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)

INTERIM RESULTS ANNOUNCEMENT FOR THE SIX MONTHS ENDED JUNE 30, 2022

The Board is pleased to announce the unaudited consolidated interim results of the Group for the six months ended June 30, 2022, together with the comparative figures for the same period in 2021.

BUSINESS HIGHLIGHTS

As at the date of this announcement, we have made significant progress in advancing our product pipeline as well as business operations:

- **HX008:** We filed (i) an NDA of HX008 in MSI-H/dMMR solid tumours with the NMPA and it was granted priority review in October 2021, which could expedite the review and marketing approval process in China; and (ii) an NDA of HX008 in melanoma, with the NMPA in June 2021. On July 19, 2022, the Company obtained conditional marketing approval for PUYOUHENG (Pucotenlimab Injection) (HX008) with the NMPA in MSI-H/dMMR solid tumors.

- **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. Patient enrollment is ongoing and encouraging data have been observed. We conducted an open label, single-arm, multicenter 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 and have entered the follow-up period, and encouraging data have been observed.

- **MRG003:** We are conducting Phase II clinical trials for HNSCC and NPC and have completed patient enrollment. We are in the follow-up period and encouraging data have been observed. We are currently communicating with the CDE for the possibility of conducting registrational trials.

– **MRG004A:** We are currently initiating Phase I/II clinical trials in China, and conducting the dose escalation trial in the US.

– **Combination Therapy of MRG003 with HX008:** We achieved first-patient-in in June 2022 for the Phase I clinical trial for the combination therapy of MRG003 with HX008.

– **Manufacturing facilities:** We are operating a 2,000L bioreactor production line at our Beijing GMP-compliant manufacturing plant. We are building (i) 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, and (ii) a manufacturing facility for oncolytic virus products with a designed capacity of 200L in Beijing.

– **Commercialization:** We are establishing our sales and marketing team dedicated to the commercialization of our pipeline products. We plan to establish a commercialization team with 50 to 100 members to engage in academic promotion, marketing and commercialization.

FINANCIAL HIGHLIGHTS

– Cash and cash equivalents amounted to approximately RMB814.5 million as at June 30, 2022.

– Research and development expenses decreased by approximately RMB182.0 million, or approximately 44.1%, to approximately RMB230.7 million.

– Administrative expenses increased by approximately RMB7.0 million, or approximately 9.0%, to approximately RMB84.7 million.

– Loss for the period attributable to the owners of the Company decreased by approximately RMB167.7 million, or approximately 32.8%, to approximately RMB344.3 million.

MANAGEMENT DISCUSSION AND ANALYSIS

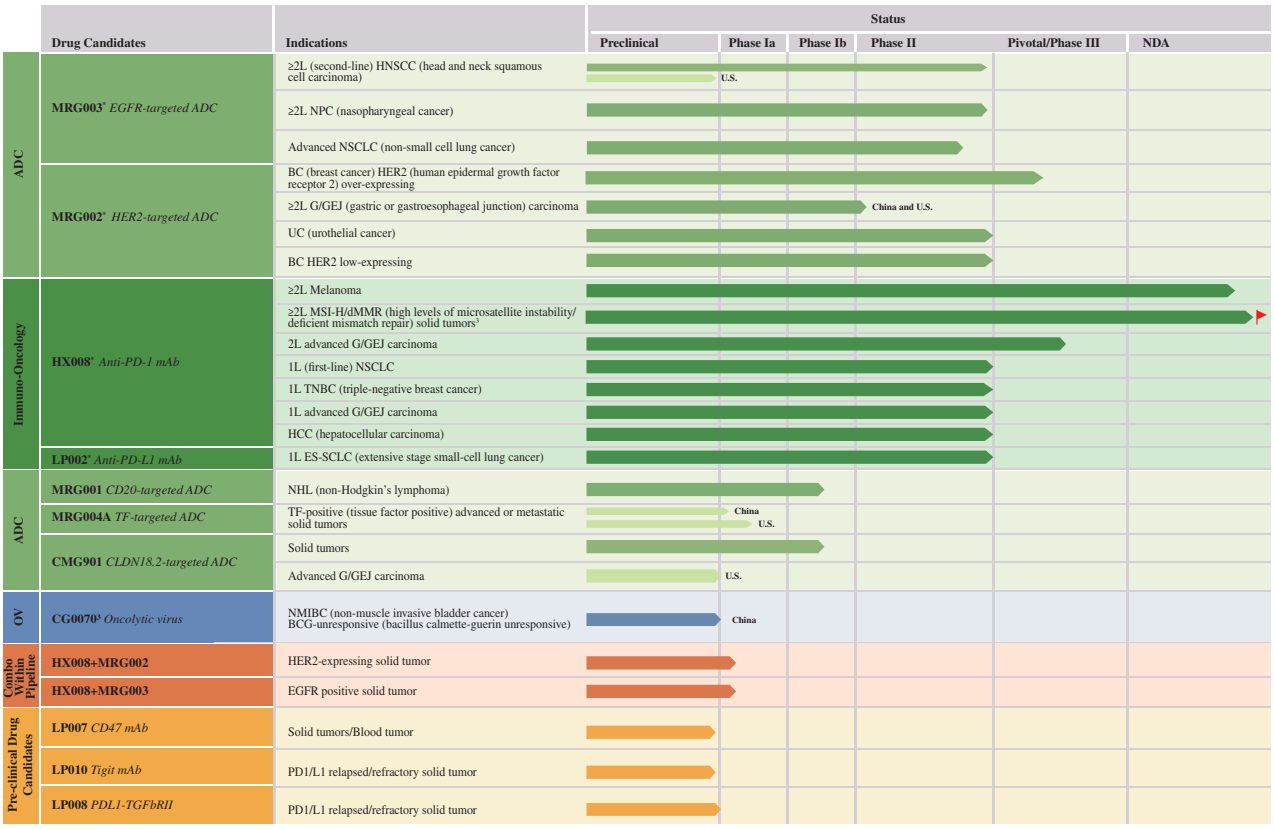
OVERVIEW

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) one clinical/commercialization-stage drug candidate; (ii) seven clinical-stage drug candidates, including one of them co-developed through a joint venture, (iii) three pre-clinical drug candidates, and (iv) two clinical-stage combination therapies of the candidates in our pipeline. One of our drug candidates has obtained marketing approval with respect to one 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 immune checkpoint drugs and the other one being oncolytic virus drug. We have initiated multiple clinical trials, amongst which two are ongoing in the US; one has entered the NDA stage; and two have entered the stage of registrational trials in the PRC. In addition, KYM, a joint venture formed by Keymed and our Group, is also conducting CMG901 clinical trials in the US and China and was granted the Fast-Track Designation and Orphan-drug Designation from FDA.

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. On July 19, 2022, we obtained conditional marketing approval for PUYOUHENG (Pucotenlimab Injection) (HX008) with the NMPA in MSI-H/dMMR solid tumors.

BUSINESS REVIEW

As at the date of this announcement, the Company has made significant progress in its pipeline products and business operations to meet investors' 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 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 currently communicating with the CDE for the possibility of conducting registrational trials. We are also exploring the potential efficacy of MRG003 in other prevalent cancer types with EGFR over-expression such as NSCLC.

    - **HNSCC:** We are conducting an open-label, single-arm, multicenter Phase II clinical study of MRG003. Patient enrollment was completed in February 2022 and have entered into the follow-up period, and encouraging data have been observed.

    - **NPC:** We are conducting an open-label, single-arm, multicenter Phase II clinical study of MRG003. Patient enrollment was completed in March 2022. It has entered the follow-up period and encouraging data have been observed.

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

- **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.

MRG002

- MRG002 is an innovative ADC targeting HER2, a molecular target abnormally overexpressed in many cancer types including BC, UC and GC/GEJ. 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. Clinical trials in the aforementioned indications are ongoing.

    - **HER2 over-expressing BC:** We achieved first-patient-in in March 2022. We are currently conducting a registrational Phase II clinical trial in China and we are enrolling patients during the Reporting Period. We have observed encouraging data.

- **UC:** We are conducting an open label, single-arm, multicenter 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 enrollment in February 2022 and have entered the follow-up period with encouraging data being observed. As of April 1, 2022, for the ITT population, the investigator-assessed ORR rate was 55%, CR was 8%, and DCR was 89%, with a median PFS of 5.8 months. On the other hand, the ORR rate in the subgroup that failed platinum-containing chemotherapy and PD-(L)1 treatment was 63% and the CR rate was 10%. The median PFS in this subgroup was 6.4 months.

- **HER2 low-expressing BC:** We are conducting an open-label, multicenter Phase II clinical trial in HER2 low-expressing BC with patient enrollment completed and which has entered the follow-up period.

- **GC/GEJ:** We are conducting an open-label, multicenter Phase II study of MRG002 in HER2-positive/low-expressing GC/GEJ patients in China with enrollment ongoing as of June 30, 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 June 30, 2022.

– **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.

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 January 2022, we obtained IND clearance for HX008 in the US.

- **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, which could expedite the review and marketing approval process in China. For further development, please refer to the section "Key Events after Reporting Period" below.

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

- **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. Patient enrollment is ongoing as of June 30, 2022.

- **Other indications:** We 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, and first-line GC/GEJ.

– **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.

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.

  o **ES-SCLC:** We have completed the patient enrollment for the 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 with encouraging data being observed. Based on the encouraging efficacy data in ES-SCLC clinical study, we obtained approval from the NMPA in December 2021 regarding potentially initiating a Phase III clinical trial.

– **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.

Combination Therapies Involving our Core Products

We are in the process of patient enrollment of Phase I/II clinical trials for the combination therapies of MRG003 with HX008 in EGFR positive solid tumor, and MRG002 with HX008 in HER2-expressing solid tumor as of June 30, 2022. We achieved first-patient-in in June 2022 for the Phase I clinical trial for the combination therapy of MRG003 with HX008.

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 are conducting the 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. We are initiating Phase I/II clinical trials in China as of June 30, 2022.

– **CG0070:** CG0070 is an oncolytic adenovirus for the treatment of BCG failed bladder cancer patients. 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 Phase I clinical trial as of June 30, 2022 in China.

– **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, pancreatic cancer 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 Phase I clinical trial of CMG901 in subjects with solid tumors in the first half of 2022, and plan to present and disclose the data from the Phase I clinical trial in academic papers/ conferences in the future. Furthermore, we also initiated the dose-expansion stage of Phase I clinical trial of CMG901 in subjects with solid tumors in China in the second quarter of 2022. In April 2022, CMG901 for the treatment of relapsed/refractory GC and GEJ adenocarcinoma has been granted the Fast Track Designation by the FDA. Previously, we have received the Orphan-drug Designation for this indication from the FDA.

– **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.

Other updates on Pipeline Products

Considering the strategic focus of the Company among various clinical trials and the continuing exploration of different indications for its drug candidates, the Company has made adjustments to the clinical trials of its pipeline products to prioritise resources on indications and drug candidates which the Company considers having the most potential in order to ensure most efficient allocation of resources. For details of the latest pipeline products of the Company, please refer to page 4 of this announcement.

Manufacturing Facilities

We are operating a 2,000L bioreactor production line at our Beijing GMP-compliant 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 been building (i) the phase one of the manufacturing facilities in the Shanghai Biotech Park with a designed total capacity of 12,000L and of which the first production line with a capacity of 6,000L is under construction, and (ii) 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. 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

Key developments of our Drug Candidates

We will continue to advance both our ongoing and planned clinical programs and trials for our pipeline products in the PRC and globally to prepare for the commercialization of our pipeline products. In particular, subsequent to the Reporting Period, on July 19, 2022, the Company obtained conditional marketing approval for PUYOUHENG (Pucotenlimab Injection) (HX008) with the NMPA in MSI-H/dMMR solid tumors.

We are very pleased to see rapid progress we have achieved during the Reporting Period. We will continue to commit to developing and commercializing our pipeline drug candidates and further expand our market share in the targeted therapeutic areas and address currently unmet medical needs for cancer patients.

THE IMPACT OF COVID-19

The outbreak of COVID-19 and its Omicron variant continued during the Reporting Period. In particular, different cities (such as Shanghai) in the PRC implemented control measures in response to the increasing number of cases of COVID-19 infection. However, the management of the Company expected that the business operations of the Company had not been significantly affected. As our clinical trial sites are geographically dispersed, the control measures in certain cities had not significantly affected the progress of clinical trials in and outside Mainland China. 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 continue to take 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 the second half of 2022, we will endeavour to accelerate the commercialization of our products pipeline. Meanwhile, we will accelerate the development of two of our ADC products, being MRG002 and MRG003. On the international front, we will step up our efforts for expansion in the global market and actively seek collaboration partners.

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. 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 six months ended June 30, 2022 and 2021, the Group has not commercialized any products and therefore has not recorded any revenue.

Other Income

The Group's other income primarily consists 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 RMB4.1 million for the six months ended June 30, 2021 by RMB1.1 million to RMB5.2 million for the six months ended June 30, 2022, 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 RMB77.8 million for the six months ended June 30, 2021 to RMB84.7 million for the six months ended June 30, 2022, primarily due to an increase in listing expenses by RMB4.5 million, professional service fees by RMB8.6 million and depreciation and amortization expenses by RMB3.7 million, net off by a decrease in the employee benefit expenses in relation to our administrative staff by RMB8.6 million.

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 decreased from RMB412.7 million for the six months ended June 30, 2021 to RMB230.7 million for the six months ended June 30, 2022.

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

	Six months ended 30 June			
	2022		2021	
	RMB'000	***%***	*RMB'000*	*%*
Clinical trial expenses	**87,034**	**37.7**	187,876	45.5
Employee benefit expenses	**54,544**	**23.6**	97,171	23.5
Pre-clinical study costs	**37,568**	**16.3**	51,479	12.5
Depreciation and amortization	**34,135**	**14.8**	39,791	9.6
Raw material and consumables used	**9,797**	**4.2**	28,691	7.0
Others	**7,628**	**3.4**	7,659	1.9
Total	**230,706**	**100**	412,667	100

(i) Clinical trial expenses decreased by RMB100.8 million, mainly due to a decrease in the number of enrolled patients.

(ii) Employee benefit expenses decreased by RMB42.6 million, mainly due to a decrease in the share-based payment expenses.

(iii) Pre-clinical study costs decreased by RMB13.9 million, mainly due to the prioritization of resources on indications and drug candidates which the Company considers have the most potential.

(iv) Depreciation and amortization costs decreased by RMB5.7 million, mainly due to the derecognition of certain right-of-use assets.

(v) Raw material and consumables expenses decreased by RMB18.9 million, mainly due to a decrease in the use of raw materials for our research and development activities.

(vi) Other expenses decreased by RMB0.03 million, mainly due to a decrease in utilities and other expenses.

Other Expenses

Our other expenses was RMB0.5 million for the six months ended June 30, 2021, which represent the depreciation of our right-of-use assets and property, plant and equipment related to rental arrangements. Our other expenses was RMB0.2 million for the six months ended June 30, 2022, which represent the cost of sales of raw materials.

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 RMB34.3 million for the six months ended June 30, 2021 and RMB60.8 million for the six months ended June 30, 2022. For the six months ended June 30, 2022, we have not recorded any fair value gains on financial assets at fair value through profit or loss, given we did not have any financial assets at fair value through profit or loss.

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.

	Six months ended 30 June	
	2022	2021
	RMB'000	*RMB'000*
Fair value losses on financial liabilities at fair value through profit or loss	**(60,776)**	(34,637)
Fair value gains on financial assets at fair value through profit or loss	**–**	358
Total	**(60,776)**	(34,279)

Finance Income and Finance Costs

Our finance income primarily represents our bank interest income. Our finance costs primarily consist of interest on lease liabilities and borrowings. Our financial income increased from RMB3.2 million for the six months ended June 30, 2021 to RMB36.8 million for the six months ended June 30, 2022, mainly due to an increase in foreign currency exchange gain for the six months ended June 30, 2022. Our finance costs increased from RMB2.6 million for the six months ended June 30, 2021 to RMB2.8 million for the six months ended June 30, 2022, due to an increase in interest on short-term bank loans.

Income Tax Expenses

For the six months ended June 30, 2022 and 2021, the Group's income tax expenses were nil.

Loss for the Period

Based on the factors described above, the Group's loss decreased from RMB522.7 million for the six months ended June 30, 2021 to RMB348.4 million for the six months ended June 30, 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 six months ended June 30, 2022, our net cash used in operating activities was RMB192.8 million, a decrease of RMB161.5 million from RMB354.3 million as of June 30, 2021. As of June 30, 2022, we had cash and cash equivalent of RMB814.5 million, an increase of RMB659.3 million from RMB155.2 million as of December 31, 2021, primarily due to the receipt of the proceeds from the Global Offering.

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 June 30, 2022, the Group's bank borrowings amounted to RMB422.4 million (December 31, 2021: RMB292.9 million), among which unsecured and unguaranteed bank borrowings amounted to RMB142.2 million in total with interest at fixed and floating interest rates. Such borrowing will be repayable within one year.

As of June 30, 2022, the Group's secured and unguaranteed bank borrowings amounted to RMB280.3 million (December 31, 2021: RMB40.4 million) in total which bear interest at floating interest rates. Such bank borrowings are repayable by instalments and will mature in September 2027 and secured by the Group's land use rights and construction-in-progress.

As of June 30, 2022, we had utilized RMB432.4 million from our banking facilities and RMB567.6 million remained unutilized under our banking facilities.

Gearing Ratio

The gearing ratio is calculated using the Group's liabilities divided by its assets. As of June 30, 2022, the Group's gearing ratio was 54.1% (December 31, 2021: 59.3%).

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 six months ended June 30, 2022.

Capital Commitments

As of June 30, 2022, the Group had capital commitments for property, plant and equipment of RMB524.0 million (December 31, 2021: RMB164.7 million), and capital commitments for intangible assets of RMB504.3 million (December 31, 2021: RMB482.0 million), reflecting the capital expenditure of our Group contracted at the end of the period/year but not yet incurred.

Contingent Liabilities

As of June 30, 2022 and December 31, 2021, the Group did not have any contingent liabilities.

Charges on Group Assets

Save as disclosed in this announcement, as of June 30, 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 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 June 30, 2022, the Group had a total of 371 employees. The total remuneration cost of the Group for the six months ended June 30, 2022 was RMB85.6 million, as compared to RMB136.8 million for the six months ended June 30, 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 during the six months ended June 30, 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 six months ended June 30, 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

Neither the Company nor any of its subsidiaries purchased, sold or redeemed any of the Company's listed securities during the six months ended June 30, 2022.

REVIEW OF FINANCIAL INFORMATION

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 unaudited interim condensed consolidated financial information of the Group for the six months ended June 30, 2022.

Scope of Work of PricewaterhouseCoopers

The unaudited interim condensed consolidated financial information for the six months ended June 30, 2022 has been reviewed by PricewaterhouseCoopers, the independent auditor of the Company, in accordance with International Standard on Review Engagements 2410, "Review of Interim Financial Information Performed by the Independent Auditor of the Entity", issued by the International Auditing and Assurance Standards Board.

Interim Dividend

The Board does not recommend the payment of an interim dividend for the six months ended June 30, 2022 (June 30, 2021: nil).

PUBLICATION OF INTERIM RESULTS ANNOUNCEMENT AND INTERIM REPORT

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

The interim report of the Company for the six months ended June 30, 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.

INTERIM CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

For the six months ended 30 June 2022

	Note	Six months ended 30 June	
		2022	2021
		RMB'000	*RMB'000*
		(Unaudited)	(Unaudited)
Other income		**5,162**	4,113
Other expenses	*6*	**(200)**	(530)
Administrative expenses	*6*	**(84,729)**	(77,755)
Research and development expenses	*6*	**(230,706)**	(412,667)
Fair value changes on financial assets and liabilities at fair value through profit or loss	*7*	**(60,776)**	(34,279)
Other gains/(losses), net		**554**	(954)
Operating loss		**(370,695)**	(522,072)
Finance income		**36,754**	3,216
Finance costs		**(2,790)**	(2,616)
Finance income, net		**33,964**	600
Share of loss of investments accounted for using the equity method		**(11,643)**	(1,251)
Loss before income tax		**(348,374)**	(522,723)
Income tax expense	*8*	**–**	–
Loss for the period		**(348,374)**	(522,723)
Loss attributable to:			
Owners of the Company		**(344,286)**	(511,954)
Non-controlling interests		**(4,088)**	(10,769)
		(348,374)	(522,723)

	Note	Six months ended 30 June	
		2022	2021
		RMB'000	*RMB'000*
		(Unaudited)	(Unaudited)
Loss per share for loss attributable to owners of the Company for the period (expressed in RMB per share)			
– Basic	*9*	**(0.21)**	(0.34)
– Diluted	*9*	**(0.21)**	(0.34)
Other comprehensive income			
Items that may be subsequently reclassified to profit or loss			
Currency translation differences		**132**	7
Total comprehensive loss		**(348,242)**	(522,716)
Total comprehensive loss attributable to:			
Owners of the Company		**(344,154)**	(511,947)
Non-controlling interests		**(4,088)**	(10,769)
		(348,242)	(522,716)

INTERIM CONDENSED CONSOLIDATED BALANCE SHEET

30 June 2022

	Note	As at June 30 2022 *RMB'000* (Unaudited)	As at December 31 2021 *RMB'000* (Audited)
Assets			
Non-current assets			
Property, plant and equipment		**881,512**	836,713
Right-of-use assets		**128,244**	141,724
Intangible assets		**460,473**	475,090
Investments accounted for using the equity method		**126,328**	137,971
Other receivables, prepayments and deposits		**103,968**	176,431
Total non-current assets		**1,700,525**	1,767,929
Current assets			
Inventories		**27,549**	24,184
Other receivables, prepayments and deposits		**100,401**	84,780
Cash and cash equivalents		**814,488**	155,168
Term deposits with initial terms of over three months		**–**	50,000
Total current assets		**942,438**	314,132
Total assets		**2,642,963**	2,082,061
Equity			
Equity attributable to owners of the Company			
Share capital	*10*	**1,659,445**	1,531,670
Reserves		**1,533,242**	947,482
Accumulated losses		**(1,986,724)**	(1,642,438)
		1,205,963	836,714
Non-controlling interests		**6,288**	10,369
Total equity		**1,212,251**	847,083

	Note	**As at June 30 2022** ***RMB'000*** **(Unaudited)**	As at December 31 2021 *RMB'000* (Audited)
Liabilities			
Non-current liabilities			
Borrowings		**255,263**	232,469
Lease liabilities		**9,718**	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*	**442,684**	384,287
Total non-current liabilities		**757,352**	685,921
Current liabilities			
Borrowings		**167,170**	60,409
Trade payables	*12*	**188,868**	158,818
Other payables and accruals		**295,129**	311,043
Lease liabilities		**22,193**	18,787
Total current liabilities		**673,360**	549,057
Total liabilities		**1,430,712**	1,234,978
Total equity and liabilities		**2,642,963**	2,082,061

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

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.

The financial information in this Results Announcement is presented in Renminbi ("**RMB**"), unless otherwise stated.

The Group's unaudited interim condensed consolidated financial information was approved for issue by the board of directors of the Company on 25 August 2022.

2 SIGNIFICANT EVENT

(a) On 23 February 2022, the Company has 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 (equivalent of RMB5 million). Details please refer to Note 10.

(b) In view of the outbreak of the Omicron variant and the control measures in different cities (such as Shanghai) in 2022, the Company believes that Coronavirus Disease 2019 ("**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. As the Group's clinical trial sites are geographically dispersed, the control measures in certain cities had not significantly affected the progress of clinical trials in and outside Mainland China. 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.

3 BASIS OF PREPARATION

The Group's interim condensed consolidated financial information for the six months ended 30 June 2022 has been prepared in accordance with International Accounting Standard 34 ("**IAS 34**") "Interim Financial Reporting" issued by the International Accounting Standards Board ("**IASB**").

The interim condensed consolidated financial information should be read in conjunction with the annual financial statements of the Company for the year ended 31 December 2021 (the "**2021 Annual Financial Statements**"), which have been prepared in accordance with International Financial Reporting Standards ("**IFRSs**"), and any public announcement made by the Company during the interim reporting period.

4 SIGNIFICANT ACCOUNTING POLICIES

The Group has applied the following amended standards in the interim condensed consolidated financial information:

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

The adoption of these amended standards did not have any material impact on the significant accounting policies of the Group and the presentation of the interim condensed consolidated financial information.

The Group has not early adopted the new standards and amendments to IFRSs that have been issued and not yet effective for the year ended 31 December 2022 in the interim condensed consolidated financial information.

Taxes on income in the interim period are accrued using the tax rate that would be applicable to expected total annual earnings.

5 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.

6 EXPENSES BY NATURE

	Six months ended 30 June	
	2022	2021
	RMB'000	*RMB'000*
Clinical trial expenses	**87,034**	187,876
Employee benefit expenses	**85,580**	136,839
Depreciation and amortisation	**45,315**	47,507
Pre-clinical study costs	**37,568**	51,479
Raw material and consumables used	**9,797**	28,691
Professional services fees	**9,491**	872
Utilities	**2,177**	2,531
Office expenses	**1,452**	1,342
Traveling and transportation expenses	**1,102**	2,465
Auditors' remuneration	**800**	–
Listing expenses	**26,783**	22,309
Others	**8,536**	9,041
Total administrative expenses, research and development expenses and other expenses	**315,635**	490,952

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

	Six months ended 30 June	
	2022	2021
	RMB'000	*RMB'000*
Fair value losses on financial liabilities at fair value through profit or loss	**(60,776)**	(34,637)
Fair value gains on financial assets at fair value through profit or loss	**–**	358
	(60,776)	(34,279)

8 INCOME TAX EXPENSE

	Six months ended 30 June	
	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.

9 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 interim period.

	Six months ended 30 June	
	2022	2021
Loss for the period and attributable to owners of the Company (in RMB'000)	**(344,286)**	(511,954)
Weighted average number of ordinary shares in issue (in thousands)	**1,621,896**	1,508,843
Basic loss per share (in RMB)	**(0.21)**	(0.34)

(b) Diluted loss per share

Diluted earnings per share presented is the same as the basic earnings per share as there were no potentially dilutive ordinary shares issued during the six months ended 30 June 2022 and 2021.

10 SHARE CAPITAL

	Number of shares	Nominal value of shares *RMB'000*
Authorised and issued and fully paid		
At 1 January 2022	**1,531,669,838**	**1,531,670**
Issuance of ordinary shares upon global offering *(a)*	**126,876,000**	**126,876**
Exercise of over-allotment option *(b)*	**899,000**	**899**
At 30 June 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 30 June 2021	1,531,669,838	1,531,670

(a) On 23 February 2022, the Company has 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.

(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 share 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 30 June 2022 *RMB'000*	As at 31 December 2021 *RMB'000*
Variable consideration payable arisen from acquisition of 40% equity of Taizhou Hanzhong from non-controlling interests	**446,242**	385,466
Less: current portion	**(3,558)**	(1,179)
Non-current portion	**442,684**	384,287

The movements of financial liabilities at fair value through profit or loss for the six months ended 30 June 2022 and 2021 are set out below:

	Six months ended 30 June	
	2022 *RMB'000*	2021 *RMB'000*
Opening balance	**385,466**	309,181
Change in fair value *(Note 7)*	**60,776**	34,637
Closing balance	**446,242**	343,818

12 TRADE PAYABLES

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

	As at 30 June 2022 *RMB'000*	As at 31 December 2021 *RMB'000*
Less than 1 year	**188,533**	157,731
Between 1 and 2 years	**335**	1,087
	188,868	158,818

13 DIVIDEND

No dividend has been paid or declared by the Company or companies comprising the Group during the six months ended 30 June 2022 and 2021.

14 EVENTS OCCURRING AFTER THE REPORTING PERIOD

There was not any significant event occurred after 30 June 2022 which needs to be disclosed in this interim condensed consolidated financial information.

The unaudited interim condensed consolidated statement of comprehensive income, the unaudited interim condensed consolidated balance sheet of the Group and its explanatory notes as presented above are extracted from the unaudited interim condensed consolidated financial information of the Group for the six months ended 30 June 2022.

"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
"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
"BC"	breast cancer
"Board"	the board of Directors of the Company
"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"	Center for Drug Evaluation (藥品審評中心) of the NMPA
"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
"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
"CR"	complete response, the disappearance of all signs of cancer in response to treatment
"CRO"	contract research organization, a pharmaceutical company that conducts research for other pharmaceutical companies on a contractual basis
"DCR"	disease control rate, the total proportion of patients who demonstrate a response to treatment, equal to the sum of complete responses (CR), partial responses (PR) and stable disease (SD)

"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 test 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
"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
"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 in-house 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 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
"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
"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
"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
"ORR"	objective response rate, which is equal to the sum of CR and PR
"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
"PFS"	progression-free survival, the length of time during and after the treatment of a disease, such as cancer, that a patient lives with the disease but it does not get worse
"pre-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 I clinical trials"	study in which a drug is introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion, and if possible, to gain an early indication of its effectiveness
"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
"PR"	partial response, refers to an at least 30% but below 100% decrease in the size of a tumor or in the extent of cancer in the body in response to treatment, according to RECIST
"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

"RECIST"	Response Evaluation Criteria in Solid Tumors, a set of published rules that define when tumors in cancer patients improve ("respond"), stay the same ("stabilize"), or worsen ("progress") during treatment. The criteria were published in February 2000 by an international collaboration including the European Organisation for Research and Treatment of Cancer (EORTC), National Cancer Institute of the United States, and the National Cancer Institute of Canada Clinical Trials Group. Now the majority of clinical trials evaluating cancer treatments for objective response in solid tumors use RECIST. These criteria were developed and published in February 2000, and subsequently updated in 2009
"Reporting Period"	the six months ended June 30, 2022
"RMB" or "renminbi"	Renminbi, the lawful currency of China
"SD"	stable disease. In oncology, it refers to cancer that is neither decreasing at least 30% nor increasing at least 20% in the size of a tumor or in the extent of cancer in the body in response to treatment, according to RECIST
"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
"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
August 25, 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.