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, 2021

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

BUSINESS HIGHLIGHTS

The Company was successfully listed on the Stock Exchange on February 23, 2022. Our product pipeline and business operations have made significant progress last year:

- **HX008:** We filed an NDA of HX008 with the NMPA in melanoma in June 2021 and received an acceptance notification of our NDA submission. We filed an NDA of HX008 with the NMPA in MSI-H/dMMR solid tumors and it was granted priority review in October 2021, which could expedite the review and marketing approval process in China.

- **MRG002:** We obtained a consent notification from the NMPA in November 2021 to conduct a registrational Phase II clinical trial in patients with HER2 over-expressing BC which could expedite the development and potential conditional approval in China.

- **MRG003:** Preliminary promising efficacy data was observed in patients with advanced HNSCC and NPC in our Phase I clinical trials. We have initiated Phase II clinical trials in HNSCC and NPC in China.

- **MRG004A:** We received an IND clearance from FDA for a Phase I/II clinical trial in treatment of tissue factor positive solid tumors in February 2021 and have initiated enrollment of patients in the US. We received an IND approval of MRG004A from the NMPA in August 2021.

- **CG0070:** We obtained an IND approval from the NMPA for a Phase I trial of CG0070 in the treatment of patients with BCG failed bladder cancer in November 2021.

– **Combination of MRG002 with HX008:** We received an IND approval from the NMPA for a Phase I trial of combination therapy with MRG002 and HX008 in the treatment of patients with HER2-expressing solid tumors in December 2021.

– **Manufacturing facilities**: We have been operating a 2,000L bioreactor production line at our Beijing GMP-compliant manufacturing plant. We have 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 a capacity of 6,000L is under construction. Meanwhile, a manufacturing facility for oncolytic virus products with a designed capacity of 200L has been under construction in Beijing.

– **Commercialization**: We are establishing our sales and marketing team dedicated to the commercialization of our pipeline products. For our pipeline product HX008, we plan to establish a commercialization team with 50 to 100 members before we obtain the approval for treatment to engage in academic promotion, marketing and commercialization. We have already contacted several cancer centers, hospitals, clinics, and doctors specializing in the relevant treatment and have started to visit the sites and medical professionals in person for pre-launch training and communication.

KEY EVENTS AFTER THE REPORTING PERIOD

Subsequent to the Reporting Period, the Company was successfully listed on the Main Board of the Stock Exchange on February 23, 2022. We obtained IND clearance for HX008 in the US in January 2022. Furthermore, the combination therapy of MRG003 and HX008 received an IND approval from the NMPA in January 2022. We also achieved first patient in for MRG002 for HER2 over-expressing BC in March 2022, and received an IND approval for LP008 anti-PD-L1-TGFBRII fusion protein from the NMPA in March 2022.

FINANCIAL HIGHLIGHTS

– Cash and cash equivalents and term deposits with initial terms of over three months amounted to approximately RMB205.2 million as at December 31, 2021.

– Research and development expenses increased by approximately RMB436.8 million, or approximately 123.3%, to approximately RMB791.2 million.

– Administrative expenses increased by approximately RMB62.5 million, or approximately 66.6%, to approximately RMB156.2 million.

– Loss for the year attributable to the owners of the Company increased by approximately RMB429.1 million, or approximately 73.8%, to approximately RMB1,011.0 million.

MANAGEMENT DISCUSSION AND ANALYSIS

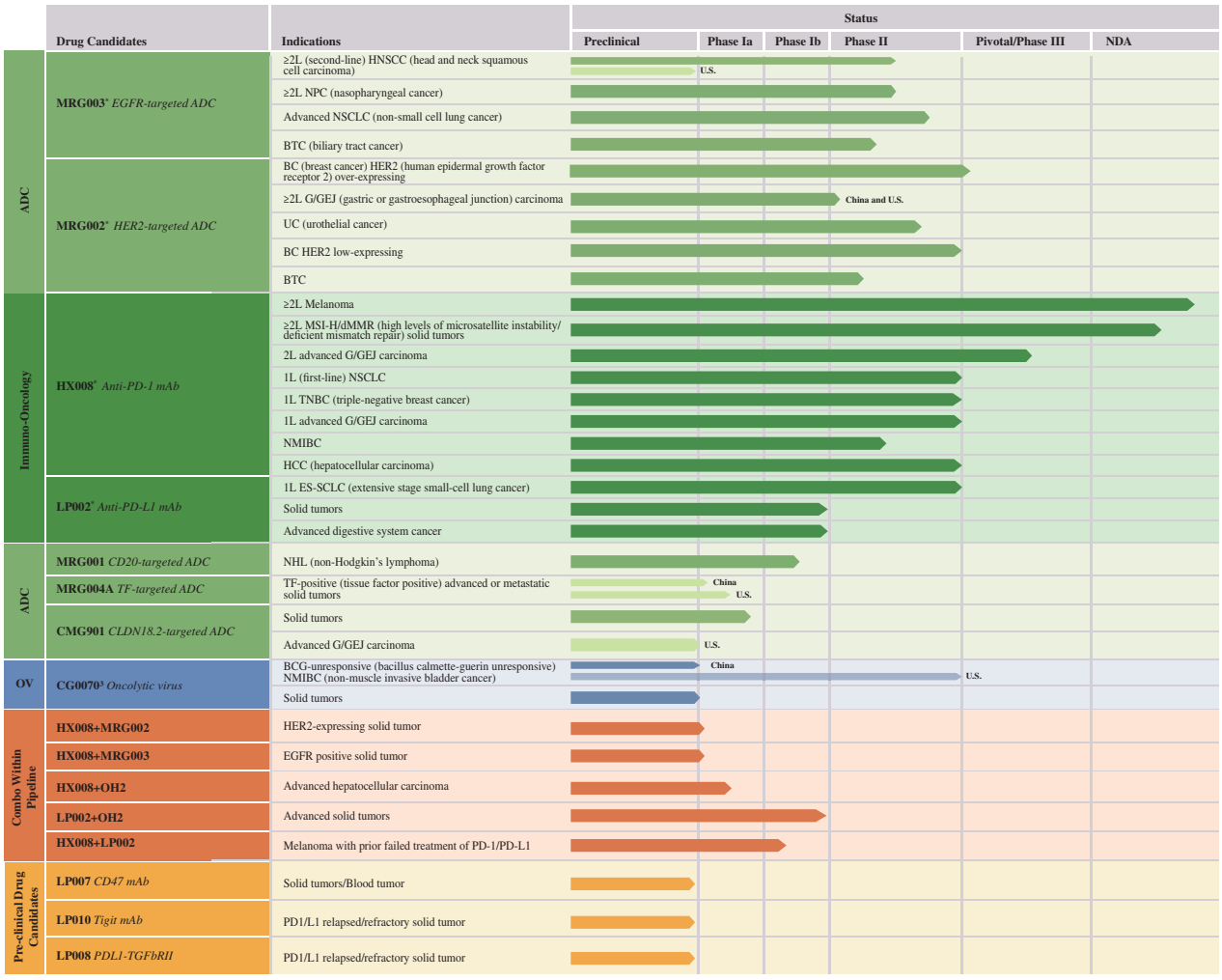
OVERVIEW

We are an innovation-driven biopharmaceutical company focusing on oncology therapeutics with a strong China foundation and global vision. Our mission is to become a leading innovative platform serving the unmet medical needs of cancer patients with first-in-class and best-in-class drugs. 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. We have (i) eight clinical-stage drug candidates, including one of them co-developed through a joint venture, (ii) three pre-clinical drug candidates, and (iii) five clinical-stage combination therapies of the candidates in our pipeline. Among the eight clinical-stage drug candidates, five are targeted therapeutics and three are immunotherapeutics, with two of the three being immune checkpoint drugs and one being oncolytic virus drug. We have initiated multiple clinical trials, amongst which two are ongoing in the US, and four have entered the stage of registrational trials in China. KYM, a joint venture formed by Keymed and our Group, is also conducting CMG901 clinical trials in the US.

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. 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

The Company was successfully listed on the Stock Exchange on February 23, 2022. During the Reporting Period and up to the date of this announcement, the Company has made significant progress in its pipeline products and business operations to meet investor expectations. The following sets out the progress the Company has made during the Reporting Period.

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 completed the Phase Ib trial for MRG003 in March 2021, and we have initiated Phase II clinical trials of MRG003 in a variety of EGFR expressing cancer types in China. Currently, we are strategically focusing on clinical investigations for HNSCC and NPC, which have demonstrated promising efficacy and indicated potential to meet these particularly significant unmet medical needs. We are also exploring the potential efficacy of MRG003 in other prevalent cancer types with EGFR over-expression including NSCLC and BTC.

    - **HNSCC:** We are conducting an open-label, single-arm, multicenter Phase II clinical study of MRG003 with 54 patients enrolled as of December 31, 2021.

    - **NPC:** We are conducting an open-label, single-arm, multicenter Phase II clinical study of MRG003 with 33 patients enrolled as of December 31, 2021.

    - **Other indications:** We are also conducting Phase II clinical trials in patients with advanced NSCLC and BTC.

- **Warning under Rule 18A.08(3) of the Listing Rules:** There is no assurance that the MRG003 will ultimately be successfully developed and marketed by the Company. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the shares of the Company.

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 trial in HER2 over-expressing BC.

    - **HER2 over-expressing BC:** Based on the combined favorable efficacy data of both Phase Ib and exploratory Phase II clinical trial in the patients with HER2 over-expressing advanced BC, we communicated with the NMPA regarding a registrational Phase II trial and we obtained a consent notification from NMPA on registrational trial of MRG002 in HER2 over-expressing advanced BC patients in November 2021. The trial has been initiated as of December 31, 2021.

- **UC:** We are conducting an open label, single-arm, multicenter Phase II trial of MRG002 in HER2-positive UC with 35 patients enrolled as of December 31, 2021.

- **HER2 low-expressing BC:** We are conducting an open-label, multicenter Phase II clinical trial in HER2 low-expressing BC with patient enrollment completed as of December 31, 2021 and treatments as well as follow up visits ongoing. We plan to initiate communication with the NMPA regarding potentially initiating a Phase III clinical trial.

- **GC:**

  - China: We are conducting an open-label, multicenter Phase II study of MRG002 in HER2-positive/low-expressing GC patients with enrollment ongoing as of December 31, 2021.

  - US: We obtained an IND clearance from the FDA for a Phase I/II clinical study of MRG002 in HER2-positive, locally advanced or metastatic GC/GEJ in May 2020. As of December 31, 2021, patient enrollment is ongoing in the US.

- **BTC:** We are conducting an open label, single-arm, multicenter Phase II clinical trial of MRG002 in HER2-positive BTC with patient enrollment ongoing as of December 31, 2021.

– **Warning under Rule 18A.08(3) of the Listing Rules**: There is no assurance that the MRG002 will ultimately be successfully developed and marketed by the Company. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the shares of the Company.

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. We have made significant progress on HX008 in 2021, where two indications including melanoma and MSI-H/dMMR solid tumors completed NDA submissions to the NMPA, which brings the Company closer to commercialization in the near future.

- **Melanoma:** We filed an NDA of HX008 in melanoma to the NMPA in June 2021.

- **MSI-H/dMMR solid tumors:** We filed an NDA of HX008 in MSI-H/dMMR solid tumors to the NMPA and it was granted priority review in October 2021.

- **GC 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. We have enrolled 278 patients as of December 31, 2021.

- **Other indications:** We have completed the enrollment and are in the follow-up period for Phase Ib clinical trial of HX008 in advanced solid tumors and for various Phase II clinical trials of HX008 in NSCLC, TNBC, first-line GC and HCC.

– **Warning under Rule 18A.08(3) of the Listing Rules**: There is no assurance that the HX008 will ultimately be successfully developed and marketed by the Company. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the shares of the Company.

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 standard of care chemotherapies.

- **ES-SCLC:** We are conducting a single-arm, open-label Phase II clinical study of LP002 in combination therapy with carboplatin and etoposide, and we have completed the patient enrollment as of December 31, 2021. Based on the encouraging efficacy data in ES-SCLC clinical study, we communicated with the NMPA regarding potentially initiating a Phase III clinical trial and obtained the approval in December 2021.

- **Advanced Digestive System Cancers:** We are conducting an open label, multi-center Phase Ib clinical study in patients with advanced digestive system cancers. Patient enrollment was completed as of December 31, 2021, and continued treatments and follow up visits are still being performed.

– **Warning under Rule 18A.08(3) of the Listing Rules:** There is no assurance that the LP002 will ultimately be successfully developed and marketed by the Company. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the shares of the Company.

Combination Therapies Involving our Core Products

We obtained an IND approval from the NMPA for the combination therapy of MRG002 and HX008 in December 2021.

Other Clinical-stage Drug Candidates

– **MRG001**: MRG001 is a clinically advancing 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 have completed the Phase Ia dose escalation stage of MRG001 in China which has shown encouraging safety and efficacy results in February 2021. We are conducting the Phase Ib dose expansion study of MRG001 in China.

– **MRG004A**: MRG004A is a novel TF-targeted site-specifically conjugated ADC. We received an IND clearance of MRG004A from the FDA in February 2021 for a Phase I/II clinical trial and are currently conducting the dose escalation trial in the US. We also received an IND approval of MRG004A from the NMPA in August 2021.

– **CG0070**: CG0070 is an oncolytic adenovirus for the treatment of BCG failed 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 obtained an IND approval from the NMPA for a Phase I trial of CG0070 in November 2021. The Phase I clinical trial has been initiated as of December 31, 2021.

– **CMG901:** CMG901 is a CLDN18.2-targeted ADC for the treatment of advanced GC/GEJ and pancreatic adenocarcinoma in which CLDN18.2 is highly expressed. It is the first CLDN18.2-targeted ADC to have received the IND approval in both China and the US, as well as the most clinically advanced anti-CLDN18.2 ADC. It is being co-developed by us and Keymed through a joint venture, KYM. Patient enrollment has been ongoing for the Phase I clinical trial of CMG901 in China as of December 31, 2021. The IND clearance was granted by the FDA in March 2021 for a multi-center, open-label Phase I clinical trial in the US to evaluate the safety, tolerability, and pharmacokinetics of CMG901 in patients with advanced unresectable or metastatic G/GEJ carcinoma.

– **Warning under Rule 18A.08(3) of the Listing Rules**: There is no assurance that the MRG001, MRG004A, CG0070 and CMG901 will ultimately be successfully developed and marketed by the Company. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the shares of the Company.

Manufacturing Facilities

We have been operating a 2,000L GMP-compliant bioreactor production line at our Beijing manufacturing plant, and during the Reporting Period, given all of our products remained in the research and development stage, our manufacturing activities are mainly conducted in support of our clinical trials.

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 a capacity of 6,000L is under construction. We have also been building a manufacturing facility for oncolytic virus products in Beijing with a designed capacity of 200L.

Commercialization

We are establishing our sales and marketing team dedicated to the commercialization of our pipeline products. Before we obtain the approval for treatment of our pipeline product HX008, we plan to establish a commercialization team comprising 50 to 100 members to engage in academic promotion, marketing, and commercialization.

With our team's expertise and rich networks, we will mainly rely on face-to-face and onsite marketing strategy focusing on direct and interactive communication with KOLs and doctors in the respective areas to promote the differentiating clinical aspects of our products. We expect the marketing efforts will commence before the expected approval for the commercialization of a drug candidate. For HX008, we have already contacted several cancer centers, hospitals, clinics, and doctors specializing in the relevant treatment and have started to visit the sites and medical professionals in person for pre-launch training and communication.

KEY EVENTS AFTER THE REPORTING PERIOD

(i) Listing of Shares of the Company on the Stock Exchange

On February 23, 2022, the Company was successfully listed on the Main Board of the Stock Exchange, in which 126,876,000 new H Shares (subject to over-allotment option) has been issued.

On March 17, 2022, as part of the Global Offering, the over-allotment option was partially exercised and the Company issued a total of 899,000 H Shares at HK$7.13 per H Share. The listing of and dealings in the over-allotment shares commenced on the Main Board of the Stock Exchange at 9:00 a.m. on March 22, 2022.

(ii) Key developments of our Drug Candidates

Based on our substantial accumulated industry experience and in-depth insights in both oncology immunotherapy and targeted therapy, we believe that there is potential for combinations of immunotherapy and targeted therapeutics to achieve enhanced efficacy and/or balanced safety, and to overcome the drug resistance. We have strategically designed our pipeline targeting critical steps across the cancer immune cycle to unlock the great potential of anti-cancer immune response by combinations of these in-house developed therapeutics. We believe our combination therapies are expected to drive and strengthen the potential commercial value of our pipeline drug candidates and further expand our market share in the targeted therapeutic areas and address currently unmet medical needs for cancer patients.

We obtained IND clearance for HX008 in the US in January 2022. We also achieved first patient in for MRG002 for HER2 over-expressing BC in March 2022. Furthermore, we obtained an IND approval from the NMPA for the combination therapy of MRG003 and HX008. We also plan to submit an IND for the combination therapy of CG0070 and HX008.

THE IMPACT OF COVID-19

Despite the outbreak of COVID-19, the management of the Company expected that clinical trials in and outside Mainland China will not be 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.

FUTURE DEVELOPMENT

The Company is an innovation-driven biopharmaceutical company with a strong Chinese root and global vision. We are dedicated to discovering, developing, and commercializing first-in-class and best-in-class drug candidates in anti-tumor targeted therapy and oncology immunotherapy in the US and PRC. The mission and goal of the Company are to develop the safest, most effective, and most readily available drugs to enhance the life quality of patients and address unmet significant clinical needs in the medical system. The Company also values the continuing build-out of our own commercialization capabilities, and is determined to pursue the goal towards strong transformation from core technology to commercialized drugs.

Looking forward to 2022, we will endeavor to accelerate the commercialization of our products pipeline. The Company will work towards obtaining the NMPA approval for launching and successfully commercializing HX008 for its treatment in melanoma and MSI-H/dMMR solid tumors. Meanwhile, we will accelerate the development of two of our ADC products, being MRG002 and MRG003, to the registrational trial phase. MRG002 has entered the registrational trial phase for advanced breast cancer and completed the first patient enrollment. We expect to apply to the NMPA for the registrational trial of MRG002 in UC in China during the second quarter of 2022. In addition, we will also progress the registrational trial application for MRG003 in advanced HNSCC and NPC. On the international front, we will step up our efforts for expansion in the global market and progress the clinical trials of our innovative product MRG004A in the US.

While the establishment of our sales and marketing team in China remains one of our key focuses, we will also keep up with formulating clear business strategies and preparing for commercialization. With our solid understanding of the Chinese market environment, we expect that our market access strategies will be able to meet the market demand successfully.

FINANCIAL REVIEW

Revenue

For the years ended December 31, 2020 and 2021, the Group has not commercialized any products and therefore has not recorded any revenue.

Other Income

The Group's other income primarily consist of (i) investment income on financial assets at fair value through profit or loss, representing the interest we earn from structured deposits; (ii) government grants to support our research and development activities; and (iii) rental and related income.

Our other income increased from RMB8.0 million in 2020 to RMB10.6 million in 2021, primarily due to an increase in subsidies received from the government.

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 increased from RMB93.8 million in 2020 to RMB156.2 million in 2021, primarily due to an increase in our employee benefit expenses in relation to our administrative staff from RMB33.4 million to RMB87.8 million resulting from an increase in the number of employees, their salaries as well as the share-based payment expenses, and listing expenses from nil to RMB31.3 million given the Company has been preparing for its listing on the Main Board of the Hong Kong Stock Exchange in 2021.

Research and Development Expenses

Our research and development expenses primarily consist of (i) clinical trial expenses, mainly in relation to our engagement of CROs, SMOs, CDMOs and hospitals; (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 increased from RMB354.4 million in 2020 to RMB791.2 million in 2021.

The following table sets forth the components of our research and development expenses for the years indicated.

	Year ended 31 December			
	2021		2020	
	RMB'000	***%***	*RMB'000*	*%*
Clinical trial expenses	**339,472**	**42.9**	146,938	41.5
Employee benefit expenses	**168,406**	**21.3**	48,214	13.6
Pre-clinical study costs	**136,784**	**17.3**	66,905	18.9
Depreciation and amortization	**77,612**	**9.8**	49,890	14.0
Raw material and consumables used	**51,139**	**6.5**	35,298	10.0
Others	**17,797**	**2.2**	7,182	2.0
Total	**791,210**	**100**	354,427	100

(i) Clinical trial expenses increased by RMB192.5 million, mainly due to the continuous development of our drug candidates;

(ii) Employee benefits expenses increased by RMB120.2 million, mainly due to an increase in the number of employees and an increase in their salaries as well as increase in the share-based payment expenses;

(iii) Pre-clinical study costs increased by RMB69.9 million, mainly due to the continuous development of our drug candidates;

(iv) Depreciation and amortization expenses increased by RMB27.7 million, mainly due to an increase in our property, plant and equipment for research and development purposes;

(v) Raw material and consumable expenses increased by RMB15.8 million, mainly due to the continuous development of our drug candidates; and

(vi) Other expenses increased by RMB10.6 million, mainly due to an increase in utilities and other miscellaneous expenses.

Other Expenses

Our other expenses primarily represent the depreciation of our right-of-use assets and property, plant and equipment related to rental arrangements. Our other expenses decreased from RMB1.9 million in 2020 to RMB1.1 million in 2021, mainly due to a decrease in our rental and related income.

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

We had fair value changes on financial assets and liabilities at fair value through profit or loss of RMB78.0 million in 2020 and RMB76.3 million in 2021. 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. For the year ended December 31, 2021, we have not recorded any fair value gains on financial assets at fair value through profit or loss (2020: RMB0.7 million), given we did not have any financial assets at fair value through profit or loss as at December 31, 2021.

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

	Year ended 31 December	
	2021	2020
	RMB'000	*RMB'000*
Fair value losses on financial liabilities at fair value through profit or loss		
– Fair value through profit or loss	**(76,285)**	(30,100)
– Convertible loans	**–**	(48,548)
Fair value gains on financial assets at fair value through profit or loss	**–**	657
Total	**(76,285)**	(77,991)

Finance Income and Finance Costs

Our finance income primarily represents our bank interest income. Our finance costs primarily consist of interest on financial instruments with preferred rights at amortized cost, lease liabilities and borrowings. Our financial income decreased from RMB5.3 million in 2020 to RMB4.1 million in 2021, mainly due to a decreased level of bank deposit for the year ended December 31, 2021. Our finance costs decreased from RMB86.3 million in 2020 to RMB5.7 million in 2021, due to a decrease in interest on financial instruments with preferred rights at amortized cost.

Income Tax Expenses

For the years ended December 31, 2020 and 2021, the Group's income tax expenses were nil.

Loss for the Year

Based on the factors described above, the Group's loss increased from RMB613.4 million in 2020 to RMB1,028.9 million in 2021.

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, 2021, our net cash used in operating activities was RMB621.7 million. As of December 31, 2021, we had cash and cash equivalent of RMB155.2 million, a decrease of RMB247.7 million from RMB402.9 million as of December 31, 2020, primarily due to the combination effect of an increase in our research and development expenses and fund raised in our financing activities.

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, 2021, the Group's bank borrowings amounted to RMB292.9 million, among which unsecured and unguaranteed bank borrowings amounted to RMB40.4 million in total with interest at fixed interest rates. Such borrowing will be repayable within one year.

The Group's secured bank borrowings were guaranteed by Dr. Pu Zhongjie, our Controlling Shareholder, and such guarantee was released on April 20, 2021. As of December 31, 2021, the Group's secured and unguaranteed bank borrowings amounted to RMB252.5 million in total which bear interest at floating interest rates. Such bank borrowings are repayable by instalments and will mature in September 2027, and secured by the Group's land use rights and construction-in-progress.

As of December 31, 2021, we had utilized RMB292.9 million from our banking facilities and RMB507.1 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 initial public offering on the Stock Exchange, raising net proceeds of approximately HK$876.3 million after 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 deduction of listing expenses.

After 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, 2021, the Group's gearing ratio was 59.32% (December 31, 2020: 38.04%).

Significant Investments, Material Acquisitions and Disposal

In January 2021, we, through our wholly-owned subsidiary, Innocube Limited, completed the acquisition of 30% equity interest in KYM from Miracogen HK at a consideration of US$100, and upon completion of such acquisition, KYM is held as to 30% and 70% by Innocube Limited and iBridge, respectively. In October 2021, the transfer of 10% equity interest has been completed, and upon completion of such transfer, Taizhou Hanzhong is owned by us as to 82%.

Save and except as aforementioned, 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, 2021.

Capital Commitments

For the years ended December 31, 2020 and 2021, the Group had capital commitments for property, plant and equipment and intangible assets of RMB309.1 million and RMB164.7 million, respectively, reflecting the capital expenditure our Group contracted at the end of year but not yet incurred.

Contingent Liabilities

As of December 31, 2020 and 2021, the Group did not have any contingent liabilities.

Charges on Group Assets

Save as disclosed in this announcement, as of December 31, 2021, 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 assets and liabilities are 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, 2021, the Group had a total of 440 employees. The total remuneration cost for 2021 was RMB256.2 million, as compared to RMB81.6 million for 2020, primarily due to an increase in the number of employees and their salaries as well as the increase 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

As the Company's shares have not been listed on the Stock Exchange as of December 31, 2021, the Corporate Governance Code set out in Appendix 14 to the Listing Rules were not applicable to the Company during the year ended December 31, 2021.

The Company is committed to implementing the best corporate governance practices to protect shareholders' rights and enhance corporate value and accountability. The Company has adopted with the code provisions under the Corporate Governance Code as its own corporate governance code since the Listing Date.

Model Code for Securities Transactions

As the Company's shares have not been listed on the Stock Exchange during the year ended December 31, 2021, the provisions regarding compliance with the Model Code under the Listing Rules were not applicable to the Company during the year ended December 31, 2021.

Following the Listing, the Company has adopted the Model Code as set out in Appendix 10 to the Listing Rules as its own code of conduct regarding securities transactions by the Directors and the Supervisors. Specific enquiries have been made to all the Directors and Supervisors and each of them has confirmed that he/she have complied with the Model Code from the Listing Date to the date of this announcement. 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

As the Company's shares have not been listed on the Stock Exchange during the year ended December 31, 2021, neither the Company nor any of its subsidiaries purchased, sold or redeemed any of the Company's listed securities during the year under review.

Audit Committee

The Board has established the Audit Committee which comprises Mr. Fengmao Hua (chairman) and Mr. Yang Haifeng as independent non-executive Directors, and Ms. Pu Jue as non-executive Director. The primary duties of the Audit Committee are to review and supervise the Company's financial reporting process and internal controls.

The Audit Committee, together with the management of the Company, has reviewed the audited annual results of the Group for the year ended December 31, 2021.

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 31 December 2021 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, 2021.

PUBLICATION OF THE GROUP'S ANNUAL RESULTS AND 2021 ANNUAL REPORT ON THE WEBSITES OF THE STOCK EXCHANGE AND THE COMPANY

This annual results announcement is published on the 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, 2021 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.

Warning under Rule 18A.08(3) of the Listing Rules: There is no assurance that the Core Products will ultimately be successfully developed and marketed by the Company. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the Shares of the Company.

CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

	Note	Year ended 31 December	
		2021	2020
		RMB'000	*RMB'000*
Other income		**10,572**	7,964
Other expenses	*4*	**(1,074)**	(1,915)
Administrative expenses	*4*	**(156,237)**	(93,757)
Research and development expenses	*4*	**(791,210)**	(354,427)
Fair value changes on financial assets and liabilities at fair value through profit or loss	*5*	**(76,285)**	(77,991)
Other gains/(losses), net		**4,598**	(225)
Operating loss		**(1,009,636)**	(520,351)
Finance income		**4,143**	5,306
Finance costs		**(5,681)**	(86,319)
Finance costs, net		**(1,538)**	(81,013)
Share of loss of investments accounted for using the equity method		**(17,695)**	(12,084)
Loss before income tax		**(1,028,869)**	(613,448)
Income tax expense	*6*	**–**	–
Loss for the year		**(1,028,869)**	(613,448)
Loss attributable to:			
Owners of the Company		**(1,010,996)**	(581,849)
Non-controlling interests		**(17,873)**	(31,599)
		(1,028,869)	(613,448)

	Note	Year ended 31 December 2021 RMB'000	2020 RMB'000
Loss per share for loss attributable to owners of the Company for the year (expressed in RMB per share)			
– Basic	7	**(0.66)**	(0.51)
– Diluted	7	**(0.66)**	(0.51)
Other comprehensive income/(loss)			
Items that may be subsequently reclassified to profit or loss			
Currency translation differences		**27**	(39)
Total comprehensive loss		**(1,028,842)**	(613,487)
Total comprehensive loss attributable to:			
Owners of the Company		**(1,010,969)**	(581,888)
Non-controlling interests		**(17,873)**	(31,599)
		(1,028,842)	(613,487)

CONSOLIDATED BALANCE SHEET

	Note	As at 31 December 2021 RMB'000	2020 RMB'000
Assets			
Non-current assets			
Property, plant and equipment		**836,713**	606,371
Right-of-use assets		**141,724**	163,666
Intangible assets		**475,090**	497,922
Investments accounted for using the equity method		**137,971**	160,294
Other receivables, prepayments and deposits		**176,431**	152,009
Total non-current assets		**1,767,929**	1,580,262
Current assets			
Inventories		**24,184**	19,569
Other receivables, prepayments and deposits		**84,780**	70,256
Financial assets at fair value through profit or loss		**–**	330,657
Cash and cash equivalents		**155,168**	402,867
Term deposits with initial terms of over three months		**50,000**	20,000
Total current assets		**314,132**	843,349
Total assets		**2,082,061**	2,423,611
Equity			
Equity attributable to owners of the Company			
Share capital	*8*	**1,531,670**	1,492,693
Reserves		**947,482**	612,260
Accumulated losses		**(1,642,438)**	(631,442)
		836,714	1,473,511
Non-controlling interests		**10,369**	28,211
Total equity		**847,083**	1,501,722
Liabilities			
Non-current liabilities			
Borrowings		**232,469**	147,266
Lease liabilities		**19,478**	33,534
Deferred government grants		**12,000**	12,000
Deferred tax liabilities		**37,687**	37,687
Financial liabilities at fair value through profit or loss	*9*	**384,287**	309,181
Total non-current liabilities		**685,921**	539,668

	Note	As at 31 December 2021 RMB'000	2020 RMB'000
Current liabilities			
Borrowings		**60,409**	–
Trade payables	*10*	**158,818**	42,448
Other payables and accruals		**311,043**	321,307
Lease liabilities		**18,787**	18,466
Total current liabilities		**549,057**	382,221
Total liabilities		**1,234,978**	921,889
Total equity and liabilities		**2,082,061**	2,423,611

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 completed a 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. 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 December 31, 2021 and operating results of the Group for the year then ended. Recent development of the COVID-19 pandemic in China, such as increasing cases reported in Shanghai in March 2022 and other cities, continues to generate uncertainties over the Company's business, results of operations, financial condition and cash flows. The Group will continue to closely monitor the development of the COVID-19 outbreak and take appropriate counter-measures if any adverse impact is arising.

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 assets and 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 2021.

For the year ended 31 December 2021, the Group has incurred net losses of RMB1,028.9 million, while net cash used in operating activities was RMB621.7 million. As at 31 December 2021, the Group had net current liabilities of RMB234.9 million, cash and cash equivalents of RMB155.2 million and term deposits with initial terms of over three months of RMB50.0 million, meanwhile, the Group had unutilised bank facilities of RMB507.1 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, term deposits with initial terms of over three months, unutilised bank facilities together with the fund raising from global offering 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 IASB has issued a number of new and amended IFRSs. For the purpose of preparing the financial statements, the Group has adopted all applicable new and amended IFRSs consistently throughout the reporting period except for any new or interpretation that are not yet effective.

(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 2021 and have not been early adopted by the Group:

		Effective for annual periods beginning on or after
Amendments to IAS 16	Property, Plant and Equipment: Proceeds before intended use	1 January 2022
Amendments to IAS 37	Onerous Contracts – Cost of Fulfilling a Contract	1 January 2022
Amendments to IFRS 3	Reference to the Conceptual Framework	1 January 2022
Annual Improvements	Annual Improvements 2018-2020 cycle	1 January 2022
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 the 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 reporting period, the Group is principally engaged in the 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 EXPENSES BY NATURE

	Year ended 31 December	
	2021	2020
	RMB'000	*RMB'000*
Clinical trial expenses	**339,472**	146,938
Employee benefit expenses	**256,211**	81,609
Pre-clinical study costs	**136,784**	66,905
Depreciation and amortisation	**95,246**	84,114
Raw material and consumables used	**51,139**	36,148
Listing expenses	**31,277**	–
Utilities	**6,806**	7,116
Traveling and transportation expenses	**5,499**	3,448
Office expenses	**5,282**	3,385
Professional services fees	**2,117**	8,165
Auditors' remuneration		
– Audit services	**1,000**	–
– Non-audit services	**170**	–
Others	**17,518**	12,271
Total administrative expenses, research and development expenses and other expenses	**948,521**	450,099

5 FAIR VALUE CHANGES ON FINANCIAL ASSETS AND LIABILITIES AT FAIR VALUE THROUGH PROFIT OR LOSS

	Year ended 31 December	
	2021	2020
	RMB'000	*RMB'000*
Fair value losses on financial liabilities at fair value through profit or loss		
– Fair value through profit or loss	**(76,285)**	(30,100)
– Convertible loans	**–**	(48,548)
Fair value gains on financial assets at fair value through profit or loss	**–**	657
	(76,285)	(77,991)

6 INCOME TAX EXPENSE

	Year ended 31 December	
	2021	2020
	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. (上海美雅珂生物技術有限責任公司) ("**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. (樂普(北京)生物科技有限公司) ("**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.

7 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	
	2021	2020
Loss for the year and attributable to owners of the Company (in RMB'000)	**(1,010,996)**	(581,849)
Weighted average number of ordinary shares in issue (in thousands) *(i)*	**1,520,350**	1,134,852
Basic loss per share (in RMB)	**(0.66)**	(0.51)

(i) The weighted average number of ordinary shares in issue before the conversion into a joint stock company was determined assuming the paid-in capital had been fully converted into share capital at the same conversion ratio of 1:1 as upon conversion into joint stock company in December 2020.

(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 2020, the Company had the convertible loans and financial instruments with preferred rights at amortised cost which are potential ordinary shares. As the Group incurred losses for the year ended 31 December 2020, the potential ordinary shares were not included in the calculation of diluted loss per share as their inclusion would be anti-dilutive. For the year ended 31 December 2021, the Company had no potential ordinary share. Accordingly, diluted loss per share for the years ended 31 December 2021 and 2020 are the same as basic loss per share of the respective years.

8 SHARE CAPITAL

	Number of shares	Nominal value of shares *RMB'000*
Authorised and issued		
Ordinary shares upon conversion	1,492,692,648	1,492,693
At 31 December 2020	1,492,692,648	1,492,693
At 1 January 2021	**1,492,692,648**	**1,492,693**
Issue of ordinary shares to series C investors *(b)*	**38,977,190**	**38,977**
At 31 December 2021	**1,531,669,838**	**1,531,670**

	Number of shares	Nominal value of shares *RMB'000*
Issued and fully paid		
Issue of ordinary shares upon conversion into a joint stock company *(a)*	1,492,692,648	1,492,693
At 31 December 2020	1,492,692,648	1,492,693
At 1 January 2021	**1,492,692,648**	**1,492,693**
Issue of ordinary shares to series C investors *(b)*	**38,977,190**	**38,977**
At 31 December 2021	**1,531,669,838**	**1,531,670**

(a) In December 2020, the Company converted into a joint stock company with limited liability under the Company Law of the PRC. The net assets of the Company as of the conversion date, including paid-in capital, reserves and accumulated losses, amounting to approximately RMB3,112,653,000 were converted into approximately 1,492,693,000 ordinary shares at RMB1 each. The excess of net assets converted over nominal value of the ordinary shares was credited to the Company's share premium.

(b) 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.

9 FINANCIAL LIABILITIES AT FAIR VALUE THROUGH PROFIT OR LOSS

	As at 31 December	
	2021	2020
	RMB'000	*RMB'000*
Variable consideration payable arisen from acquisition of 40% equity of Taizhou Hanzhong from non-controlling interests	**385,466**	309,181
Less: current portion	**(1,179)**	–
Non-current portion	**384,287**	309,181

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 2021 and 2020 was determined by an independent valuer. And the changes in fair value was recognised in the consolidated statements of comprehensive loss.

The movements of financial liabilities at fair value through profit or loss for the years ended 31 December 2021 and 2020 are set out below:

	Year ended 31 December	
	2021	2020
	RMB'000	*RMB'000*
Opening balance	**309,181**	279,081
Additions	**–**	–
Change in fair value	**76,285**	30,100
Closing balance	**385,466**	309,181

10 TRADE PAYABLES

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

	As at 31 December	
	2021	2020
	RMB'000	*RMB'000*
Less than 1 year	**157,731**	40,785
Between 1 and 2 years	**1,087**	1,663
	158,818	42,448

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.

11 DIVIDEND

No dividend has been paid or declared by the Company or companies comprising the Group during the years ended 31 December 2021 and 2020.

12 EVENTS OCCURRING AFTER THE REPORTING PERIOD

Other than the events as disclosed in Note 1 to financial statements, there is no other significant event occurred after the balance sheet date.

"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
"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
"BTC"	biliary trat cancer
"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
"CDMO"	contract development and manufacturing organization, a pharmaceutical company that develops and manufactures drugs for other pharmaceutical companies on a contractual basis
"CG Oncology"	CG Oncology, Inc. (previously known as Cold Genesys, Inc.), a clinical-atage 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 (蒲珏) serves as a director
"chemotherapy"	a category of cancer treatment that uses one or more anti-cancer small molecule chemical agents as part of its standardized regimen

"China", "Mainland China" or "PRC"	the People's Republic of China excluding, for the purpose of this announcement, Hong Kong, Macau Special Administrative Region and Taiwan
"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)
"Company Law"	the Company Law of the PRC (《中華人民共和國公司法》), enacted by the Standing Committee of the Eighth National People' Congress on December 29, 1993 and effective on July 1, 1994, and subsequently amended on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013 and October 26, 2018, as amended, supplemented or otherwise modified from time to time
"Companies Ordinance"	the Companies Ordinance (Chapter 622 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
"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
"CRO"	contract research organization, a pharmaceutical company that conducts research for other pharmaceutical companies on a contractual basis
"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

"EGFR"	epidermal growth factor receptor
"ES-SCLC"	extensive stage small-cell lung cancer
"FDA"	Food and Drug Administration of the United States
"first-line" or "1L"	with respect to any disease, the first line therapy, which is the treatment regimen or regimens that are generally accepted by the medical establishment for initial treatment. It is also called primary treatment or therapy
"FISH"	fluorescence in situ hybridization, a test that maps the genetic material in human cells, including specific genes or portions of genes
"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
"HCC"	hepatocellular carcinoma, a common form of liver cancer
"HER2"	human epidermal growth factor receptor 2
"HER2-expressing"	HER2 status of tumor cells identified with a test score of IHC 1+ or above
"HER2 low-expressing"	HER2 status of tumor cells identified with a teat score of IHC 1+ or IHC 2+ plus FISH (or ISH)-
"HER2-positive" or "HER2 over-expressing"	HER2 status of tumor cells identified with a test score of either IHC 3+ or IHC 2+/FISH (or ISH) + (IHC 2+ plus FISH (or ISH)+)

"HK$" or "Hong Kong dollars"	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
"iBridge"	iBridge HK Holding Limited, and an affiliate of Keymed
"IC50"	half maximal inhibitory concentration
"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
"IHC"	immunohistochemistry, the most common application of immunostaining. It involves the process of selectively identifying antigens in cells of a tissue section by exploiting the principle of antibodies binding specifically to antigens in biological tissues
"IND"	investigational new drug or investigational new drug application, also known as clinical trial application in China or the US
"Independent Third Party(ies)"	person(s) or company(ies) and their respective ultimate beneficial owner(s), who/which, to the best of our Directors' knowledge, information and belief, having made all reasonable enquiries, is/are not connected with our Company
"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
"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 on the Main Board of the Stock Exchange on the Listing Date
"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
"Main Board"	the Main Board of the Stock Exchange
"metastatic"	in reference to any disease, including cancer, disease producing organisms or of malignant or cancerous cells transferred to other parts of the body by way of the blood or lymphatic vessels or membranous surfaces
"Miracogen HK"	Miracogen Limited, a limited liability company established under the laws of Hong Kong and a special purpose investment vehicle wholly-owned by Miracogen Inc., which in turn is a company wholly-owned by Dr. Hu Chaohong, our executive Director and co-chief executive officer of our Company
"Miracogen Shanghai"	Shanghai Miracogen Inc. (上海美雅珂生物技術有限責任公司), a limited liability company incorporated in the PRC on January 27, 2014, and our wholly-owned subsidiary
"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

"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
"per-clinical studies"	studies or programs testing a drug on non-human subjects, to gather efficacy, toxicity, pharmacokinetic and safety information and to decide whether the drug is ready for clinical trials
"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
"placebo"	any dummy medical treatment administered to the control group in a controlled clinical trial in order that the specific and non-specific effects of the experimental treatment can be distinguished
"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, 2021
"RMB" or "renminbi"	Renminbi, the lawful currency of China
"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

"Shenzhen Stock Exchange"	the Shenzhen Stock Exchange (深圳證券交易所)
"SMO"	site management organization, an organization that provides clinical trial related services to medical device companies having adequate infrastructure and staff to meet the requirements of the clinical trial protocol
"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
"standard of care"	treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals
"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)"	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
"TGFBRII"	TGF-β receptor II
"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
"TNBC"	triple-negative breast cancer
"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 "the U.S."	the United States of America, its territories and possessions, any State of the United States, and the District of Columbia

"US$"	United States dollars, the lawful currency of the United States
"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 29, 2022

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.