”). During the Reporting Period, we have made significant progress on product commercialisation, clinical trial advancement, innovative R&D, and production, including:

1. The first prescription of HLX01 漢利康 (Rituximab) was issued in May 2019, becoming the first commercialised domestic biosimilar; during the Reporting Period, primarily through the profit sharing arrangements under the cooperation agreement with Shanghai Fosun Pharmaceutical Industrial Development Company Limited (“**Fosun Pharma Industrial Development**”), the Group achieved a total sales revenue of HLX01 (漢利康) of RMB79.0 million.

2. The New Drug Application (NDA) of HLX02 (Trastuzumab) was accepted by National Medical Products Administration of the People's Republic of China (the "NMPA") in April 2019 and is currently in the priority review process; the Marketing Authorisation Application ("MAA") was accepted by European Medicines Agency (the "EMA") in June 2019, becoming the first biosimilar made by China whose MAA was accepted by the EMA.
3. The NDA of HLX03 (Adalimumab) was accepted by the NMPA in January 2019 and is currently in the priority review process.
4. In August 2019, phase 2 clinical trial of HLX10 (innovative anti-PD-1 mAb) for the treatment of unresectable or metastatic microsatellite instability-high or mismatch repair-deficient solid tumours that have failed standard treatment completed the first patient dosing in Mainland China; in December 2019, phase 2 clinical trial for the treatment of chronic hepatitis B has completed the first patient dosing in Taiwan, China .
5. HLX10+chemotherapy: phase 3 clinical trials of 4 HLX10 in combination with chemotherapies have completed the first patient dosing, whose indications cover locally advanced/metastatic esophageal squamous cell carcinoma, extensive small cell lung cancer, gastric cancer, locally advanced or metastatic squamous non-small cell lung cancer.
6. HLX10+HLX04: 2 clinical trials of HLX10 in combination with HLX04 have completed the first patient dosing, whose indications cover metastatic non-squamous non-small cell lung cancer (clinical phase 3) and advanced hepatocellular carcinoma (clinical phase 2).
7. HLX10+HLX07: an application of HLX10 in combination with HLX07 for the treatment of recurrent or metastatic head and neck squamous cell carcinoma was approved by the NMPA.
8. HLX22 (innovative anti-HER2 mAb) and HLX12 (ramucirumab biosimilar): phase 1 clinical trial has completed the first patient dosing in Mainland China in July 2019 and June 2019, respectively.
9. HLX55 (innovative anti-c-MET mAb): the clinical trial applications for the treatment of solid tumours were approved by the "Ministry of Health and Welfare" of Taiwan and the NMPA in September 2019 and October 2019, respectively. HLX11 (Pertuzumab biosimilar): the clinical trial application for the treatment of breast carcinoma was accepted by the NMPA in October 2019.
10. In September 2019, the Group reached an agreement with PT Kalbe Genexine Biologics ("KG Bio"), granting it exclusive license to develop and commercialise several indications and combination therapies of HLX10 (PD-1) in 10 countries in Southeast Asia. According to the agreement, the Group is entitled to the prepayment of US\$10,000,000, a total of not more than US\$672,000,000 in milestone payment, and a fixed royalty of 15% or 18% of annual net sales.
11. The Group also commenced the construction of the Songjiang First Plant during the Reporting Period. The planned production capacity of the Songjiang First Plant was 24,000L including formulation filling line, which was the preparation for the Group's estimated production needs before the Henlius Biopharmaceutical Industrialization Base II (the "**Songjiang Second Plant**") was built and put in operation. During the Reporting Period, the Group's Songjiang Second Plant with a total planned area of 200 mu was under construction. The pile foundation engineering operation, as well as the foundation pit enclosure, foundation and basic engineering of the main production building have been completed in the Phase 1 of the construction project. The subsequent phases of construction will be gradually commenced in accordance with the Group's strategies.

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.

Product Pipeline

Product (Reference Drug)		Target	Indication									
☆ 漢利康 (rituximab) ⁽¹⁾				CD20		Non-Hodgkin lymphoma						
With near-term commercial visibility	HLX01 (rituximab)		CD20	Rheumatoid arthritis ⁽²⁾					 			
	HLX02 (trastuzumab) ⁽³⁾		HER2	Breast cancer and metastatic gastric cancer					 			
	HLX03 (adalimumab) ⁽⁴⁾		TNF-α	Psoriasis, ankylosing spondylitis and rheumatoid arthritis								
	HLX04 (bevacizumab)		VEGF	Metastatic colorectal cancer and non-squamous non-small cell lung cancer								
Under clinical research				Wet age-related macular degeneration and diabetic retinopathy ⁽²⁾								
	HLX10	Monotherapy	PD-1	Solid tumours					 			
				Chronic hepatitis B								
		+ Chemo	PD-1	Metastatic esophageal squamous-cell carcinomas								
				Squamous non-small cell lung cancer								
				Extensive small cell lung cancer								
				Gastric cancer								
				Cervical cancer								
				Non-squamous non-small cell lung cancer								
		+HLX04	PD-1+VEGF	Hepatocellular carcinoma								
				Squamous cell carcinoma of the head and neck								
	+HLX07		PD-1+EGFR									
	HLX07		EGFR	Solid tumours								
	HLX06		VEGFR 2	Solid tumours								
	HLX05 (cetuximab) ⁽⁵⁾		EGFR	Metastatic colorectal cancer and squamous cell carcinoma of the head and neck								
	HLX12 (ramucirumab)		VEGFR 2	Gastric cancer, metastatic non-small cell lung cancer and metastatic colorectal cancer								
HLX20		PD-L1	Solid tumours					 				
HLX22		HER2	Breast cancer and gastric cancer									
HLX55 ⁽⁶⁾		c-MET	Solid tumours									
HLX11 (pertuzumab)		HER2	Breast cancer									
HLX13 (ipilimumab)		CTLA-4	Melanoma, renal cell carcinoma and metastatic colorectal cancer									
Pre-clinical	HLX14 (denosumab)		RANKL	Osteoporosis								
	HLX56 ⁽⁷⁾		DR	Solid tumours								
	HLX26		LAG3	Solid tumours								
	HLX23		CD73	Solid tumours								
	HLX15 (daratumumab)		CD38	Multiple myeloma								
	HLX09		CTLA-4	Solid tumours								
	HLX24		CD47	Solid tumours								
	HLX59		CD27	Solid tumours								
	HLX51		OX40	Solid tumours								
	HLX52		TIM-3	Solid tumours								
	HLX53		TIGIT	Solid tumours								
	HLX58		Claudin 18.2	Solid tumours								
	HLX63		GPC3	Solid tumours								

Tumour-specific target ●

Angiogenesis target ●

Tumour immunology target ●

Combination therapy ●

Others ●

(1) Approved by the NMPA in February 2019, being the first domestic biosimilar

(2) Deemed as the bio-innovative product since the reference product has not yet been approved for the relevant indication

(3) Marketing application for HLX02 has been accepted by the NMPA and the EMA, and HLX02 is the first domestic mAb biosimilar to be produced in the EU

(4) Marketing application for HLX03 has been accepted by the NMPA

(5) Commercialisation rights in China have been granted to Shanghai Jingze

(6) Commercialisation rights in certain countries such as China, Southeast Asia, Central Asia and South Asia were obtained

(7) Commercialisation rights in China were obtained

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Core products

MANAGEMENT DISCUSSION AND ANALYSIS

I. BUSINESS REVIEW

Adhering to our vision of “be the most trusted and admired biotech company providing innovative and affordable medicines for all patients”, and benefitting from our efficient biopharmaceutical industry-wide platform that integrates R&D, production and commercialisation into a whole, outstanding global regulatory registration and clinical operational capability as well as comprehensive quality management system, the Group has gradually made significant progress on product R&D and commercialisation during the Reporting Period.

(I) Promoting the Sustainable and Steadily Growing Product Pipeline

Based on the main product development strategy of combining imitation and innovation, the Group took the lead in launching the first domestic biosimilar, HLX01 (漢利康), and gradually developed innovative mAb products, combining self-developed anti-PD-1 and PD-L1 mAb, being the first to launch combined immunotherapy in China, and prospectively laid out a comprehensive pipeline integrating innovative mAb and tumour combination immunotherapy into a whole. As of 16 March 2020, being the latest practicable date for the publication of this announcement (the “**Latest Practicable Date**”), 1 product has been successfully marketed, 2 products’ NDA have been accepted by the NMPA in China, 1 product’s MAA has been submitted and accepted in the European Union (“EU”), 15 products and 2 mAb combination therapies have been adopted worldwide, which obtained 35 clinical trial approvals, and carried out more than 20 clinical trials on 10 products and 8 combination therapies in many countries and regions around the world, such as Mainland China, Taiwan, China, Australia, Poland, Ukraine, and the Philippines. In February 2019, the NDA for the first monoclonal antibodies (“mAb”) biosimilar HLX01 (漢利康) self-developed by the Group was approved by the NMPA, becoming the first case according to the “The Guiding Principles for Biosimilar” approved for marketed mAb. Since its commercialisation in late May 2019, primarily through the profit sharing arrangements under the cooperation agreement with Fosun Pharmaceutical Industrial Development, the Group achieved a total sales revenue of HLX01 (漢利康) of RMB79.0 million in 2019, and has improved the accessibility of drugs for domestic lymphoma patients. In order to benefit a wider patient population, the Group adopted a differentiated development strategy for HLX01 (漢利康), and concurrently carried out the clinical research of the original drug on rheumatoid arthritis indications that have not yet been approved in China. Currently, the enrollment of patients for Phase 3 clinical trial has been completed.

1. *mAb Biosimilars that are Expected to be Commercialised in the Near Future*

The Group's R&D activities for other core products also achieved significant results during the Reporting Period. In April 2019, the NDA for HLX02 self-developed by the Group was accepted by the NMPA and is currently in the priority review process; in June 2019, the Group and its business partner Accord Healthcare Limited ("**Accord**") jointly promoted the submission of a MAA to the EMA on HLX02 and was accepted, becoming the first biosimilar made by China whose MAA was accepted by the EMA; at present, it has passed the EMA "good clinical practice" ("**GCP**") inspection, and the "good manufacturing practice" ("**GMP**") on-site inspection has been completed and moved forward according to the plan. In October 2019, the Phase 3 clinical study of HLX02 for the treatment of metastatic breast cancer has been completed, which showed that the efficacy is equivalent to the original drug, and the safety and immunogenicity of the treatment for one year are similar to the original one. In January 2019, the NDA for HLX03 self-developed by the Group was accepted by the NMPA and is currently in the priority review process; In July 2019, HLX03 for the treatment of plaque psoriasis indications has completed the phase 3 clinical trial in Mainland China, which showed that the efficacy of HLX03 for moderate to severe plaque psoriasis is equivalent to that of the original drug, and it is similar to the original drug in terms of safety, immunogenicity and pharmacokinetics. As of the Latest Practicable Date, the Phase 3 clinical trial of the Avastin biosimilar HLX04 (recombinant humanised anti-VEGF monoclonal antibody injection) developed by the Group has completed the enrollment of patients and is preparing for submitting the NDA for its metastatic non-squamous non-small cell lung cancer indications and metastatic colorectal cancer indications to the NMPA.

2. *Continuous and Efficient Advancement on Clinical Research Products*

As of the Latest Practicable Date, the Group has established a highly efficient and experienced global clinical development team to actively promote the clinical research of multiple candidate drugs in multiple locations around the world, and achieved promising progress. HLX10 (PD-1) is the core innovative mAb in the Group's product pipeline. At present, HLX10 (PD-1) has been successively approved for clinical trials in the United States, Taiwan, China and Mainland China. In August 2019, the Phase 2 clinical study of HLX10 (PD-1) for the treatment of unresectable or metastatic microsatellite instability-high or mismatch repair-deficient solid tumours (MSI-H/dMMR) that failed standard treatment completed the first patient dosing in Mainland China; in December 2019, the Phase 2 clinical trial of HLX10 (PD-1) for the treatment of chronic hepatitis B completed the first patient dosing in Taiwan, China. While actively promoting the clinical development of HLX10 (PD-1), the Group is also actively implementing the differentiated strategy of "Global + Combo". With HLX10 (PD-1) as the core, and combining with other pharmaceutical products to increase its global presence, clinical trials are being conducted simultaneously in multiple countries and regions worldwide. As of the Latest Practicable Date, "HLX10 + chemotherapy" is used to treat locally advanced/metastatic esophageal squamous cell carcinoma ("**ESCC**"), locally advanced/metastatic squamous non-small cell lung cancer ("**sqNSCLC**"), and previously untreated extensive-stage small cell lung cancer ("**ES-SCLC**"), neoadjuvant/adjuvant treatment of gastric cancer ("**GC**"), and advanced cervical

cancer (“CC”) that five phase 2/3 clinical trials have all completed the first patient dosing in Mainland China. The “HLX10 + HLX04” Phase 2 clinical trial for the treatment of advanced hepatocellular carcinoma and the Phase 3 clinical trial for the treatment of non-squamous non-small cell lung cancer were both completed in Mainland China. In December 2019, “HLX10 + HLX07”, the second monoclonal antibody combination therapy developed by the Group was approved by the NMPA for clinical trial, which is expected to be used in the treatment for advanced solid tumours such as recurrent or metastatic head and neck squamous cell carcinoma in the future.

The Group has also promoted clinical research on a number of other products in an orderly manner: As of the Latest Practicable Date, the improved innovative anti-EGFR mAb HLX07 is in the phase 1b/2 clinical trial process and is expected to be used in the treatment for nasopharyngeal cancer, colorectal cancer and other solid tumour indications; the innovative anti-PD-L1 mAb HLX20 is in the phase 1 clinical trial in Australia, which is expected to be combined with other products to develop tumour immunotherapy, and to be widely used in the treatment of solid tumours. Ramucirumab biosimilar HLX12 (recombinant anti-VEGFR2 domain II-III fully humanised monoclonal antibody injection) has completed the first patient dosing of Phase 1 clinical research in Mainland China in June 2019; innovative anti-HER2 mAb HLX22 has completed the first patient dosing of Phase 1 clinical trial in Mainland China in July 2019; the innovative anti-c-MET mAb HLX55 has completed the first patient dosing in March 2020.

3. Accelerating the Development of Multiple Pre-clinical Research Projects

The Group accelerated the development of the pre-clinical research pipeline simultaneously. As of the Latest Practicable Date, the investigational new drug application of HLX04 (bevacizumab biosimilar) submitted by the Group for treating the indications of wet age-related macular degeneration and diabetic retinopathy has been approved by the NMPA. In January 2020, the investigational new drug application (“IND”) of Pertuzumab biosimilar HLX11 (recombinant anti-HER2 domain II humanised monoclonal antibody injection) was approved by the NMPA, whose indications include metastatic breast cancer and early breast cancer. The product is expected to be combined with HLX02 or chemotherapy in the adjuvant treatment of HER2-positive breast cancer, neoadjuvant therapy, and treatment of HER2-positive metastatic breast cancer. In January 2020, the IND of ipilimumab biosimilar HLX13 (recombinant anti-CTLA-4 fully humanised monoclonal antibody injection) was accepted by the NMPA, whose indications include: (i) unresectable or metastatic melanoma, (ii) advanced renal cell carcinoma, (iii) microsatellite highly unstable or mismatch repair defects in metastatic colorectal cancer, and (iv) adjuvant melanoma treatment. In March 2020, the IND of Denosumab biosimilar HLX14 (recombinant anti-RANKL fully humanised monoclonal antibody injection) was accepted by the NMPA, whose indication is for postmenopausal osteoporosis in women with high fracture risks. The Group’s current development plans and results are summarised in the following table:

Name of product (reference drugs/targets)	Progress as of the Latest Practicable Date	Other recognitions
Commercialised product		
HLX01 (漢利康)	– In February 2019, NDA approved – In May 2019, the first prescription was made	1. An article was published based on the HLX01 similarity study in <i>mAbs</i> 2. In December 2019, Farma De Colombia S.A.S (“Farma De Colombia”) was granted the exclusive commercialisation rights of HLX01 in Colombia, Peru, Ecuador and Venezuela 3. In November 2019, cooperated with Ascentage Pharma Group International to develop HLX01 combined with APG-2575 for the treatment of chronic lymphocytic leukemia
Products with near-term commercial visibility		
HLX02 (trastuzumab)	– In April 2019, NDA accepted and currently in the priority review process – In June 2019, the MAA accepted, the EMA GCP inspection passed, and the GMP on-site inspection completed and moving forward according to the plan	1. In October 2019, Phase 3 clinical study of HLX02 for the treatment of metastatic breast cancer completed 2. An article was published based on the HLX02 similarity study in <i>BioDrugs</i>

Name of product (reference drugs/targets)	Progress as of the Latest Practicable Date	Other recognitions
HLX03 (adalimumab)	– In January 2019, NDA accepted and currently in the priority review process	1. In July 2019, HLX03 for the treatment of plaque psoriasis indication completed the Phase 3 clinical trial in Mainland China, which showed that the efficacy of HLX03 for moderate to severe plaque psoriasis is equivalent to that of the original drug, and it is similar to the original drug in terms of safety, immunogenicity and pharmacokinetics
HLX04 (bevacizumab)	– Phase 3 clinical trial completed the enrollment of patients, and NDA being prepared for submission	
HLX01 (漢利康)	– Phase 3 clinical trial of rheumatoid arthritis indications completed the enrollment of patients	
Products under clinical studies being continuously and efficiently promoted		
HLX10 (innovative anti-PD-1 mAb)	– In December 2019, Phase 2 clinical trial for the treatment of chronic hepatitis B completed the first patient dosing in Taiwan, China – In August 2019, phase 2 clinical study for the treatment of unresectable or metastatic microsatellite instability-high or mismatch repair-deficient solid tumours that have failed standard treatment completed the first patient dosing in Mainland China	1. In September 2019, exclusive license to develop and commercialise several indications and combination therapies of HLX10 (PD-1) in 10 countries in Southeast Asia granted to KG Bio 2. In October 2019, jointly explored the global commercial development of PD-L1 companion diagnostic kit with Shanghai Wuxi Diagnostics Co. Ltd.* (上海藥明奧測醫療科技有限公司)

Name of product (reference drugs/targets)	Progress as of the Latest Practicable Date	Other recognitions
HLX10+HLX04	– Phase 3 clinical trial in progress (metastatic non-squamous non-small cell lung cancer) – Phase 2 clinical trial in progress (advanced hepatocellular carcinoma)	
HLX10+HLX07	– In December 2019, clinical trial for recurrent or metastatic head and neck squamous cell carcinoma approved by the NMPA	
HLX10+chemotherapy	– 5 Phase 2/3 clinical trials ongoing (locally advanced/metastatic esophageal squamous cell carcinoma, extensive advanced small cell lung cancer, gastric cancer, locally advanced or metastatic squamous non-small cell lung cancer, advanced cervical cancer).	
HLX07 (improved innovative anti-EGFR mAb)	– Phase 1b/2 clinical trial in progress in Mainland China	
HLX20 (innovative anti-PD-L1 mAb)	– Phase 1 clinical trial in progress in Australia	
HLX12 (ramucirumab)	– In June 2019, Phase 1 clinical study completed first patient dosing in Mainland China	

Name of product (reference drugs/targets)	Progress as of the Latest Practicable Date	Other recognitions
– HLX22 (innovative anti-HER2 mAb)	– In February 2019, IND for gastric and breast cancer indications approved; – In July 2019, Phase 1 clinical study completed first patient dosing	
– HLX55 (innovative anti-c-MET mAb)	– In September 2019, IND approved in Taiwan, China – In October 2019, IND approved in Mainland China – In March 2020, Phase 1 clinical study completed first patient dosing in Taiwan, China	
Applications for clinical trials of the pre-clinical research project accelerated		
HLX04 (anti-VEGF mAb)	– In January 2019, IND for indications for wet age-related macular degeneration and diabetic retinopathy approved	
HLX11 (pertuzumab)	– In January 2020, IND approved	
HLX13 (ipilimumab)	– In January 2020, IND accepted	
HLX14 (denosumab)	– In March 2020, IND accepted	

(II) Forward-looking Production Capacity Layout with High Cost-efficiency

In order to meet the expected demand for the gradual marketing of candidate drugs in the Group's product pipelines, the Group has formulated a phase-based capacity planning for the product development cycle, gradually improved and enhanced large-scale production capacity based on a sound quality control system, and maintained high quality standards while expanding production capacity and improving cost-efficiency. Meanwhile, the Group has established a quality control system that complies with international quality standards, covering the entire life cycle from project development to material management, product production, quality control, product supply chain management, and product follow-up after marketing, which lays a solid foundation for the commercialisation in multiple jurisdictions and regions.

As of the end of the Reporting Period, the Group has established a biopharmaceutical production facility in Shanghai Caohejing Hi-Technology Park ("**Xuhui Facility**"), which has a capacity of 14,000L and covers a total area of approximately 11,000 square metres. Xuhui Facility and its supporting quality control system have passed a number of on-site inspections and/or audits by EU qualified person and international business partners, which can meet the Group's short-term production needs. As of the Latest Practicable Date, the Xuhui Facility of the Group has accepted the GMP on-site inspection and moved forward according to the plan. To further improve the capacity plan, the Group also commenced the construction of the Songjiang First Plant during the Reporting Period. The planned production capacity of the Songjiang First Plant was 24,000L including formulation filling line, which was the preparation for the Group's estimated production needs before Songjiang Second Plant was built and put in operation. During the Reporting Period, the Group's Songjiang Second Plant with a total planned area of 200 mu was under construction. The pile foundation engineering operation, as well as the foundation pit enclosure, foundation and basic engineering of the main production building have been completed in the Phase 1 of the construction project. The subsequent phases of construction will be gradually commenced in accordance with the Group's strategies.

(III) Advanced Commercialisation Strategy and Layout

Based on the mission of "to improve patients' lives by timely providing them with quality and affordable protein therapeutics through technical innovation and operational excellence", the Group continues to explore efficient business operation models with the purpose of improving the accessibility and affordability of biopharmaceuticals, implementing a commercialisation strategy of "Focusing on product portfolio, production capacity and commercial operations, to be the biomedical leader in China". To coordinate the gradual commercialisation of the Group's products, the Group has further improved the overall business planning and the formulation of product market strategies to create a professional and efficient international business operation team.

- ***Commercial sales planning for 漢利康 (products treating haematological tumours) :***

As the first domestic biosimilar in the strict sense, HLX01 漢利康 was successfully approved for marketing in 2019, which commenced the development of the domestic biosimilar market. After the launch of 漢利康, Jiangsu Fosun Pharmaceutical Sales Co., Ltd.* (“**Jiangsu Fosun**”), a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd.* (“**Fosun Pharma**”) (controlling shareholder of the Company) is responsible for the domestic commercial sales. Jiangsu Fosun has a professional academic promotion team for key hospitals and a mixed-line sales team for a broad market, in which all members of two teams have passed the technical training and assessment in professional fields, with solid medical knowledge and communication skills. At the same time, the Group will also promote the approval for HLX01 in treating the rheumatoid arthritis indication.

- ***Commercial sales planning led by the Group (in the field of oncology treatment)***

Being committed to providing quality and affordable innovative biopharmaceuticals to patients worldwide, the Group’s products under development mainly focus on the field of oncology, and this part of the product is planned to be promoted by the commercialisation team of the Group. As of the Latest Practicable Date, the Group has established a commercial core team for the Chinese market, which consists of about 100 experts with extensive industry experience (the staff mainly come from multinational foreign companies such as Roche, AZ, MSD, Sanofi, Amgen). The Group’s commercialisation team comprises five major segments: marketing, channel management, pricing and market access, domestic sales, and strategic planning, with a complete organisational structure and a clear division of responsibilities. It is expected to effectively promote the Group’s commercialisation and achieve a stable growth of sales scale.

- ***Commercial sales planning for products represented by HLX03 (products treating autoimmune diseases)***

According to the cooperation agreement signed between the Company and Jiangsu Wanbang (Group) Biopharmaceutical Co., Ltd.* (“**Jiangsu Wanbang**”), a subsidiary of Fosun Pharma, Jiangsu Wanbang will be responsible for domestic commercial sales after the product launch of HLX03, and it has a large-scale professional rheumatology sales team and a mixed-line sales team for more markets, which are equipped with professional communication skills and medical knowledge as well as the experience in successful commercialisation of 優立通 (Febuxostat Tablets) in the field of rheumatism treatment.

(IV) Results of Internationalised Layout

Based on the internationalised positioning set at the Group's establishment and the long-term internationalisation strategy, the Group actively implements a comprehensive internationalised R&D and operation strategies, and promotes the smooth development of commercialisation of products in the international market. With the feature of "global linkage, integrated innovation" as the product development concept, the Group possesses R&D laboratories in China Shanghai, China Taipei, and USA California, and the three R&D centres collaborate closely to ensure high-productivity and cost-effective R&D processes to jointly create a diverse and complete technology platform and strong independent R&D capabilities, laying a solid foundation for the Group's internationalisation strategy and entering the international market.

At the same time, the Group is proactively carrying out its global commercialisation layout. Prior to the products to be approved for marketing, it has reached strategic commercialisation cooperation with some of the world's leading pharmaceutical companies in order to rapidly occupy the global market share through the partners' existing capabilities and resources. As of the Latest Practicable Date, the Group has signed commercial cooperation agreements with international pharmaceutical companies such as Accord, Cipla Limited, Biosidus S.A., Jacobson Medical (Hong Kong) Limited, KG Bio, Farma De Colombia in respect of a number of core products of the Company, with many foreign authorisations covering more than 90 countries and regions worldwide. The Group successfully submitted a MAA for HLX02 in the EU with its business partner Accord in June 2019. The HLX02 self-developed by the Group became the first domestic mAb biosimilar whose MAA has been submitted and accepted in the EU. The Group reached a cooperation agreement with KG Bio in September 2019, and agreed to grant KG Bio exclusive development and commercialisation rights for indications and combination therapies of HLX10 (PD-1) in 10 countries in Southeast Asia, pursuant to which, the Group has the right to receive a prepayment of US\$10,000,000, a milestone payment in a total of not more than US\$672,000,000, and a fixed royalty of 15% or 18% of annual net sales (depending on the sales of the relevant products), and KG Bio agreed to provide US\$10,000,000 in funding to support the two HLX10 (PD-1) combination therapy trials that the Group will launch. In December 2019, the Group also announced that Farma De Colombia has been granted exclusive commercialisation licenses of HLX01 in Colombia, Peru, Ecuador and Venezuela, pursuant to which, the Group has the right to receive a signing payment of US\$500,000 and related milestone payments.

(V) Social Responsibility, Environmental Policies and Performance

Always adhering to the mission of “to improve patients’ lives by timely providing them with quality and affordable protein therapeutics through technical innovation and operational excellence”, the Group actively fulfills its responsibilities to stakeholders such as patients, employees, partners, and communities, being committed to serving global patients and providing more affordable biopharmaceuticals. In terms of social public welfare, the Company and Shanghai Fosun Foundation established the Fosun Foundation Henlius Special Public Welfare Fund (上海復星公益基金會復宏漢霖公益專項基金) to give full play to its industrial advantages and focus on public welfare projects in areas such as health education and patient care. 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.

II. OUTLOOK FOR 2020

In 2020, the Group will further expand its biopharmaceutical product portfolio covering oncology, auto-immune diseases and more fields, capitalise the achieved first-entrant advantages to further advance the implementation of the Group’s internationalisation strategy, improve the production base construction, expand production capacity and accelerate the commercialisation of more high-quality biological products to benefit more patients worldwide.

(I) CAPITALISE ON FIRST-ENTRANT ADVANTAGES AND ACCELERATE THE LAUNCH OF COMMERCIAL SALES

As one of the leading domestic biopharmaceutical companies, the Group will actively respond to national calls and cooperate with national pharmaceutical reforms to provide patients with high-quality and affordable biopharmaceuticals. Meanwhile, the Group has clearly established a comprehensive and efficient business operation mode in market access, market development and sales with patient-centric, to improve the accessibility and affordability of biopharmaceuticals, and continue to promote the successful commercialisation of more products. Given the low development risk and identified market potential of biosimilars, the Group will accelerate the commercialisation of multiple biosimilar products in the pipeline in 2020. The two products, HLX02 and HLX03, are expected to be approved for launching in 2020 and to become the main driving factor for the Group’s short-term revenue growth besides 漢利康.

HLX02 is the core tumour product whose sales promotion will be led by the Group's self-built commercialisation team. In order to successfully conduct the commercialisation of HLX02 in China, the Group has completed the formulation of the project's commercialisation strategy and the establishment of a commercialisation core management team, and will continue to actively expand the commercialisation team according to the product's launching progress, promote the establishment of marketing system and market access capability as planned, and plan to build an efficient team of more than 500 professionals in 2020, aiming to cover a total of more than 2,700 grade A/B hospitals in more than 260 first to third tier cities in the six major sales regions of the Country.

In 2020, the Group will also continue to strengthen the sales landing of 漢利康, capitalise the first-entrant advantages, and work closely with Jiangsu Fosun to focus on the continued growth of 漢利康 in the field of haematological tumours. The Group will cooperate with Jiangsu Wanbang to carry out the sales of HLX03 and make full use of Jiangsu Wanbang's successful commercialization experience in the field of rheumatology treatment product 優立通 (febuxostat tablets) to fully prepare for the future commercialisation of HLX03.

(II) MAINTAIN HIGH-QUALITY STANDARDS AND EFFICIENTLY PLAN PRODUCTION CAPACITY CONSTRUCTION AND UTILISATION

The Group will further improve the production system construction in accordance with the product R&D and launching, plan to complete the production base construction and increase production capacity to provide strong guarantees for the successive commercial sales of products, while achieving efficient utilisation of production capacity. The Group's Xuhui Facility has a total existing capacity of 14,000L. The Group plans to further expand capacity to 18,000L and promote the certification approval of EU GMP at the Facility and improve production efficiency through a series of lean management and process optimisation measures to reduce production costs. Meanwhile, the Group plans to promote the development and industrialisation of continuous flow technology in 2020 in order to ensure the production efficiency and quality of large-scale commercial production of future products. The Group also started the construction of the Songjiang First Plant during the Reporting Period to prepare for the estimated capacity demand before the Songjiang Second Plant was put into operation. The Songjiang First Plant plans to build a production capacity of 24,000L including drug preparation filling line. The production workshop is expected to conduct trial production of clinical samples in the first half of 2020. In order to achieve long-term capacity planning, the Group will continue to promote the construction of the Songjiang Second Plant to enhance the overall production capacity of the Group. It is expected to be completed and put into trial production and conduct related verification work in 2021. Upon completion of construction, the Songjiang Second Plant will become the Group's base for R&D, pilot production and production of mAb biopharmaceutical drugs. This will further enhance the Group's R&D capability in core business area, and satisfy the commercialised production demand for biosimilar and bio-innovative drugs of the Group.

(III) ACTIVELY PROMOTE R&D OF INNOVATIVE DRUGS BASED ON OUR EXTENSIVE PIPELINE

The Group will fully utilise the globally integrated independent development platform, keep up with the international trend, continue to expand and enrich the product target layout, optimise the development platform of bi-specific antibodies, and create a high-quality and affordable innovative product pipeline. In 2020, the Group will actively carry out and promote the development of innovative drugs based on the existing extensive product pipelines and mature R&D platforms. NDAs for the Group's independently developed core product innovative drug HLX10 (PD-1) and bevacizumab biosimilar drug HLX04 are planned to be submitted to the NMPA at the end of 2020/early 2021. Meanwhile, clinical trials of combined immunotherapy of tumours with HLX10 (PD-1) as the core, for indications such as recurrent or metastatic SCCHN and metastatic colorectal cancer, are also planned to be further developed and advanced in 2020.

While rapidly advancing the progress of clinical trials of candidate drugs in the pipeline, the Group will also continue to effectively and efficiently promote the preclinical R&D process of products under development, and accelerate the deployment of innovative anti-LAG3 mAb HLX26, innovative anti-CD73 mAb HLX23, daratumumab biosimilar HLX15 and other products in the global registration and approval of multiple products, and then carry out clinical research programs. At present, the Group's mAb pipeline has extensively covered tumour-specific targets (such as EGFR, HER2 and c-Met), anti-angiogenesis targets (such as VEGF and VEGFR2) and immunotherapeutic targets (such as PD-1, PD-L1, CTLA-4, LAG3、TIGIT and CD73) and during the development, the Group has accumulated a wealth of research data and practical experience on the target biological pathways and antibody interactions as well as the relationship between antibody structure and pharmacodynamics. Synthesising such data and experience, and relying on the Group's comprehensive bi-specific antibody development platform, newly developed phage library of humanised monoclonal antibody and strong clinical trial advancing capabilities, it is expected to make important breakthroughs in the R&D of bi-specific antibodies containing PD-1, PD-L1, EGFR and HER2 targets in the short term.

The Group will further capitalise on its international resources and advantages, further establish differentiated R&D pipelines to expand and optimise existing product pipelines, and further promote the R&D of the Group's innovative drug.

(IV) MAINTAIN EFFICIENT OPERATIONS AND FURTHER PROMOTE THE IMPLEMENTATION OF INTERNATIONALISATION STRATEGIES

In 2020, the Group will continue to maintain the efficient operation of multiple R&D centres around the world and leverage the unique advantages of each centre: the California R&D centre in the United States continues to lead the application of cutting-edge technologies and expand the layout of differentiated targets; the Taipei R&D centre has rapidly promoted the development of animal experiments for innovative products and the development of the Phase 1 of clinical research based on the established animal experiment model. The Shanghai R&D centre has continued to improve the production process, formulation development and other process development to achieve product process optimisation.

In 2020, the Group will also continue to propel the international commercialisation of its products, actively promote the commercial cooperation of products, and the global registration and clinical research of multiple projects. During the Reporting Period, HLX02, independently developed by the Group, became the first domestic mAb whose MAA has been submitted and accepted in the EU. The core products HLX10 (PD-1) and HLX01 (漢利康) also successfully entered the markets of Southeast Asia and South America through business partners. In 2020, the Group will continue to collaborate with Accord, our cooperative partner, in actively proceeding with the commercialisation for HLX02 in the EU. Meanwhile, the Group plans to seek potential strategic cooperation with more international partners through implementing business development strategy for entering the international market through these international strategic partners, in particular for the entry to emerging markets with significant unfulfilled medical needs for affordable pharmaceutical products, to benefit patients overseas.

III. FINANCIAL REVIEW

(I) REVENUE

The Group began the commercialisation of HLX01 (漢利康) in China in May 2019. Prior to that, the Group did not commercialise any products and therefore did not generate revenue from the sale of products. The total revenue of the Group for the year ended 31 December 2019 was approximately RMB90.9 million, representing an increase of approximately RMB83.5 million as compared with that for the year ended 31 December 2018, which was mainly from the sales growth of the commercialisation of the Group's core product. According to the cooperation arrangement with Fosun Pharma Industrial Development, Fosun Pharma Industrial Development fully reimbursed the related expenditures incurred for clinical trials of HLX01 (漢利康) conducted by the Group after the signing of relevant cooperation agreement. After the commercialisation of HLX01 (漢利康), the Group was responsible for the production and the supply of HLX01 (漢利康) to Fosun Pharma Industrial Development in China, and shared a portion of the profit with Fosun Pharma Industrial Development from the sales in China pursuant to the contract. During the Reporting Period, primarily through the profit sharing arrangements under the cooperation agreement with Fosun Pharmaceutical Industrial Development, the Group achieved a total sales revenue of HLX01 (漢利康) of RMB79.0 million, and realised licensing income of RMB8.6 million. We intend to further raise public awareness of HLX01 (漢利康) by ramping up our marketing and sales efforts. We also plan to market our drug products through our commercialisation partners under well-established strategies.

On 25 September 2019, the Group entered into a cooperative R&D and commercialisation agreement ("**Cooperation Agreement**") with KG Bio on HLX10 (the Group's bio-innovative drug with exclusive patents and technical knowledge). During the Reporting Period, the Group recognised the revenue from services of approximately RMB2.6 million.

In addition, the Group recorded revenue through providing consultation and research services. During the Reporting Period, the Group recognised the revenue of approximately RMB0.7 million through providing consultation and research services.

(II) COST OF SALES

The Group's cost of sales primarily represents raw materials, production employee compensation, outsourcing expenses, utilities expenses and depreciation and amortisation. For the year ended 31 December 2019, the Group recorded cost of sales of RMB71.8 million, representing an increase of approximately RMB66.4 million as compared with that for the year ended 31 December 2018, which was due to the production cost of HLX01 (漢利康).

(III) GROSS PROFIT

For the year ended 31 December 2019, the Group recorded a gross profit of RMB19.1 million, representing an increase of approximately RMB17.1 million as compared with that for the year ended 31 December 2018, or 855.0%, mainly because the Group received the NDA approval for HLX01 (漢利康) in February 2019 and commenced commercial sales in May 2019.

(IV) OTHER INCOME AND GAINS

Other income and gains of the Group mainly included bank interest income and government grants. Government grants included (1) government support 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 RMB24.7 million.

	Year ended 31 December	
	2019	2018
	<i>RMB'000</i>	<i>RMB'000</i>
Interest income	16,062	5,208
Government grants	7,448	15,886
Exchange gains	—	8,927
Others	1,164	287
Total	24,674	30,308

(V) R&D Expenditure

	Year ended 31 December	
	2019	2018
	<i>RMB'000</i>	<i>RMB'000</i>
Expensed R&D expenses		
Share-based compensation	68,333	55,173
R&D employee salaries	182,910	88,201
Outsourcing fees	62,759	30,222
Reagents and consumables	83,266	62,687
Utilities	7,308	12,435
Depreciation and amortisation	45,637	34,290
Consulting expense	16,176	12,225
Clinical trials	107,595	26,654
Others	33,843	43,495
Total expensed R&D expenses	607,827	365,382
Capitalised R&D expenses		
Clinical trials	517,194	399,642
R&D employee salaries	107,098	84,192
Reagents and consumables	30,199	30,543
Depreciation and amortisation	31,125	32,484
Utilities	4,310	5,252
Outsourcing fees	47,427	6,829
Share-based compensation	26,517	20,861
Others	35,067	27,298
Total capitalised R&D expenses	798,937	607,101

During the year ended 31 December 2019, the Group recognised R&D expenditure of approximately RMB1,406.8 million, representing an increase of approximately RMB434.43 million or approximately 44.66% as compared with approximately RMB972.45 million for the year ended 31 December 2018. The increase in our research and development expenditure was mainly due to (1) the increases in clinical trial expenses and costs of pre-clinical 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 year ended 31 December 2019, the Group recognised administrative expenses of approximately RMB174.8 million, representing an increase of 60.2% as compared to that of approximately RMB109.1 million for the year ended 31 December 2018. 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 (such as relevant listing expenses).

(VII) SELLING AND DISTRIBUTION EXPENSES

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

During the year ended 31 December 2019, the Group recognised selling and distribution expenses of approximately RMB45.7 million, which was mainly used for the establishment of business operation team ahead of the formal launching of HLX02 in 2020.

(VIII) INCOME TAX EXPENSE

For the year ended 31 December 2019 and 2018, the Group did not incur any income tax expenses as the Group did not generate taxable income during those two years. Income tax expenses are non-deductible income tax expenses for certain subsidiaries.

(IX) LOSS FOR THE YEAR

In view of the above, the Group's loss increased by RMB370.7 million from RMB504.8 million for the years ended 31 December 2018 to RMB875.5 million for the year ended 31 December 2019.

(X) LIQUIDITY AND CAPITAL RESOURCES

As of 31 December 2019, the cash and cash equivalents of the Group were RMB2,301.1 million, mainly denominated in Renminbi ("RMB"), United States Dollars ("USD"), New Taiwan Dollars ("NTD") and Euro, where such increase was mainly due to the successful initial public offering on the Stock Exchange. As of 31 December 2019, the current assets of the Group were RMB2,660.7 million, including cash and cash equivalents of RMB2,301.1 million, pledged deposits of RMB3.6 million, inventories of RMB129.9 million and prepayments, deposits and other receivables of RMB196.3 million. As of 31 December 2019, the current liabilities of the Group were RMB959.6 million, including trade and bills payables of RMB240.2 million, other payables and accruals of RMB409.2 million and interest-bearing bank and other borrowings of RMB278.2 million.

As of 31 December 2019, the foreign exchange bank balances of the Group are as follows:

	<i>RMB'000</i>
RMB	369,582
Hong Kong Dollars (“ HKD ”)	988,236
USD	941,035
Euro	1,531
NTD	4,267
	<u><u> </u></u>

(XI) INVENTORIES

Inventories of the Group increased from approximately RMB25.2 million as of 31 December 2018 to approximately RMB129.9 million as of 31 December 2019, mainly due to the increased purchases of raw materials and consumables in order to facilitate the clinical trial and commercialised production.

(XII) TRADE AND BILLS RECEIVABLES

As of 31 December 2018 and 31 December 2019, trade and bills receivables from customer contracts were RMB6.8 million and RMB29.8 million, respectively. There are no changes in accounting estimates or material assumptions made in both years.

	As at 31 December	
	2019	2018
	<i>RMB'000</i>	<i>RMB'000</i>
Within 3 months	29,830	1,521
3 to 6 months	–	–
6 to 9 months	–	–
9 to 12 months	–	–
1 to 2 years	–	5,300
	<u> </u>	<u> </u>
Total	<u><u>29,830</u></u>	<u><u>6,821</u></u>

(XIII) INTEREST-BEARING BANK AND OTHER BORROWINGS

As of 31 December 2019, bank and other borrowings (exclusive of lease liabilities) of the Group were RMB431.1 million. The Group incurred new borrowings for the following reasons: ongoing clinical research trials and pre-clinical research for drug candidates, commercialisation of HLX01 (漢利康) and normal operating expenses.

Such borrowings bear interest at fixed annual interest rates.

(XIV) MATURITY STRUCTURE OF OUTSTANDING DEBTS

The following table sets forth the maturity structure of outstanding debts as of 31 December 2019 and 31 December 2018. Of which, lease liabilities were initially recognised upon the adoption of IFRS 16 – Leases on 1 January 2017.

	31 December 2019 RMB'000	31 December 2018 RMB'000
Within one year	278,241	142,678
In the second year	206,418	121,434
In the third to fifth year (inclusive)	96,153	204,847
Over five years	28,577	59,059
Total	<u>609,389</u>	<u>528,018</u>

(XV) COLLATERAL AND PLEDGED ASSETS

As of 31 December 2019, the Group's pledged assets in relation to borrowings including trade receivables and other receivables of RMB8.1 million and fixed assets (machine equipment and electronic equipment) of RMB117.7 million.

(XVI) KEY FINANCIAL RATIOS

	31 December 2019	31 December 2018
Current ratio ⁽¹⁾ :	277.3%	203.8%
Quick ratio ⁽²⁾ :	263.7%	199.0%
Gearing ratio ⁽³⁾ :	N/A⁽⁴⁾	N/A ⁽⁴⁾

Notes:

- (1) Current ratio is calculated as current assets divided by current liabilities as of 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 and 31 December 2018 as the Group's balance of cash and cash equivalents exceeded the Group's total indebtedness on that date.

(XVII) MATERIAL INVESTMENT

In order to satisfy the expected market demand of 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. The Group expects the Songjiang Second Plant to support our future global commercial needs when fully operational.

The Company is expected to invest not more than RMB1 billion for the construction of the Phase I project of Songjiang Second Plant (first 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 Songjiang Second Plant will be mainly funded through debt financing.

For details of the Songjiang Second Plant, please refer to the section headed “Business Review – Forward-looking Production Capacity Layout with High Cost-efficiency”. Save as disclosed in this announcement, as of 31 December 2019, the Group did not make other significant investments.

(XVIII) CAPITAL COMMITMENTS AND CAPITAL EXPENDITURES

	31 December 2019 RMB'000	31 December 2018 RMB'000
Plant and machinery	146,439	41,980
Construction in progress	36,143	1,787
Electronic equipment	15,990	13,855
Leasehold improvements	32,686	15,270
Others	–	509
Total	<u>231,258</u>	<u>73,401</u>

We had capital commitments for plant and machinery contracted but not provided for of RMB496.4 million as of 31 December 2019. These capital commitments primarily relate to expenditures expected to be incurred for the purchase of machinery, renovation of our existing laboratories and buildings.

(XIX) CONTINGENT LIABILITIES

As of 31 December 2019, the Group did not have any significant contingent liabilities.

(XX) MATERIAL ACQUISITIONS AND DISPOSALS

As of 31 December 2019, the Group did not have material acquisitions and disposals.

(XXI) DIVIDENDS

The Company did not pay or declare any dividend during the two years ended 31 December 2019 and 31 December 2018.

IV. RISK MANAGEMENT

(I) FOREIGN EXCHANGE RISK

As of 31 December 2019, the Group is principally engaged in business in the People's Republic of China (“**PRC**”), in which most of the transactions are 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. Following the listing, the Group may also maintain a significant portion of the proceeds from the offering in HKD to put them into operation in the future. Furthermore, with the acceleration of the Group's development in overseas markets, it is expected 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 commercialised products and products that may be commercialised in the future face competition from pharmaceutical companies around the world on various factors such as treatment indication, drug novelty, drug quality and reputation, breadth of our 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 market new products and technologies that meet market needs in a timely manner to capture market share.

2. *Business and Operational Risk*

The global biologics market is constantly evolving, and the Group invests significant amounts of human and capital resources to develop, enhance or acquire technologies that will allow the Group to enhance the scope and quality of our services. Most of the Group's drug candidates are 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, there can be no assurance from the Group of the development and clinical results. Furthermore, if the clinical development and regulatory approval process of our drug candidates were delayed or terminated, the successful development and commercialisation of the Group's drug candidates in a timely manner maybe adversely affected.

3. *Potential Risks of Novel Coronavirus*

The epidemic of COVID-19 may have potential impacts on the Group's business, including but not limited to the advancement of clinical trials, 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 2019:

Function	Number of employees
Management and administrative	135
R&D	326
Quality and technical support	193
Manufacturing	245
Clinical medical affairs	220
Commercial Operation	53
Total	1,172

The Group enters into individual employment contracts with our employees setting out terms such as salaries, bonuses, grounds for termination and confidentiality. Employment contracts with our R&D personnel also typically contain a non-competition clause. The Group also provides benefits to our employees as part of their compensation package which we believe is in line with industry norm. 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, ongoing objective for the employees. All employees participate in formal training on an annual basis, where the Group focuses on the latest technical developments and updates in regulatory requirements.

COMMUNICATION WITH SHAREHOLDERS AND INVESTORS

The Group is committed to creating two-way channels of communication between senior management and investors, maintaining close relations with the shareholders of the Company (“**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 (“**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 (“**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 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

Since the date of listing, 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.

Since the date of listing, the Company has complied with all applicable 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 from the date of listing.

WORK SCOPE OF AUDITORS

The financial figures in respect of the Group's consolidated statement of financial position, consolidated statement of profit or loss and other comprehensive income and the related notes thereto for the year ended 31 December 2019 as set out in the preliminary announcement have been compared by the Group's auditor, Ernst & Young, Certified Public Accountants, to the amounts set out in the Group's consolidated financial statements for the year. The work performed by Ernst & Young in this respect did not constitute an assurance engagement in accordance with Hong Kong Standards on auditing, Hong Kong Standards on Review Engagements or Hong Kong Standards on Assurance Engagements issued by the Hong Kong Institute of Certified Public Accountants and consequently, no assurance has been expressed by Ernst & Young on this preliminary announcement.

AUDIT COMMITTEE

The audit committee of the Company has reviewed the Group's 2019 annual results and the financial statements for the year ended 31 December 2019 prepared in accordance with the IFRSs.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS

Year ended 31 December 2019

		2019	2018
	<i>Notes</i>	<i>RMB'000</i>	<i>RMB'000</i>
REVENUE	3	90,929	7,421
Cost of sales		<u>(71,821)</u>	<u>(5,398)</u>
Gross profit		19,108	2,023
Other income and gains	4	24,674	30,308
Selling and distribution expenses		(45,689)	–
Administrative expenses		(174,834)	(109,050)
Impairment losses on financial assets		(5,300)	–
Research and development expenses		(607,827)	(365,382)
Other expenses		(36,635)	(223)
Finance costs	6	<u>(48,307)</u>	<u>(57,896)</u>
LOSS BEFORE TAX	5	(874,810)	(500,220)
Income tax expense	7	<u>(655)</u>	<u>(4,569)</u>
LOSS FOR THE YEAR		<u>(875,465)</u>	<u>(504,789)</u>
Attributable to:			
Owners of the parent		(875,465)	(493,686)
Non-controlling interests		<u>–</u>	<u>(11,103)</u>
		<u>(875,465)</u>	<u>(504,789)</u>
Loss per share attributable to ordinary equity holders of the parent:	9		
Basic and diluted (<i>RMB</i>)		<u>(1.76)</u>	<u>(1.16)</u>

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME*Year ended 31 December 2019*

	2019 <i>RMB'000</i>	2018 <i>RMB'000</i>
LOSS FOR THE YEAR	<u>(875,465)</u>	<u>(504,789)</u>
OTHER COMPREHENSIVE (LOSS)/INCOME		
Other comprehensive (loss)/income that may be reclassified to profit or loss in subsequent periods:		
Exchange differences:		
Exchange differences on translation of foreign operations	(1,180)	656
Reclassification adjustments for a foreign operation disposed of during the year	1,024	—
OTHER COMPREHENSIVE (LOSS)/INCOME FOR THE YEAR, NET OF TAX	<u>(156)</u>	<u>656</u>
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	<u>(875,621)</u>	<u>(504,133)</u>
Attributable to:		
Owners of the parent	(875,621)	(491,533)
Non-controlling interests	<u>—</u>	<u>(12,600)</u>
	<u>(875,621)</u>	<u>(504,133)</u>

CONSOLIDATED STATEMENT OF FINANCIAL POSITION*31 December 2019*

	<i>Notes</i>	2019 <i>RMB'000</i>	2018 <i>RMB'000</i>
NON-CURRENT ASSETS			
Property, plant and equipment		500,713	323,979
Intangible assets		2,175,149	1,382,572
Right-of-use assets		356,678	170,822
Other non-current assets		206,578	130,432
Total non-current assets		3,239,118	2,007,805
CURRENT ASSETS			
Inventories		129,871	25,203
Trade and bills receivables	<i>10</i>	29,830	6,821
Prepayments, deposits and other receivables		196,347	89,947
Pledged deposits		3,559	6,024
Cash and cash equivalents		2,301,092	958,990
Total current assets		2,660,699	1,086,985
CURRENT LIABILITIES			
Trade and bills payables	<i>11</i>	240,158	85,309
Other payables and accruals		409,199	296,348
Contract liabilities		32,039	9,108
Interest-bearing bank and other borrowings		278,241	142,678
Total current liabilities		959,637	533,443
NET CURRENT ASSETS		1,701,062	553,542
TOTAL ASSETS LESS CURRENT LIABILITIES		4,940,180	2,561,347

	2019 <i>RMB'000</i>	2018 <i>RMB'000</i>
NON-CURRENT LIABILITIES		
Interest-bearing bank and other borrowings	331,148	385,340
Contract liabilities	572,515	335,347
Deferred income	36,102	38,111
Total non-current liabilities	939,765	758,798
Net assets	4,000,415	1,802,549
EQUITY		
Share capital	543,495	474,433
Reserves	3,456,920	1,328,116
Equity attributable to owners of the parent and total equity	4,000,415	1,802,549

NOTES TO FINANCIAL STATEMENTS

1.1 BASIS OF PREPARATION

These financial statements have been prepared in accordance with 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 RMB, and all values are rounded to the nearest thousand except when otherwise indicated.

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 2019. 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 has directly disposed of the related assets or liabilities.

1.2 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

Pursuant to the Accountants' Report of the Group in connection with the listing of the shares of the Company on the Stock Exchange, all IFRSs effective for the accounting period commencing from 1 January 2019 set below had been early adopted by the Group in the preparation of the consolidated statements of profit or loss, statements of comprehensive income, statements of changes in equity and statements of cash flows of the Group for each of the years ended 31 December 2017 and 2018 and the three months ended 31 March 2019, and the consolidated statements of financial position of the Group and the statements of financial position of the Company as at 31 December 2017 and 2018 and 31 March 2019. Thus, the effectiveness of the below accounting policies and disclosures have no impact to the Group's financial statements for the year end of 31 December 2019.

Amendments to IFRS 9	<i>Prepayment Features with Negative Compensation</i>
IFRS 16	<i>Leases</i>
Amendments to IAS 19	<i>Plan Amendment, Curtailment or Settlement</i>
Amendments to IAS 28	<i>Long-term Interests in Associates and Joint Ventures</i>
IFRIC-Int 23	<i>Uncertainty over Income Tax Treatments</i>
<i>Annual Improvements to IFRSs</i> <i>2015-2017 Cycle</i>	Amendments to IFRS 3, IFRS 11, IAS 12 and IAS 23

1.3 ISSUED BUT NOT YET EFFECTIVE HONG KONG 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	<i>Definition of a Business¹</i>
Amendments to IFRS 9, IAS 39 and IFRS 7	<i>Interest Rate Benchmark Reform¹</i>
Amendments to IFRS 10 and IAS 28	<i>Sale or Contribution of Assets Between and Investor and its Associate or Joint Venture⁴</i>
IFRS 17	<i>Insurance Contracts²</i>
Amendments to IAS 1 and IAS 8	<i>Definition of Material¹</i>
Amendments to IAS 1	<i>Classification of Liabilities as Current or Non-current³</i>

¹ Effective for annual periods beginning on or after 1 January 2020

² Effective for annual periods beginning on or after 1 January 2021

³ Effective for annual periods beginning on or after 1 January 2022

⁴ No mandatory effective date yet determined but available for adoption

These issued but not yet effective IFRSs are not expected to have any significant impact on the Group's consolidated financial statements in the future.

2. OPERATING SEGMENT INFORMATION

The Group is engaged in biopharmaceutical research, biopharmaceutical service 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

	2019 <i>RMB'000</i>	2018 <i>RMB'000</i>
Mainland China	88,312	3,724
Overseas	<u>2,617</u>	<u>3,697</u>
	<u>90,929</u>	<u>7,421</u>

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

(b) Non-current assets

	2019 <i>RMB'000</i>	2018 <i>RMB'000</i>
Mainland China	3,223,215	1,990,671
Overseas	<u>15,903</u>	<u>17,134</u>
	<u>3,239,118</u>	<u>2,007,805</u>

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

3. REVENUE

An analysis of the Group's revenue from contracts with customers is as follows:

Revenue from contracts with customers

(a) Revenue information

	2019 RMB'000	2018 RMB'000
Type of goods or service		
Sales of biopharmaceutical products	78,951	—
License revenue	8,578	—
Research and development services	3,400	7,421
	<u>90,929</u>	<u>7,421</u>
Total revenue from contracts with customers	<u>90,929</u>	<u>7,421</u>
Timing of revenue recognition		
Transferred at a point in time	79,734	7,421
Transferred over time	11,195	—
	<u>90,929</u>	<u>7,421</u>
Total revenue from contracts with customers	<u>90,929</u>	<u>7,421</u>

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:

	2019 RMB'000	2018 RMB'000
Revenue recognised that was included in contract liabilities at the beginning of the Reporting Period:		
License revenue	8,578	—

(b) Performance obligations

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

Sales of biopharmaceutical products

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

License revenue

The performance obligation satisfied overtime during the expected commercialization period after the Group obtain the commercialization authorization from the local authorities. Payment in advance is normally required.

Research and development services

Based on the terms of the contract, the performance obligation is satisfied over time as services are rendered or at a point in time as services are completed and accepted. Payment in advance is normally required.

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

	2019 RMB'000	2018 <i>RMB'000</i>
Amounts expected to be recognised as revenue:		
Within one year	32,039	9,108
After one year	652,276	335,347
	684,315	344,455

The remaining performance obligations expected to be recognised after one year mainly relate to the transaction prices allocated to license and research and development service. The license revenue is expected to be recognised during the future estimated commercialized period. The revenue of research and development is expected to be recognised during the period of rendering of service. The amounts disclosed above do not include variable consideration.

4. OTHER INCOME AND GAINS

	2019 RMB'000	2018 <i>RMB'000</i>
Interest income	16,062	5,208
Government grants	7,448	15,886
Exchange gains	–	8,927
Reclassification adjustments for a foreign operation disposed of during the year	1,024	–
Others	140	287
	24,674	30,308

5. LOSS BEFORE TAX

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

	2019 <i>RMB'000</i>	2018 <i>RMB'000</i>
Cost of sales	71,821	5,398
Depreciation of property, plant and equipment*	38,858	22,606
Depreciation of right-of-use assets*	27,704	19,700
Amortisation of intangible assets*	15,937	662
Research and development expenses:		
Current year expenditure	607,827	365,382
Lease payments under short-term leases and leases of low-value assets	249	124
IPO listing expenses	18,443	15,897
Auditor's remuneration	1,750	250
Employee benefit expense (including directors' and chief executive's remuneration (note 9)):		
Wages and salaries	206,754	101,207
Staff welfare expenses	39,159	25,195
Share-based payment expense*	97,117	71,686
Foreign exchange loss/(gain)	32,283	(8,927)
Impairment losses on financial assets	5,300	–
Bank interest income	(16,062)	(5,208)
Loss on disposal of items of property plants and equipment	11	111

* The depreciation of property, plant and equipment, the depreciation of right-of-use asset, 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:

	2019 <i>RMB'000</i>	2018 <i>RMB'000</i>
Interest expense on bank and other borrowings	36,208	7,518
Interest expense on lease liabilities	12,099	12,261
Interest expense on entrusted loans from a related party	–	38,117
	<u>48,307</u>	<u>57,896</u>

7. INCOME TAX EXPENSE

The provision for Mainland China current income tax is based on the statutory rate of 25% (2018: 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.

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 Henlix Biotech Co., Ltd, a subsidiary of the Group incorporated in Taiwan, is based on the statutory rate of 19% (2018: 18%) for the year ended 31 December 2019.

	2019 <i>RMB'000</i>	2018 <i>RMB'000</i>
Current – Mainland China	655	3,380
Current – Elsewhere	–	1,189
Total tax charged for the year	655	4,569

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 497,157,841 (2018: 426,598,066) 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 the basic and diluted earnings per share are based on:

	2019 <i>RMB'000</i>	2018 <i>RMB'000</i>
Loss		
Loss attributable to ordinary equity holders of the parent, used in the basic earnings per share calculation	(875,465)	(493,686)

	Number of shares	
	2019	2018
Shares		
Weighted average number of ordinary shares in issue during the year used in the basic loss per share	497,157,841	426,598,066
Effect of dilution – weighted average number of ordinary shares:		
Restricted Shares under share award scheme	–	–
	497,157,841	426,598,066

Because the diluted loss per share amount is decreased when taking restricted shares issued under 2018 share award scheme into account the restricted shares had an anti-dilutive effect on the basic loss per share for the year and were ignored in the calculation of diluted earnings per share.

10. TRADE AND BILLS RECEIVABLES

	2019	2018
	<i>RMB' 000</i>	<i>RMB' 000</i>
Trade receivables	35,130	5,821
Bills receivables	–	1,000
Impairment	(5,300)	–
	29,830	6,821

Trade and bills receivables are non-interest-bearing.

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

	2019	2018
	<i>RMB' 000</i>	<i>RMB' 000</i>
Within 3 months	29,830	1,521
3 to 6 months	–	–
6 to 9 months	–	–
9 to 12 months	–	–
1 to 2 years	–	5,300
	29,830	6,821

11. TRADE AND BILLS PAYABLES

	2019 <i>RMB' 000</i>	2018 <i>RMB' 000</i>
Trade payables	236,599	79,285
Bills payables	<u>3,559</u>	<u>6,024</u>
	<u>240,158</u>	<u>85,309</u>

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 invoice date, is as follows:

	2019 <i>RMB' 000</i>	2018 <i>RMB' 000</i>
Within 1 year	239,957	85,299
1 to 2 years	<u>201</u>	<u>10</u>
	<u>240,158</u>	<u>85,309</u>

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 2019 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, 23 March 2020

As at the date of this announcement, the board of directors of the Company comprises Dr. Scott Shi-Kau Liu 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.