LEPU BIOPHARMA CO., LTD.
樂普生物科技股份有限公司

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

(Stock Code: 2157)

ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED DECEMBER 31, 2022

The Board is pleased to announce the audited consolidated annual results of the Group for the year ended December 31, 2022, together with the comparative figures of 2021.

BUSINESS HIGHLIGHTS

Our product pipeline and business operations have made significant progress last year:

- **HX008:** We received an approval of PUYOUHENG (Pucotenlimb Injection) from NMPA in MSI-H/dMMR solid tumors in July 2022 and an approval in melanoma in September 2022. We then initiated the marketing and commercialization process and achieved sales of RMB15.6 million for the year ended December 31, 2022.

- **MRG003:** MRG003 has been granted ODD from FDA and BTD from CDE in September 2022 for the treatment of NPC. In November 2022, the encouraging data from the Phase II clinical study of MRG003 for the treatment of NPC was disclosed on the annual conference of CSCO 2022. We are conducting a Phase II clinical study of MRG003 in HNSCC and have obtained approval of a Phase III clinical study in HNSCC from CDE in October 2022.

- **MRG002:** We are conducting a registrational Phase II clinical study of MRG002 in HER2 over-expressing BC and have observed encouraging data. We have obtained approval of a Phase III clinical study of MRG002 in UC from CDE in September 2022. In August 2022, MRG002 has been granted ODD from FDA for the treatment of GC/GEJ.

- **MRG004A:** We have initiated the Phase I/II clinical study of MRG004A in solid tumors in China with FPI in October 2022. We have observed efficacy signal on PC and TNBC.

- **CMG901:** We observed encouraging preliminary data from the Phase Ia clinical study and initiated a Phase Ib clinical study of CMG901 in China with FPI in May 2022. CMG901 has been granted the Fast Track Designation and ODD from the FDA in April 2022 for the treatment of GC/GEJ. Furthermore, CMG901 obtained BTD from CDE in September 2022 for the same indication.

– **Combination therapy of MRG003 with HX008:** We are conducting a Phase I trial of combination therapy with MRG003 and HX008 in the treatment of patients with EGFR positive solid tumors with FPI in July 2022. We have observed encouraging preliminary data.

– **Combination therapy of MRG002 with HX008:** We are conducting a Phase I trial of combination therapy with MRG002 and HX008 in the treatment of patients with HER2 expressing solid tumors. We have observed encouraging preliminary data.

KEY EVENTS AFTER THE REPORTING PERIOD

– **MRG003:** We obtained approval for registrational Phase IIb clinical study in NPC from CDE in January 2023.

– **MRG002:** We have completed patient enrollment for registrational Phase II trial of MRG002 on HER2 over-expressing BC. We expect to file NDA in 2023.

– **CMG901:** In January 2023, the encouraging data from the Phase Ia trial of CMG901 in solid tumors was presented at 2023 American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO GI 2023). KYM, a joint venture formed by us and Keymed, has entered into an exclusive license agreement with AstraZeneca for CMG901 in February 2023.

– **Combination therapy of CG0070 with HX008:** We received an IND approval from the NMPA for a Phase I trial of combination therapy with CG0070 and HX008 in the treatment of patients with BCG-unresponsive NMIBC in January 2023.

FINANCIAL HIGHLIGHTS

– Revenue was approximately RMB15.6 million for the year ended December 31, 2022 and the gross profit was approximately RMB13.6 million.

– Cash and cash equivalents amounted to approximately RMB669.4 million as at December 31, 2022.

– Research and development expenses decreased by approximately 33.7% from approximately RMB791.2 million for the year ended December 31, 2021 to approximately RMB524.3 million for the year ended December 31, 2022.

– Administrative expenses decreased by approximately 11.1% from approximately RMB156.2 million for the year ended December 31, 2021 to approximately RMB138.8 million for the year ended December 31, 2022.

– Loss for the year attributable to the owners of the Company decreased by approximately 31.8% from approximately RMB1,011.0 million for the year ended December 31, 2021 to approximately RMB689.1 million for the year ended December 31, 2022.

MANAGEMENT DISCUSSION AND ANALYSIS

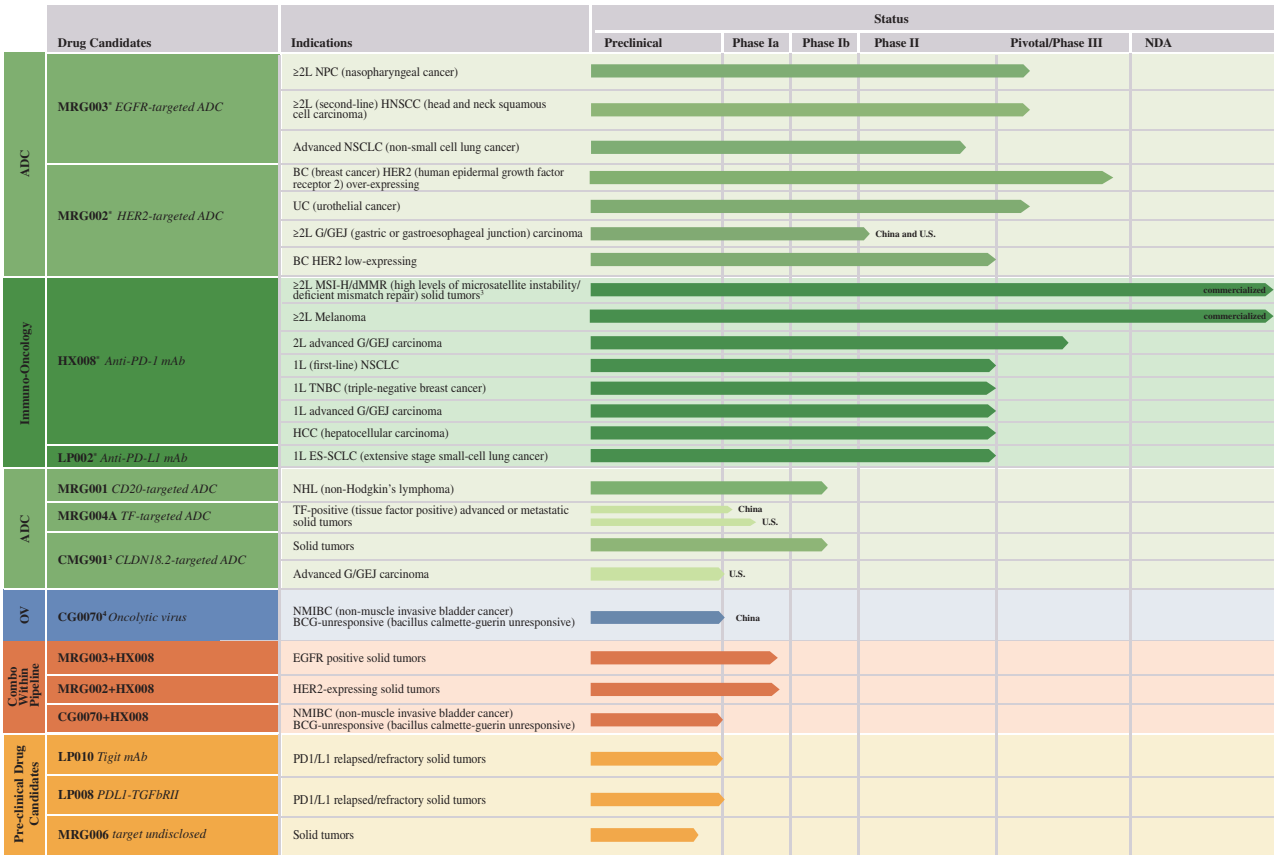
OVERVIEW

We are an innovation-driven biopharmaceutical company focusing on oncology therapeutics, in particular, drug candidates in anti-tumor targeted therapy and oncology immunotherapy, with a strong China foundation and global vision. Since our inception, we are dedicated to promoting the technological advancement of innovative ADCs in China, establishing an advanced and systematic ADC technology development platform, and developing more optimal and innovative drugs to better serve the unmet medical needs of cancer patients. We endeavor to continuously develop a market-differentiating pipeline by combining in-house research and development and strategic collaborations, strengthen our in-house manufacturing capabilities and commercialize our pipeline products in China through dedicated sales and marketing forces and internationally via partnerships. Since our inception, we have established an integrated end-to-end platform across drug discovery, clinical development, CMC and GMP-compliant manufacturing, encompassing all critical functions of the biopharmaceutical value chain, and are building dedicated sales and marketing forces.

We have strategically designed our pipeline with a range of oncology products. For clinical-stage candidates, we have (i) one clinical/commercialization-stage drug candidate; (ii) seven clinical-stage drug candidates, including one co-developed through a joint venture; and (iii) three clinical-stage combination therapies of our candidates. One of our drug candidates has obtained marketing approval with respect to two of its targeted indications, with clinical trials for other indications ongoing. Among the seven clinical-stage drug candidates, five are targeted therapeutics and two are immunotherapeutics, with one being an immune checkpoint drug and the other one being an oncolytic virus drug. We have initiated multiple clinical trials, amongst which two are ongoing in the US, and five have entered the stage of registrational trials in the PRC. MRG003 was granted ODD from FDA and BTD from CDE. MRG002 was granted ODD from FDA. CMG901 was granted the Fast-Track Designation and ODD from FDA, and obtained BTD from CDE.

PRODUCT PIPELINE

The following chart illustrates our pipeline and summarizes the development status of our clinical-stage and pre-clinical drug candidates:



Notes:

1. * denotes the Core Products.
2. Unless otherwise stated, the progress shown under the "Status" column refers to the clinical development progress of the relevant drug candidate and combination therapy in China.
3. In February 2023, KYM has entered into a global exclusive out-license agreement with AstraZeneca AB to grant an exclusive global license for research, development, registration, manufacturing and commercialization of CMG901 to AstraZeneca AB. Please refer to section headed "Key Events after the Reporting Period" in this announcement.
4. The clinical trial of CG0070 in the U.S. is conducted by CG Oncology, a third-party business partner with whom we have a licensed-in arrangement to develop, manufacture and commercialize CG0070 in Mainland China.

BUSINESS REVIEW

For the year ended December 31, 2022 and up to the date of this announcement, the Group has made the following significant progress:

HX008

- HX008 is a humanized IgG4 mAb against human PD-1, which can antagonize the PD-1 signal to restore the capability of the immune cells to kill cancer cells through blocking PD-1 binding to their ligands PD-L1 and PD-L2.

- In July and September 2022, the NMPA granted conditional marketing approval for HX008 for the treatment of MSI-H/dMMR and inoperable or metastatic melanoma, respectively. We then initiated the marketing and commercialization process and achieved sales of RMB15.6 million for the year ended December 31, 2022. Furthermore, in January 2022, we obtained IND clearance for HX008 in the US.

    - **MSI-H/dMMR solid tumors:** NMPA granted conditional marketing approval for HX008 for the treatment of MSI-H/dMMR in China in July 2022. We are conducting an open label, multi-center and randomized Phase III clinical trial in first-line MSI-H/dMMR metastatic colorectal cancer as a confirmatory clinical study.

    - **Melanoma:** NMPA granted conditional marketing approval for HX008 for the treatment of inoperable or metastatic melanoma in China in September 2022. We are conducting an open label, multi-center and randomized Phase III clinical trial in first-line treatment of subjects with stage IV (M1c) melanoma as a confirmatory clinical study.

    - **GC/GEJ in second-line therapy:** We are conducting a multi-center, randomized, double-blinded and placebo-controlled Phase III clinical study of HX008 in combination therapy with irinotecan. As of December 31, 2022, patient enrollment is ongoing.

    - **Other indications:** We are in the follow-up period for various Phase II clinical trials of HX008 in NSCLC, TNBC and HCC.

MRG003

- MRG003 is an ADC comprised of an EGFR-targeted mAb conjugated with the potent microtublin disrupting payload MMAE via a vc linker. It binds specifically with high affinity to human EGFR on the surface of tumor cells, releases the potent payload upon internalization and lysosomal protease cleavage of the linker and results in tumor cell death.

- We are strategically focusing on clinical investigations for HNSCC and NPC, which have demonstrated promising efficacy and indicated potential to serve the particularly significant unmet medical needs. CDE has granted MRG003 BTD for the treatment of NPC in September 2022. In the same month, MRG003 has been granted ODD from the FDA for the treatment of NPC. In October 2022, we have obtained approval of a Phase III clinical study of MRG003 in HNSCC.

- **NPC:** We are conducting an open-label, single-arm, multi-center Phase II clinical study of MRG003. We have completed patient enrollment of IIa stage in March 2022 and have entered the follow-up period. We have observed encouraging data. Such data of Phase II clinical study of MRG003 for the treatment of NPC was disclosed on the annual conference of CSCO 2022. As of August 24, 2022, the ORR was 47.4% and DCR was 79.0%. For 2.0mg/kg dose group, the ORR was 39.3% and DCR was 71.4%. The PFS and three-month PFS ratio in this group was 6.3 month and 62.3%, respectively. For 2.3mg/kg dose group, the ORR was 55.2% and DCR was 86.2%. The three-month PFS ratio in this group was 88.7%. Based on the promising data of MRG003 on NPC, CDE has granted MRG003 BTD for the treatment of NPC in September 2022. In the same month, MRG003 has been granted ODD from the FDA for the treatment of NPC.

- **HNSCC:** We are conducting an open-label, single-arm, multi-center Phase II clinical study of MRG003. We have completed patient enrollment in February 2022 and have entered the follow-up period with promising data. Based on the Phase I and Phase II data, CDE has approved MRG003 in a Phase III clinical study of HNSCC in October 2022.

- **NSCLC:** We are conducting Phase II clinical trials in patients with advanced NSCLC.

– For development progress of MRG003 after the Reporting Period, please refer to section headed "Key Events after the Reporting Period" below.

– **Warning: There is no assurance that the MRG003 will ultimately be successfully developed and marketed by the Company. Shareholders and potential investors are advised to exercise caution when dealing in the Shares.**

MRG002

– MRG002 is an innovative ADC targeting HER2, a molecular target abnormally overexpressed in many cancer types including BC, UC, GEJ and GC. Our clinical development strategy for MRG002 in China aims at realizing the efficacy potential of MRG002 in various prevalent malignancies, especially for second- or later-line systemic therapy of BC, UC and GC/GEJ. We are currently conducting clinical trials in aforementioned indications, including a registrational Phase II clinical trial in HER2 over-expressing BC and we are also initiating a Phase III clinical study in UC. In August 2022, MRG002 for the treatment of GC/GEJ cancer has been granted ODD from the FDA.

- **HER2 over-expressing BC:** We are currently conducting a registrational Phase II clinical trial for MRG002 in HER2 over-expressing BC in China and have observed encouraging data.

- **UC:** We are conducting an open label, single-arm, multi-center Phase II trial of MRG002 in HER2-positive inoperable locally advanced or metastatic HER2-expressing UC (including bladder, renal pelvis, ureter and urethral orifice) with prior treatment of first-line systemic chemotherapy. We have completed patient enrollment in February 2022 and have entered the follow-up period with encouraging data observed. Such data was disclosed on the annual conference of CSCO 2022. As of October 12, 2022, for the ITT population, the investigator-assessed ORR rate was 56.1%, CR was 7.3%, and

DCR was 87.8%, with a median PFS of 6.4 months. On the other hand, the ORR rate in the sub group that failed platinum-containing chemotherapy and PD-(L)1 treatment was 57.1%. The median PFS in this subgroup was 7.0 months. Based on such encouraging data, we have obtained an approval of Phase III clinical study from CDE in September 2022.

- o **GC/GEJ:** We are conducting an open-label, multi-center Phase II study of MRG002 in HER2-positive/low-expressing GC/GEJ patients in China with enrollment ongoing as of December 31, 2022. In the US, the patient enrollment for Phase I/II clinical trials for MRG002 in HER2-positive, locally advanced or metastatic GC/GEJ is ongoing as of December 31, 2022. In August 2022, MRG002 has been granted the ODD from the FDA for the treatment of GC/GEJ.

- o **HER2 low-expressing BC:** We are conducting an open-label, multi-center Phase II clinical trial in HER2 low-expressing BC. The patient enrollment has completed and we have entered the follow-up period.

– For development progress of MRG002 after the Reporting Period, please refer to section headed "Key Events after the Reporting Period" below.

– **Warning: There is no assurance that the MRG002 will ultimately be successfully developed and marketed by the Company. Shareholders and potential investors are advised to exercise caution when dealing in the Shares.**

LP002

– LP002 is a humanized anti-PD-L1 mAb with unique targeted epitope, which employs IgG1 isotype with aglycosylated mutation. It has demonstrated favorable safety and efficacy in clinical trials, which serves as the basis for the further development of combination therapies with immunotherapy.

- o **ES-SCLC:** We have completed the patient enrollment for a single-arm, open-label Phase II clinical study of LP002 in combination therapy with carboplatin and etoposide in July 2022. It has entered the follow-up period and encouraging data have been observed. Based on such encouraging efficacy data in ES-SCLC clinical study, we have obtained approval from the NMPA regarding potentially initiating a Phase III clinical trial.

– **Warning: There is no assurance that the LP002 will ultimately be successfully developed and marketed by the Company. Shareholders and potential investors are advised to exercise caution when dealing in the Shares.**

Combination Therapies Involving our Product Candidates

– **MRG003+HX008:** We obtained the IND approval in January 2022. We are conducting a Phase I trial of combination therapy with MRG003 and HX008 in the treatment of patients with EGFR positive solid tumors with FPI in July 2022. We have observed encouraging preliminary data.

– **MRG002+HX008:** We are conducting a Phase I clinical study of MRG002 and HX008 combination therapy in HER2 positive solid tumors. We have observed encouraging preliminary data.

– For development progress of combination therapies involving our product candidates after the Reporting Period, please refer to section headed "Key Events after the Reporting Period" below.

Other Clinical-stage Drug Candidates

– **MRG001:** MRG001 is a clinically advanced CD20-targeted ADC to address medical needs of B-cell NHL patients with either primary drug resistance to rituximab or acquired drug resistance to the combination therapy of rituximab and standard chemotherapies. We are conducting a Phase Ib dose expansion study of MRG001 in China.

– **MRG004A:** MRG004A is a novel TF-targeted site-specifically conjugated ADC. We are currently conducting the dose escalation trial in the US and we are conducting an open-label, multi-center Phase I/II clinical trials in China with FPI in October 2022. We have observed efficacy signal on PC and TNBC and will continue to explore the potential clinical value of MRG004A.

– **CMG901**: CMG901 is a CLDN 18.2-targeting ADC comprising a CLDN 18.2-specific antibody, a cleavable linker and a toxic payload, MMAE. It is the first CLDN 18.2 ADC to have received IND clearance both in China and the U.S. CLDN 18.2 is selectively and widely expressed in GC, PC and other solid tumors, which makes it an ideal tumor target for therapeutic development. It is being co-developed by us and Keymed through a joint venture, KYM. We have completed the patient enrollment of dose-escalation stage of a Phase I clinical trial of CMG901 and we have observed encouraging preliminary data. Furthermore, we also initiated the dose-expansion stage of a Phase I clinical trial of CMG901 in subjects with solid tumors in China in May 2022. CMG901 has been granted the Fast Track Designation and ODD from the FDA in April 2022 for the treatment of GC/GEJ. Furthermore, CMG901 obtained BTD from CDE in September 2022 for the same indication. For details of the data of the Phase Ia clinical study of CMG901, please refer to section headed "Key Events after the Reporting Period" below.

– **CG0070:** CG0070 is an oncolytic adenovirus for the treatment of BCG unresponsive bladder cancer patients and is currently in Phase III clinical study conducted by our partner, CG Oncology, in the US. We in-licensed CG0070 from CG Oncology and were granted the rights to develop, manufacture and commercialize it in greater China including Mainland China, Hong Kong and Macau. We are initiating a Phase I clinical trial in China as of December 31, 2022.

– **Warning: There is no assurance that the MRG001, MRG004A, CMG901 and CG0070 will ultimately be successfully developed and marketed by the Company. Shareholders and potential investors are advised to exercise caution when dealing in the Shares.**

Manufacturing Facilities

We have been operating a 2,000L GMP-compliant bioreactor production line at our Beijing manufacturing plant, and during the Reporting Period, it mainly supported the production of clinical samples. We have also been building a manufacturing facility for oncolytic virus products in Beijing with a designed capacity of 200L.

During the Reporting Period, we have also been building the phase one of the manufacturing facilities in the Shanghai Biotech Park, which has a designed total capacity of 12,000L and of which the first production line with capacity of 6,000L is under construction. In October 2022, our research and development center in Shanghai Biotech Park was put into operation.

Commercialization

After obtaining marketing approval of PUYOUHENG (Pucotenlimb Injection) in the second half of 2022, we have initiated the marketing and commercialization process in November 2022 and we have already generated revenue in the amount of RMB15.6 million from its sales by December 31, 2022.

We are building up a highly efficient sales and market team based on our commercialized product, PUYOUHENG (Pucotenlimb Injection). Our commercialization team is mainly responsible for developing strategies for product promotion, product positioning and brand management, establishing a good brand image in the market through academic promotion activities and product education to increase product awareness among leading physicians and patient population. On sales channel establishment, we actively develop cooperative relationships with various business channel partners. As of December 31, 2022, we have already established sales channels covering 18 provinces and 38 cities, and we will further expand and deepen our sales network.

Proposed Issue of A Shares and Listing on the Sci-Tech Innovation Board of the Shanghai Stock Exchange

On September 1, 2022, the Company announced that it proposed to apply to the relevant PRC regulatory authorities for the allotment and issuance of not more than 414,861,209 A Shares, and proposed to apply to the Shanghai Stock Exchange for the listing and trading of A Shares on the Sci-Tech Board of the Shanghai Stock Exchange. On September 23, 2022, the Shareholders considered and approved the issuance of no more than 414,861,209 A Shares and the application to the Shanghai Stock Exchange for the listing of A Shares on the Sci-Tech Board and relevant matters in the 2022 first extraordinary general meeting, the 2022 first class meeting of H Shareholders and the 2022 first class meeting of Domestic Shareholders. The proposed issuance of A Shares is subject to, amongst other things, approval from the Shanghai Stock Exchange and registration with the China Securities Regulatory Commission.

KEY EVENTS AFTER THE REPORTING PERIOD

Development Progress of our Drug Candidates After the Reporting Period

- **MRG003:** we have obtained approval for the registrational Phase IIb clinical study for MRG003 in NPC from CDE in January 2023, and we are currently initiating the clinical study with FPI expected in April 2023. We are also initiating a multi-center and randomized Phase III clinical trial of MRG003 in HNSCC and we expect to have FPI in March 2023.

- **MRG002:** In January 2023, we have completed patient enrollment for the registrational Phase II clinical trial of MRG002 in HER2 over-expressing BC in China. We expect to file NDA in 2023. We are initiating an open-label, multi-center Phase III clinical trial in UC in 2023 and expect to have FPI in April 2023.

- **CMG901:** Phase Ia trial of CMG901 was conducted for advanced solid tumors. CMG901 showed a favorable safety and tolerability profile in this trial. Recently, Phase Ia trial data has been presented as a poster at 2023 American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO GI 2023). As of August 4 2022, in CLDN18.2-positive GC/GEJ patients, ORR and DCR were 75.0% and 100%, respectively. Especially, in dose group of 2.6mg/kg, 3.0mg/kg and 3.4 mg/kg, ORR was 100%.

- **Combination therapy of CG0070 with HX008:** We received an IND approval from the NMPA for a Phase I trial of combination therapy with CG0070 and HX008 in the treatment of patients with BCG-unresponsive NMIBC in January 2023. We plan to initiate a Phase I/II clinical study of CG0070 and HX008 combination therapy in BCG-unresponsive NMIBC.

Exclusive License Agreement with AstraZeneca for CMG901

On February 23, 2023, KYM, a joint venture formed by us and Keymed, entered into a global exclusive out-license agreement (the "**License Agreement**") with AstraZeneca to develop and commercialize CMG901, pursuant to which AstraZeneca will be granted an exclusive global license for research, development, registration, manufacturing, and commercialization of CMG901, and shall be responsible for all costs and activities associated with the further development and commercialization of CMG901 except as otherwise agreed. According to the License Agreement and subject to the terms and conditions thereof, KYM shall receive an upfront payment of US$63 million with the potential for additional payments up to US$1,125 million subject to achievement of certain development, regulatory and commercial milestones. KYM is also entitled to receive tiered royalties on net sales from AstraZeneca.

For details of the exclusive license agreement, please refer to the Company's announcement dated February 23, 2023.

THE IMPACT OF COVID-19

Despite the continuous and resurging outbreak of COVID-19 during the year of 2022, the management of the Company expected that clinical trials in and outside Mainland China was not significantly affected. Based on the information available as of the date of this announcement, the Company believes that the outbreak of COVID-19 would not result in a material disruption to the Group's business operations or cause a material impact on the financial position or financial performance of the Group.

In response to the outbreak of COVID-19, we have taken various measures, including but not limited to reducing face-to-face meetings by means of telephone or video conferences; avoiding unnecessary travels and trips for interviews as well as providing face masks, hand sanitizers and other sanitation supplies to minimise the chance of the COVID-19 infection.

Since the end of 2022, with the continuous optimization of the pandemic prevention policy and the implementation of a series of policies of "strengthening confidence, stabilizing economy and promoting development", the Company believes the impact of COVID-19 to the Group's business operations would be further reduced and would not cause a material impact on the financial position or financial performance of the Group.

FUTURE DEVELOPMENT

The Company is an innovation-driven biopharmaceutical company focusing on oncology therapeutics, dedicated to promoting the technological advancement of innovative ADCs in China to better serve the unmet medical needs of cancer patients. We strive to develop and broaden our product pipeline by combining our in-house research with development and strategic collaborations. Looking forward to 2023, we will accelerate the development of our two key ADC products, MRG003 and MRG002, to the next milestones. We will make our best efforts on pushing MRG002 to NDA stage and accelerating the MRG003 registrational clinical studies to prepare for NDA application. We will continue to explore the potential clinical value of MRG004A.

In 2023, we will be working to deepen our efforts on marketing and commercialization and to actively expand our market footprint and product recognition within China. We will expand our commercialization team by recruiting talents with the appropriate skills and expertise in commercialization of pharmaceutical products, and leveraging the expertise and industry connections of our commercialization team and our solid understanding of the Chinese market environment, we will seek to foster our brand's image and market knowledge of our product through various methods, such as academic promotion, KOL engagement and medical education. We believe that these enhancement of our efforts on market outreach would translate into better market access, increased market share and increased sales of our commercialized product and our brand in general, thereby laying a solid market and channel foundation for the future commercialization of our ADC product pipeline.

On the international front, we will step up our efforts for expansion in the global market. As our ADC platform has been endorsed by multi-national companies, we expect our other ADC products to have more promising business development opportunities. We will continue to approach multiple overseas companies and seek the chance for potential business development cooperation.

FINANCIAL REVIEW

Revenue

For the year ended December 31, 2022, we have recorded a revenue of RMB15.6 million (2021: nil) due to the successful commercialization of HX008. Before that, the Group had not commercialized any products and therefore had not generated any revenue from sales of products.

Other Income

The Group's other income primarily consist of (i) government grants to support our research and development activities; (ii) research and development service income; and (iii) sales of raw materials.

Our other income increased from RMB10.6 million in 2021 to RMB11.3 million in 2022, primarily due to an increase in subsidies received from the government.

Selling and Marketing Expenses

For the year ended December 31, 2022, the Group has recorded selling and marketing expenses of RMB1.7 million (2021: nil). This is mainly because the Group has commercialized HX008 during the year and therefore has conducted selling and marketing activities.

Administrative Expenses

Our administrative expenses primarily consist of (i) employee benefit expenses (mainly including wages, salaries and bonuses and share-based payment expenses) relating to our administrative staff; (ii) depreciation and amortization expenses, primarily representing depreciation expenses for right-of-use assets and property, plant and equipment; (iii) listing expenses; and (iv) others, mainly representing utilities as well as traveling and transportation expenses.

Our administrative expenses decreased from RMB156.2 million in 2021 to RMB138.8 million in 2022, primarily due to a decrease in our employee benefit expenses in relation to our administrative staff from RMB87.8 million to RMB60.2 million resulting from a decrease in the share-based payment expenses.

Research and Development Expenses

Our research and development expenses primarily consist of (i) clinical trial and CMC expenses; (ii) pre-clinical study costs; (iii) depreciation and amortization expenses for property, plant and equipment as well as amortization expenses for intangible assets such as intellectual properties; (iv) employee benefit expenses (mainly including wages, salaries and bonuses and share-based payment expenses) relating to our research and development staff; and (v) raw materials and consumables used, primarily representing expenses for procuring raw materials and consumables used in pre-clinical studies and clinical trials. Our research and development expenses decreased from RMB791.2 million in 2021 to RMB524.3 million in 2022. The following table sets forth the components of our research and development expenses for the years indicated.

	Year ended 31 December			
	2022		2021	
	RMB'000	***%***	*RMB'000*	*%*
Clinical trial and CMC expenses	**204,991**	**39.1**	339,472	42.9
Employee benefit expenses	**127,211**	**24.3**	168,406	21.3
Pre-clinical study costs	**71,211**	**13.6**	136,784	17.3
Depreciation and amortization	**72,705**	**13.9**	77,612	9.8
Raw material and consumables used	**34,235**	**6.5**	51,139	6.5
Others	**13,932**	**2.6**	17,797	2.2
Total	**524,285**	**100**	791,210	100

(i) Clinical trial and CMC expenses decreased by RMB134.5 million, mainly due to the prioritization of resources on drug candidates and indications which the Company considers to have the most potential;

(ii) Employee benefits expenses decreased by RMB41.2 million, mainly due to the decrease in share-based payment expenses;

(iii) Pre-clinical study costs decreased by RMB65.6 million, mainly due to some of our drug candidates progressing beyond pre-clinical study stage, hence lowering pre-clinical study costs;

(iv) Depreciation and amortization expenses decreased by RMB4.9 million, mainly due to a decrease in our right-of-use assets;

(v) Raw material and consumable expenses decreased by RMB16.9 million, mainly due to a decrease in the use of raw materials for our research and development activities; and

(vi) Other expenses decreased by RMB3.9 million, mainly due to a decrease in utilities and other miscellaneous expenses.

Fair Value Changes on Financial Liabilities at Fair Value through Profit or Loss

We had fair value changes on financial liabilities at fair value through profit or loss of RMB76.3 million in 2021 and of RMB62.8 million in 2022. Our financial liabilities include financial liabilities at fair value through profit or loss, representing the variable part of the consideration arisen from the acquisition of 40% equity interests of Taizhou Hanzhong from non-controlling interest, being 4.375% of future annual net sales revenue of relevant PD-1 products.

The following table sets forth a breakdown of our fair value changes on financial liabilities at fair value through profit or loss for the years indicated.

	Year ended 31 December	
	2022	2021
	RMB'000	*RMB'000*
Fair value losses on financial liabilities at fair value through profit or loss		
– Fair value through profit or loss	**(62,816)**	(76,285)

Finance Income and Finance Costs

Our finance income primarily represents our bank interest income and foreign exchange gains. Our finance costs primarily consist of interest costs on lease liabilities and borrowings. Our finance income increased from RMB4.1 million in 2021 to RMB45.9 million in 2022, mainly due to foreign exchange gains from the proceeds from the Global Offering for the year ended December 31, 2022. Our finance costs increased from RMB5.7 million in 2021 to RMB8.6 million in 2022, due to an increase in interest costs on borrowings.

Income Tax Expenses

For the years ended December 31, 2021 and 2022, the Group's income tax expenses were nil.

Loss for the Year

Based on the factors described above, the Group's loss decreased from RMB1,028.9 million in 2021 to RMB699.4 million in 2022.

Liquidity and Financial Resources

We have incurred net losses and negative cash flows from operations since inception. Our primary use of cash is to fund our research and development activities. For the year ended December 31, 2022, our net cash used in operating activities was RMB480.9 million. As of December 31, 2022, we had cash and cash equivalent of RMB669.4 million, an increase of RMB514.2 million from RMB155.2 million as of December 31, 2021, primarily due to the combination effect of an increase of fund raised in our financing activities and a decrease in our research and development expenses.

The main sources of the Group's liquidity are equity financing and bank borrowings.

Our bank borrowings are divided into secured loans and unsecured loans. As of December 31, 2022, the Group's bank borrowings amounted to RMB650.0 million, among which unsecured and unguaranteed bank borrowings amounted to RMB329.6 million in total with interest at fixed and floating interest rates. Such borrowing will be repayable within one year.

As of December 31, 2022, the Group's secured and unguaranteed bank borrowings amounted to RMB320.4 million in total which bear interest at floating interest rates. Such bank borrowings are repayable by instalments and will mature in September 2027, and are secured by the Group's land use rights and construction-in-progress.

As of December 31, 2022, we had utilized RMB688.8 million from our banking facilities and RMB486.6 million remained unutilized under our banking facilities.

On February 23, 2022, the Company issued 126,876,000 new H Shares at HK$7.13 per H Share through the Global Offering on the Stock Exchange, raising net proceeds of approximately HK$876.3 million after the deduction of listing expenses.

On March 17, 2022 as part of the Global Offering, the over-allotment option was exercised partially and the Company issued a total of 899,000 H Shares at HK$7.13 per H Share, raising net proceeds of approximately HK$6.2 million after the deduction of listing expenses.

After the deduction of listing expenses, the total net proceeds from the Global Offering (including the partial exercise of the over-allotment option) was approximately HK$882.5 million.

Gearing Ratio

The gearing ratio is calculated using the Group's liabilities divided by its assets. As of December 31, 2022, the Group's gearing ratio was 64.39% (December 31, 2021: 59.32%).

Significant Investments, Material Acquisitions and Disposal

The Group did not have any significant investments or material acquisitions or disposals of subsidiaries, associates and joint ventures for the year ended December 31, 2022.

Capital Commitments

As of December 31, 2021 and 2022, the Group had capital commitments for property, plant and equipment of RMB164.7 million and RMB482.0 million, respectively, reflecting the capital expenditure our Group contracted at the end of year but not yet incurred.

Contingent Liabilities

As of December 31, 2022, the Group did not have any contingent liabilities.

Charges on Group Assets

Save as disclosed in this announcement, as of December 31, 2022, the Group did not have any charges over its assets.

Foreign Exchange Exposure

Our financial statements are expressed in RMB, but certain of our Group's subsidiaries in PRC are exposed to foreign exchange risk arising from recognized financial liabilities denominated in foreign currencies. We currently do not have a foreign currency hedging policy. However, our management manages foreign exchange risk by performing regular reviews and will consider hedging significant foreign currency exposure should the need arise.

Employees and Remuneration

As of December 31, 2022, the Group had a total of 396 employees. The total remuneration cost for 2022 was RMB188.3 million, as compared to RMB256.2 million for 2021, primarily due to a decrease in the share-based payment expenses.

To maintain the quality, knowledge and skill levels of our workforce, the Group provides regular and specialized trainings tailored to the needs of our employees in different departments, including regular training sessions conducted by senior employees or third-party consultants covering various aspects of our business operations, for our employees to stay up to date with both industry developments and skills and technologies. The Group also organizes workshops from time to time to discuss specific topics.

We provide various incentives and benefits to our employees. We offer competitive remuneration packages to our employees to effectively motivate our business development team. We participate in various social security plans (including housing provident fund, pension insurance, medical insurance, maternity insurance and work-related injury insurance and unemployment insurance) for our employees in accordance with applicable PRC laws.

OTHER INFORMATION

Compliance with the Corporate Governance Code

The Company has adopted the principles and code provisions as set out in the Corporate Governance Code, and has complied with all applicable code provisions for the period from the Listing Date to December 31, 2022.

Model Code for Securities Transactions

The Company has adopted the Model Code as its own code of conduct regarding securities transactions by the Directors and Supervisors. Having made specific enquiries with all Directors and Supervisors, each of them has confirmed that he/she has complied with the Model Code for the period from the Listing Date to December 31, 2022. No incident of non-compliance of the Model Code by the employees who are likely to be in possession of inside information of the Company was noted by the Company.

Purchase, Sale or Redemption of Listed Securities

During the year ended December 31, 2022, neither the Company nor any of its subsidiaries purchased, sold or redeemed any of the Company's listed securities.

Audit Committee

The Audit Committee has reviewed the consolidated financial statements and this annual results announcement of the Group for the year ended 31 December 2022, reviewed the accounting principles and practices adopted by the Group and discussed auditing, internal controls and financial reporting matters.

Scope of Work of PricewaterhouseCoopers

The figures in respect of the Group's consolidated balance sheet and consolidated statement of comprehensive loss and the related notes thereto for the year ended December 31, 2022 as set out in this annual results announcement have been agreed by the Group's auditor, PricewaterhouseCoopers, to the amounts set out in the Group's audited consolidated financial statements for the year. The work performed by PricewaterhouseCoopers in this respect did not constitute an assurance engagement and consequently no assurance has been expressed by PricewaterhouseCoopers on this annual results announcement.

Final Dividend

The Board does not recommend the payment of a final dividend for the year ended December 31, 2022.

PUBLICATION OF ANNUAL RESULTS ANNOUNCEMENT AND ANNUAL REPORT ON THE WEBSITES OF THE STOCK EXCHANGE AND THE COMPANY

This annual results announcement is published on the respective websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.lepubiopharma.com).

The annual report of the Company for the year ended December 31, 2022 containing all the information required by the Listing Rules will be dispatched to the Shareholders and will be published on the respective websites of the Stock Exchange and the Company in due course.

CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

For The Year Ended December 31, 2022

	Note	Year ended 31 December	
		2022	2021
		RMB'000	*RMB'000*
Revenue	*4*	**15,572**	–
Cost of sales	*5*	**(2,005)**	–
Gross profit		**13,567**	–
Other income		**11,284**	10,572
Other expenses	*5*	**(729)**	(1,074)
Selling and marketing expenses	*5*	**(1,749)**	–
Administrative expenses	*5*	**(138,830)**	(156,237)
Research and development expenses	*5*	**(524,285)**	(791,210)
Fair value changes on financial liabilities at fair value through profit or loss	*6*	**(62,816)**	(76,285)
Other (losses)/gains, net		**(924)**	4,598
Operating loss		**(704,482)**	(1,009,636)
Finance income		**45,919**	4,143
Finance costs		**(8,647)**	(5,681)
Finance income/(costs), net		**37,272**	(1,538)
Share of loss of investments accounted for using the equity method		**(32,231)**	(17,695)
Loss before income tax		**(699,441)**	(1,028,869)
Income tax expense	*7*	**–**	–
Loss for the year		**(699,441)**	(1,028,869)
Loss attributable to:			
Owners of the Company		**(689,052)**	(1,010,996)
Non-controlling interests		**(10,389)**	(17,873)
		(699,441)	(1,028,869)

	Note	Year ended 31 December 2022 RMB'000	2021 RMB'000
Losses per share for loss attributable to owners of the Company for the year (expressed in RMB per share)			
– Basic losses per share	*8*	**(0.42)**	(0.66)
– Diluted losses per share	*8*	**(0.42)**	(0.66)
Other comprehensive income			
Items that may be subsequently reclassified to profit or loss			
Currency translation differences		**109**	27
Total comprehensive loss		**(699,332)**	(1,028,842)
Total comprehensive loss attributable to:			
Owners of the Company		**(688,943)**	(1,010,969)
Non-controlling interests		**(10,389)**	(17,873)
		(699,332)	(1,028,842)

CONSOLIDATED BALANCE SHEET
For The Year Ended December 31, 2022

	Note	As at 31 December 2022 RMB'000	2021 RMB'000
Assets			
Non-current assets			
Property, plant and equipment		**916,409**	836,713
Right-of-use assets		**122,662**	141,724
Intangible assets		**450,813**	475,090
Investments accounted for using the equity method		**122,392**	137,971
Other receivables, prepayments and deposits		**104,095**	176,431
Total non-current assets		**1,716,371**	1,767,929
Current assets			
Inventories		**24,061**	24,184
Notes receivables	*9*	**3,040**	–
Other receivables, prepayments and deposits		**116,303**	84,780
Cash and cash equivalents		**669,397**	155,168
Term deposits with initial terms of over three months		**–**	50,000
Total current assets		**812,801**	314,132
Total assets		**2,529,172**	2,082,061
Equity			
Equity attributable to owners of the Company			
Share capital	*10*	**1,659,445**	1,531,670
Reserves		**1,572,807**	947,482
Accumulated losses		**(2,331,490)**	(1,642,438)
		900,762	836,714
Non-controlling interests		**–**	10,369
Total equity		**900,762**	847,083
Liabilities			
Non-current liabilities			
Borrowings		**290,057**	232,469
Lease liabilities		**3,093**	19,478
Deferred government grants		**12,000**	12,000
Deferred tax liabilities		**37,687**	37,687
Financial liabilities at fair value through profit or loss	*11*	**441,787**	384,287
Total non-current liabilities		**784,624**	685,921

	Note	As at 31 December 2022 RMB'000	2021 RMB'000
Current liabilities			
Borrowings		**359,988**	60,409
Trade payables	*12*	**166,129**	158,818
Other payables and accruals		**287,242**	311,043
Lease liabilities		**30,427**	18,787
Total current liabilities		**843,786**	549,057
Total liabilities		**1,628,410**	1,234,978
Total equity and liabilities		**2,529,172**	2,082,061

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1 GENERAL INFORMATION

Lepu Biopharma Co., Ltd. (the "**Company**") was incorporated in Shanghai, the People's Republic of China (the "**PRC**") on 19 January 2018 as a limited liability company. Upon approval by the shareholders' general meeting held on 10 December 2020, the Company was converted into a joint stock company with limited liability under the Company Law of the PRC.

The Company, together with its subsidiaries (collectively referred to as the "**Group**"), are principally focus on the discovery, development and commercialisation in global of drugs for cancer targeted therapy and immunotherapy.

Upon incorporation of the Company in January 2018, the Company had a registered capital of RMB1,000,000,000 and was owned by Ningbo Houde Yimin Information Technology Co., Ltd. (寧波厚德義民信息科技有限公司) ("**Ningbo Houde Yimin**") and Lepu Medical Technology (Beijing) Co., Ltd. (樂普(北京)醫療器械股份有限公司) ("**Lepu Medical**") as to 80% and 20%, respectively.

Ningbo Houde Yimin was incorporated in the PRC on 29 March 2017 with Dr. Pu Zhongjie being its 100% ultimate controlling shareholder (the "**Controlling Shareholder**") and Lepu Medical was incorporated in the PRC on 11 June 1999 which listed on the Shenzhen Stock Exchange (stock code: 300003).

On 23 February 2022, the Company has completed the Global Offering of 126,876,000 H Shares of par value of RMB1.00 each at the price of HK$7.13 per H Share (the "**Offering Price**"), and its shares were listed on the Main Board of The Stock Exchange of Hong Kong Limited. The gross proceeds arising from the listing amounted to approximately HK$905 million (equivalent of RMB734 million). On 22 March 2022, the Company issued additional 899,000 new H Shares upon the exercises of over-allotment of the Global Offering at the Offering Price.

After the Coronavirus Disease 2019 ("**COVID-19**") outbreak in early 2020, a series of precautionary and control measures have been and continued to be implemented across the PRC. The Group prioritises the health and safety of its employees, and has taken various preventative and quarantine measures across the Group soon after the COVID-19 outbreak. In later December 2022, the government of PRC has announced that China will manage COVID-19 with measures against Class B infectious diseases, instead of Class A infectious diseases, in a major shift of its epidemic response policies. Accordingly, government has downgraded management of the disease from Class A to Class B in accordance with the law on prevention and treatment of infectious disease. As of the date of these consolidated financial statements, the Group was not aware of any material adverse effects on the financial position as of 31 December 2022 and operating results of the Group for the year then ended.

2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The principal accounting policies applied in the preparation of the consolidated financial statements are set out below. These policies have been consistently applied throughout all the years presented, unless otherwise stated.

2.1 Basis of preparation

The principal accounting policies applied in the preparation of consolidated financial statements are in accordance with International Financial Reporting Standards ("**IFRSs**") issued by the International Accounting Standards Board ("**IASB**") and the requirements of the Hong Kong Companies Ordinance (Cap. 622).

The consolidated financial statements of the Group have been prepared under the historical costs convention, as modified by the revaluation of certain financial financial liabilities measured at fair value.

The preparation of consolidated financial statements in conformity with IFRSs requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Group's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in the Company's annual report for the year ended 31 December 2022.

For the year ended 31 December 2022, the Group has incurred net losses of approximately RMB699.4 million, while net cash used in operating activities was approximately RMB480.9 million. As at 31 December 2022, the Group had net current liabilities of approximately RMB31.0 million and cash and cash equivalents of approximately RMB669.4 million. Historically, the Group has relied principally on non-operational sources of financing from investors and banks to fund its operations and business development. The Group's ability to continue as a going concern is dependent on management's ability to successfully execute its business plan. The directors of the Company believes that the cash and cash equivalent, unutilised bank facilities together with the cash generated from operating activities are sufficient to meet the cash requirements to fund planned operations and other commitments for at least the next twelve months from the date of the issuance of this consolidated financial statement. The Group therefore continues to prepare this consolidated financial statements on a going concern basis.

(a) New and amended standards adopted by the Group

The Group has applied the following amendments or annual improvements for the first time for their annual reporting period commencing 1 January 2022:

- Property, Plant and Equipment: Proceeds before intended use – Amendments to IAS 16
- Onerous Contracts – Cost of Fulfilling a Contract – Amendments to IAS 37
- Annual Improvements 2018–2020 cycle, and
- Reference to the Conceptual Framework – Amendments to IFRS 3.

(b) New/amended standards and interpretations not yet adopted

The following new/amended standards and annual improvements have been published (which may be applicable to the Group) but not mandatory for the year ended on 31 December 2022 and have not been early adopted by the Group:

		Effective for annual periods beginning on or after
Amendment to IAS 1	Classification of Liabilities as Current or Non-current	Originally 1 January 2021, but extended to 1 January 2023
IFRS 17	Insurance Contracts	Originally 1 January 2021, but extended to 1 January 2023
Amendments to IAS 1 and IFRS Practice Statement 2	Disclosure of Accounting Policies	1 January 2023
Amendments to IAS 8	Definition of Accounting Estimates	1 January 2023
Amendments to IFRS 1 and IAS 12	Deferred Tax related to Assets and Liabilities arising from a Single Transaction	1 January 2023
Amendments to IFRS 10 and IAS 28	Sale or contribution of assets between an investor and its associate or joint venture	To be determined

The Group has already commenced an assessment of the impact of these new/amended standards and annual improvements, and amendments, certain of which are relevant to the Group's operations. According to the preliminary assessment made by the directors, no significant impact on the financial performance and positions of the Group is expected when they become effective.

3 SEGMENT INFORMATION

Management has determined the operating segments based on the reports reviewed by chief operating decision maker ("**CODM**"). The CODM, who is responsible for allocating resources and assessing performance of the operating segment, has been identified as the executive directors of the Group.

During the year ended 31 December 2022, the Group is principally engaged in the sales of pharmaceutical products and research and development of new drugs. Management reviews the operating results of the business as one operating segment to make decisions about resources to be allocated. Therefore, the CODM of the Company regards that there is only one segment which is used to make strategic decisions.

The major operating entity of the Group is domiciled in the PRC. Accordingly, the Group's results were primarily derived in the PRC during the reporting period.

4 REVENUE

	Year ended 31 December	
	2022	2021
	RMB'000	*RMB'000*
Revenue from sales of pharmaceutical products	**15,572**	–
Timing of revenue recognition		
– at a point in time	**15,572**	–

All revenues are generated in the PRC.

For the year ended 31 December 2022, revenue of approximately RMB2,466,000 (2021: Nil) was derived from a single external customer, which accounted for 15.84% (2021: Nil) of the Group's total revenue. Other than the aforementioned customer, the revenues derived from any of the remaining external customers were less than 10% of the Group's total revenue.

5 EXPENSES BY NATURE

	Year ended 31 December	
	2022	2021
	RMB'000	*RMB'000*
Clinical trial expenses	**204,991**	339,472
Employee benefit expenses	**188,344**	256,211
Depreciation and amortisation	**95,446**	95,246
Pre-clinical study costs	**71,211**	136,784
Raw material and consumables used	**37,021**	51,139
Changes in inventories of finished goods	**(1,688)**	–
Listing expenses	**34,334**	31,277
Utilities	**5,461**	6,806
Professional services fees	**3,854**	2,117
Office expenses	**4,039**	5,282
Traveling and transportation expenses	**2,942**	5,499
Licensing fee	**1,091**	–
Business promotion expenses	**652**	–
Auditors' remuneration		
– Audit services	**2,300**	1,000
– Non-audit services	**–**	170
Others	**17,600**	17,518
Total cost of sales, selling and marketing expenses, administrative expenses, research and development expenses and other expenses	**667,598**	948,521

6 FAIR VALUE CHANGES ON FINANCIAL LIABILITIES AT FAIR VALUE THROUGH PROFIT OR LOSS

	Year ended 31 December	
	2022	2021
	RMB'000	*RMB'000*
Fair value losses on financial liabilities at fair value through profit or loss – FVPL	**62,816**	76,285

7 INCOME TAX EXPENSE

	Year ended 31 December	
	2022	2021
	RMB'000	*RMB'000*
Current income tax expense	**–**	–
Deferred income tax expense	**–**	–
Income tax expense	**–**	–

The Group's principal applicable taxes and tax rates are as follows:

Shanghai Miracogen Inc. ("**Miracogen Shanghai**") is qualified as a High and New Technology Enterprise ("**HNTE**") under the relevant PRC laws and regulations on 18 November 2020. Accordingly, it was entitled to a preferential corporate income tax rate of 15% on its estimated assessable profits for the years ended 31 December 2020 to 2022.

Lepu (Beijing) Biopharma Co., Ltd. ("**Lepu Beijing**") is qualified as a HNTE under the relevant PRC laws and regulations on 25 October 2021. Accordingly, it was entitled to a preferential corporate income tax rate of 15% on its estimated assessable profits for the years ended 31 December 2021 to 2023.

The Company and the Company's other subsidiaries established and operated in Mainland China are subject to the PRC corporate income tax at the rate of 25%.

According to the relevant laws and regulations promulgated by the State Administration of Taxation of the PRC that has been effective from 2018 onwards, enterprise engaging in research and development activities are entitled to claim 175% of their research and development expenses incurred as tax deductible expenses when determining their assessable profits for that year. Pursuant to the relevant tax regulations, effective from 2021 onwards, manufacturing enterprises are entitled to claim 200% of their research and development expenses incurred as tax deductible expenses.

8 LOSS PER SHARE

(a) Basic loss per share

Basic loss per share is calculated by dividing:

- the loss attributable to owners of the Company, excluding any costs of servicing equity other than ordinary shares
- by the weighted average number of ordinary shares outstanding during the financial year.

	Year ended 31 December	
	2022	2021
Loss for the year and attributable to owners of the Company (in RMB'000)	**(689,052)**	(1,010,996)
Weighted average number of ordinary shares in issue (in thousands)	**1,640,825**	1,520,350
Basic loss per share (in RMB)	**(0.42)**	(0.66)

(b) Diluted loss per share

Diluted loss per share is calculated by adjusting the weighted average number of ordinary shares outstanding to assume conversion of all dilutive potential ordinary shares. For the year ended 31 December 2022 and 2021, the Company had no potential ordinary share. Accordingly, diluted loss per share for the years ended 31 December 2022 and 2021 are the same as basic loss per share of the respective years.

9 NOTES RECEIVABLES

As of 31 December 2022, notes receivables amounted to RMB3,040,000 (31 December 2021: nil) were all bank acceptance notes with maturity date within 6 months.

The Group's notes receivables' contractual cash flow was solely principal and interest. The Group's business model is achieved by collecting contractual cash flows. As a result, the Group's notes receivables are classified as financial assets measured at amortised cost.

10 SHARE CAPITAL

	Number of shares	Nominal value of shares *RMB'000*
Authorised issued and fully paid		
At 1 January 2022	1,531,669,838	1,531,670
Issuance of ordinary shares upon the Global Offering (a)	126,876,000	126,876
Exercise of over-allotment option (b)	899,000	899
At 31 December 2022	1,659,444,838	1,659,445
At 1 January 2021	1,492,692,648	1,492,693
Issue of ordinary shares to series C investors (c)	38,977,190	38,977
At 31 December 2021	1,531,669,838	1,531,670

(a) On 23 February 2022, the Company has completed the Global Offering of 126,876,000 H Shares of par value of RMB1.00 each at the price of HK$7.13 per H Share.

(b) On 22 March 2022, the Company issued additional 899,000 new H Shares upon the exercises of over-allotment of the Global Offering at the price of HK$7.13 per H Share.

Share issuance costs related to the Global Offering mainly include share underwriting commissions, lawyers' fees, reporting accountant's fee and other costs. Incremental costs that are directly attributable to the issue of the new shares amounting to approximately RMB33,287,000 was treated as a deduction against the share premium arising from the issuance.

(c) On 8 April 2021, the Company entered into investment agreement with Vivo Capital Fund IX, L.P. ("**Vivo Capital**") and Shanghai Biomedical Industrial Equity Investment Fund Partnership (Limited Partnership) ("**Shanghai Biomedical**"), pursuant to which Vivo Capital and Shanghai Biomedical subscribed 24,360,744 and 14,616,446 shares of the Company respectively, with consideration of RMB163,200,000 and RMB97,920,000, respectively. The issuance cost to be paid is approximately RMB423,000. The par value of the shares under subscription is approximately RMB38,977,000, and the difference with the total consideration after deducting insurance cost of approximately RMB221,720,000 is charged to share premium. The issuance of shares was completed on 17 April 2021.

11 FINANCIAL LIABILITIES AT FAIR VALUE THROUGH PROFIT OR LOSS

	As at 31 December	
	2022	2021
	RMB'000	*RMB'000*
Variable consideration payable arisen from acquisition of 40% equity of Taizhou Hanzhong from non-controlling interests	**448,282**	385,466
Less: current portion	**(6,495)**	(1,179)
Non-current portion	**441,787**	384,287

On 29 September 2019, the Group entered into an equity purchase agreement with Hangzhou HanX Biomedical Co., Ltd. ("**HanX**") to acquire 40% equity interests of Taizhou Hanzhong held by HanX at (i) the fixed consideration of RMB350,000,000; and (ii) the variable consideration payable of 4.375% of the annual net sales revenue of PD-1 products which will be settled annually after the PD-1 products launched into the market.

The fair value of variable consideration payable as at 31 December 2022 and 2021 was determined by an independent valuer, and the changes in fair value was recognised in the consolidated statements of comprehensive loss.

As at 31 December 2022, the current portion of variable consideration payable consisted of 4.375% of actual net sales of PD-1 products in 2022 accounting to approximately RMB681,000 and 4.375% of estimated net sales of PD-1 products in 2023 accounting to approximately RMB5,814,000.

The movements of financial liabilities at fair value through profit or loss for the years ended 31 December 2022 and 2021 are set out below:

	Year ended 31 December	
	2022	2021
	RMB'000	*RMB'000*
Opening balance	**385,466**	309,181
Change in fair value	**62,816**	76,285
Closing balance	**448,282**	385,466

12 TRADE PAYABLES

The aging analysis of the trade payables based on their respective invoice and issue dates are as follows:

	As at 31 December	
	2022	2021
	RMB'000	*RMB'000*
Less than 1 year	**165,642**	157,731
Between 1 and 2 years	**487**	1,087
	166,129	158,818

Trade payables are unsecured and are usually paid within 30 days from the date of initial recognition.

The carrying amounts of trade payables are considered to be the same as their fair values, due to their short-term nature.

The trade payables are all denominated in RMB.

13 DIVIDEND

No dividend has been paid or declared by the Company or companies comprising the Group during the years ended 31 December 2022 and 2021.

14 EVENTS OCCURRING AFTER THE REPORTING PERIOD

There is no significant event occurred after the balance sheet date which has material impact to the consolidated financial statements of the Group.

"A Share(s)"	the ordinary Share(s) with a nominal value of RMB1.00 each in the share capital of the Company proposed to be allotted, issued and listed on the Sci-Tech Board
"ADC"	antibody drug conjugate, a class of biopharmaceutical drugs that combine monoclonal antibodies specific to surface antigens present on particular tumor cells with highly potent antitumor small molecule agents linked via a chemical linker
"Audit Committee"	the audit committee of the Board
"AstraZeneca"	AstraZeneca AB, a global pharmaceutical company who to the best knowledge and belief of the Company, is independent of and not connected with the Company and its connected persons (as defined in the Listing Rules)
"BC"	breast cancer
"B-cell"	a type of white blood cell that differs from other types of lymphocytes by expressing B-cell receptors on its surface, and responsible for producing antibodies
"Bacillus Calmette-Guerin" or "BCG"	a type of bacteria that causes a reaction in a patient's immune system that can destroy cancer cells located in the lining of the bladder. It is also widely used as a vaccine against tuberculosis
"Board"	the board of Directors of the Company
"BTD"	Breakthrough Therapy Designation
"CD20"	a B-lynphocyte antigen that is expressed on the surface of B cells, starting at the per-B cell atage and also on mature B cells in the bone marrow and in the periphery
"CDE"	the Center for Drug Evaluation of the National Medical Products Administration of the People's Republic of China
"China", "Mainland China" or the "PRC"	the People's Republic of China, excluding, for the purpose of this announcement, Hong Kong, Macau Special Administrative Region and Taiwan
"CG Oncology"	CG Oncology, Inc. (previously known as Cold Genesys, Inc.), a clinical-stage immuno-oncology company headquartered in the US, of which Lepu Medical holds approximately 7.73% equity interest through Lepu Holdings Limited, a company wholly-owned by Lepu Medical, and Ms. Pu Jue serves as a director

"chemotherapy"	a category of cancer treatment that uses one or more anticancer small molecule chemical agents as part of its standardized regimen
"CLDN18.2"	Claudin 18.2, a highly specific tissue junction protein for gastric tissue
"CMC"	chemistry, manufacturing, and controls processes in the development, licensure, manufacturing, and ongoing marketing of pharmaceutical products
"combination therapy"	a treatment modality that combines two or more therapeutic agents
"Company"or "our Company"	Lepu Biopharma Co., Ltd. (樂普生物科技股份有限公司), a joint stock company incorporated in the PRC with limited liability, the H Shares of which are listed on the Stock Exchange (Stock code: 2157)
"Controlling Shareholder"	has the meaning ascribed to it under the Listing Rules and, unless the context requires otherwise, refers to Dr. Pu Zhongjie
"Core Product(s)"	has the meaning ascribed to it in Chapter 18A of the Listing Rules; for purposes of this announcement, our core products include MRG003, MRG002, HX008 and LP002
"Corporate Governance Code"	the Corporate Governance Code as set out in Appendix 14 to the Listing Rules
"CSCO"	Chinese Society of Clinical Oncology
"DCR"	disease control rate
"Director(s)"	the director(s) of the Company
"Domestic Share(s)"	ordinary share(s) in the share capital of the Company, with a nominal value of RMB1.00 each, which are subscribed for and paid up in RMB and are unlisted Shares which are currently not listed or traded on any stock exchange
"Domestic Shareholders"	holders of the Domestic Shares
"ES-SCLC"	extensive stage small-cell lung cancer
"EGFR"	epidermal growth factor receptor
"FDA"	Food and Drug Administration of the United States
"FPI"	first-patient-in

"GC"	gastric cancer
"GEJ"	gastroesophageal junction
"Global Offering"	the offer of H Shares for subscription as described in the Prospectus
"GMP"	a system for ensuring that products are consistently produced and controlled according to quality standards, which is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. It is also the practice required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of pharmaceutical products
"Group", "we","us" or "our"	The Company and its subsidiaries
"H Share(s)"	overseas listed foreign invested ordinary share(s) in the ordinary share capital of our Company, with a nominal value of RMB1.00 each, which are listed on the Main Board of the Stock Exchange
"H Shareholders"	holders of the H Shares
"HCC"	hepatocellular carcinoma, a common form of liver cancer
"HER2"	human epidermal growth factor receptor 2
"HER2 over-expressing" or "HER2-positive"	HER2 status of tumor cells identified with a test score of either IHC3+ or FISH (or ISH)+
"HER2 low-expressing"	HER2 status of tumor cells identified with a test score of IHC 1+ or IHC 2+ plus FISH (or ISH)-
"HK$"	Hong Kong dollars, the lawful currency of Hong Kong
"HNSCC"	head and neck squamous cell carcinoma
"Hong Kong"	the Hong Kong Special Administrative Region of the PRC

"IgG"	human immunoglobulin G, the most common antibody type found in blood circulation that plays an important role in antibody-based immunity against invading pathogens
"IND"	investigational new drug or investigational new drug application, also known as clinical trial application in China or the US
"ITT"	intention to treat
"Keymed"	Keymed Bioscience (Chengdu) Co., Ltd. (康諾亞生物醫藥科技(成都)有限公司), a limited liability company incorporated in the PRC on September 1, 2016, which is a third-party biotechnology company focusing on the inhouse discovery and development of innovative biological therapies in the autoimmune and oncology therapeutic areas
"KOL"	key opinion leader
"KYM"	KYM Biosciences Inc., a Delaware corporation and a joint venture formed in the US by Keymed and our Group
"Lepu Medical"	Lepu Medical Technology (Beijing) Co., Ltd. (樂普(北京)醫療器械股份有限公司), a joint stock company incorporated in the PRC on June 11, 1999 and listed on the Shenzhen Stock Exchange (stock code: 300003), and the promoter of our Company
"Listing"	the listing of the H Shares of the Company on the Main Board of the Stock Exchange
"Listing Date"	February 23, 2022
"Listing Rules"	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time
"mAb"	monoclonal antibody, an antibody generated by identical cells that are all clones of the same parent cell
"Macau"	the Macau Special Administrative Region of the PRC
"Main Board"	the Main Board of the Stock Exchange

"MMAE"	monomethyl auristatin E, a potent tubulin binder with a half maximal inhibitory concentration (IC50) in the subnanomolar range
"Model Code"	the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix 10 to the Listing Rules
"MSI-H/dMMR"	high levels of microsatellite instability/deficient mismatch repair
"NDA"	new drug application
"NHL"	non-Hodgkin's lymphoma
"NK cell"	natural killer cell, a kind of cells that play important roles in immunity against viruses and in the immune surveillance of tumors
"NMIBC"	non-muscle invasive bladder cancer
"NMPA"	the National Medical Products Administration of the PRC (中國國家藥品監督管理局)
"NPC"	nasopharyngeal cancer
"NSCLC"	non-small cell lung cancer
"ODD"	orphan drug designation
"ORR"	overall response rate
"PC"	pancreatic cancer
"PD-1"	programmed cell death protein 1, an immune checkpoint receptor expressed on T cells, B cells and macrophages
"PD-L1"	PD-1 ligand 1, which is a protein on the surface of a normal cell or a cancer cell that binds to its receptor, PD-1, on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell
"Phase II clinical trials"	study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases, and to determine dosage tolerance and optimal dosage

"Phase III clinical trials"	study in which a drug is administered to an expanded patient population generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to provide adequate information for the labeling of the product
"Prospectus"	the prospectus issued by the Company dated February 10, 2022
"registrational trial"	a clinical trial or study intended to provide evidence for a drug marketing approval
"Reporting Period"	the year ended December 31, 2022
"PFS"	progression-free-survival
"RMB"	Renminbi, the lawful currency of China
"Sci-Tech Board"	the Sci-Tech Innovation Board of the Shanghai Stock Exchange
"second-line" or "2L"	with respect to any disease, the therapy or therapies that are tried when the first-line treatments do not work adequately
"Share(s)"	shares in the share capital of the Company, with a nominal value of RMB1.00 each, comprising the Domestic Shares, Unlisted Foreign Shares and H Shares
"Shareholder(s)"	holder(s) of the Shares
"solid tumors"	an abnormal mass of tissue that usually does not contain cysts or liquid areas. Solid tumors may be benign (not cancer), or malignant (cancer). Different types of solid tumors are named for the type of cells that form them
"Stock Exchange"	The Stock Exchange of Hong Kong Limited
"subsidiaries"	has the meaning ascribed to it in section 15 of the Companies Ordinance
"Supervisor(s)"	the supervisor(s) of the Company

"Taizhou Hanzhong"	Taizhou Hanzhong Biotechnology Co., Ltd. (泰州翰中生物醫藥有限公司), a limited liability company incorporated in the PRC on November 25, 2016, and our non-wholly owned subsidiary
"T cell"	a lymphocyte of a type produced or processed by the thymus gland and actively participating in the immune response, which plays a central role in cell-mediated immunity. T cells can be distinguished from other lymphocytes, such as B cells and NK cells, by the presence of a T cell receptor on the cell surface
"TNBC"	triple-negative breast cancer
"tissue factor" or "TF"	a protein encoded by the F3 gene, present in subendothelial tissue and leukocytes. Many cancer cells express high level of TF
"UC"	unrothelial cancer
"Unlisted Foreign Shares"	ordinary shares issued by the Company with a nominal value of RMB1.00 each and are held by foreign investors and are not listed on any stock exchange
"US" or "United States" or "U.S."	the United States of America, its territories and possessions, any State of the United States, and the District of Columbia
"vc linker"	valine-citrulline linker, which is adequately stable in blood circulation and cleaved effectively by the lysosomal cathepsin enzyme after the ADC is internalized and enters lysosome

By order of the Board
Lepu Biopharma Co., Ltd.
Dr. Pu Zhongjie
Chairman and Executive Director

Shanghai, the PRC
March 17, 2023

As at the date of this announcement, the Board comprises Dr. Pu Zhongjie (Chairman), Dr. Sui Ziye (Chief Executive Officer) and Dr. Hu Chaohong (Co-Chief Executive Officer) as executive Directors; Ms. Pu Jue, Mr. Yang Hongbing and Mr. Lin Xianghong as non-executive Directors; and Mr. Zhou Demin, Mr. Yang Haifeng and Mr. Fengmao Hua as independent non-executive Directors.