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, 2023

The Board is pleased to announce the audited consolidated annual results of the Group for the year ended December 31, 2023, together with the comparative figures of 2022.

FINANCIAL HIGHLIGHTS

- Revenue increased by approximately 1,347.2% from approximately RMB15.6 million for the year ended December 31, 2022 to approximately RMB225.4 million for the year ended December 31, 2023.

- Research and development expenses decreased by approximately 12.6% from approximately RMB524.3 million for the year ended December 31, 2022 to approximately RMB458.1 million for the year ended December 31, 2023.

- Other gains and losses, net increased from losses of RMB0.9 million for the year ended December 31, 2022 to gains of RMB213.5 million for the year ended December 31, 2023.

- Loss for the year attributable to the owners of the Company decreased significantly by approximately 96.8% from approximately RMB689.1 million for the year ended December 31, 2022 to approximately RMB22.1 million for the year ended December 31, 2023.

- Adjusted net loss (non-IFRS measure)[(1)] for the year decreased from approximately RMB699.4 million for the year ended December 31, 2022 to approximately RMB250.6 million for the year ended December 31, 2023.

(1) We define "adjusted net loss (non-IFRS measure) for the year" as our loss for the year, deducting certain items as set out in the section headed "Adjusted Net Loss (Non-IFRS Measure) for the Reporting Period". We exclude these items because they are non-recurring income related to our associate companies that are non-operating in nature.

BUSINESS HIGHLIGHTS

We recorded a breakthrough in our revenue and made significant progress in our product pipeline and business operations during the Reporting Period:

Achieving breakthroughs in BD and commercialization with total revenue of RMB225.4 million, coupled with a remarkable decrease in loss

– Licensing income from BD activity: During the Reporting Period, the Group recorded a total revenue of approximately RMB124.0 million in relation to the License Agreement entered into between KYM, a joint venture formed by us and Keymed, and AstraZeneca on February 23, 2023 to develop and commercialize CMG901. Under the License Agreement, we have received approximately RMB109.5 million from KYM as licensing income, and the remaining revenue was from AstraZeneca for the supply of services and drug products.

– Commercialization of PUYOUHENG (Pucotenlimab Injection): During the Reporting Period, PUYOUHENG (Pucotenlimab Injection) recorded a sales revenue of approximately RMB101.4 million.

– Other gains from partial disposal of HealSun Biopharma and dilution of equity interests in Wuhan Binhui: During the Reporting Period, we made net gains of RMB103.9 million on the disposal of investment in HealSun Biopharma and RMB116.4 million on the dilution of equity interests in Wuhan Binhui, respectively, totalling other gains of approximately RMB220.3 million.

– Remarkable decrease in loss: The significant increase in revenue, together with other gains recognized from the Group's investment activities, have largely contributed to a remarkable decrease in loss of approximately 95.7% as compared to the year ended December 31, 2022.

Significant advancement of ADC Pipeline

– **MRG003:** We have completed patients enrollment of the registrational Phase IIb clinical study on NPC and expect to file NDA in 2024. In the United States, MRG003 for the treatment of NPC has been granted IND approval in October 2023 and FTD in November 2023 from the FDA. In October 2023, the encouraging data from the Phase IIa clinical study of MRG003 for the treatment of NPC and the Phase II clinical study for the treatment of HNSCC was disclosed at the annual conference of ESMO 2023.

– **MRG002:** We have completed patients enrollment of the pivotal Phase II clinical trial on HER2 over-expressing BC with liver metastasis in China and observed encouraging data. We are making our best efforts on pushing it to the NDA stage. Meanwhile, we are conducting a Phase III clinical trial on HER2 positive BC.

– **MRG004A:** We are conducting a Phase I clinical study of MRG004A on solid tumors in the United States and China and have observed encouraging data on PC, TNBC and CC. We are planning to present such data in the ASCO Annual Meeting 2024. MRG004A for the treatment of PC has been granted ODD from the FDA in December 2023.

Completion of Phase III patients enrollment of CG0070 in the U.S. and concurrent bridging Phase I clinical study in China

– CG0070: Our U.S. partner, CG Oncology, is currently conducting a Phase III clinical trial of CG0070 in the United States with encouraging data observed, and has completed patients enrollment as of July 2023. In December 2023, CG0070 was also granted FTD and BTD by the FDA in the United States. As of December 31, 2023, we are conducting a bridging Phase I clinical study in China.

Notable synergy observed clinically with combination therapy of ADC and PD-1

– Combination therapy of MRG003 with PUYOUHENG (Pucotenlimab Injection): We have completed the Phase I trial of combination therapy with MRG003 and pucotenlimab in the treatment of solid tumor and have observed encouraging preliminary data, which is anticipated to be showcased at the ASCO Annual Meeting 2024. We are currently conducting a Phase II trial and have observed encouraging data on NPC and HNSCC.

– Combination therapy of MRG002 with PUYOUHENG (Pucotenlimab Injection): We are conducting a Phase II trial of combination therapy with MRG002 and pucotenlimab in the treatment of HER2 expressing solid tumor and have observed encouraging preliminary data on UC, which is expected to be presented at the ESMO Congress 2024.

Encouraging pre-clinical data from candidates developed on innovation platforms

We have observed encouraging data in pre-clinical studies of the ADC candidate MRG006A and the new-generation T cell agonistic antibody CTM012, which are developed based on our Hi-TOPi and TOPAbody platforms respectively. Pre-clinical data of MRG006A and TOPAbody platforms are expected to be presented at AACR annual meeting in April 2024.

KEY EVENTS AFTER THE REPORTING PERIOD

– **MRG004A:** In March 2024, MRG004A was granted FTD from the FDA for the treatment of pancreatic cancer which have relapsed or are refractory to prior approved therapies, and this designation signified the innovativeness and the potential of MRG004A to fulfill the unmet medical needs.

MANAGEMENT DISCUSSION AND ANALYSIS

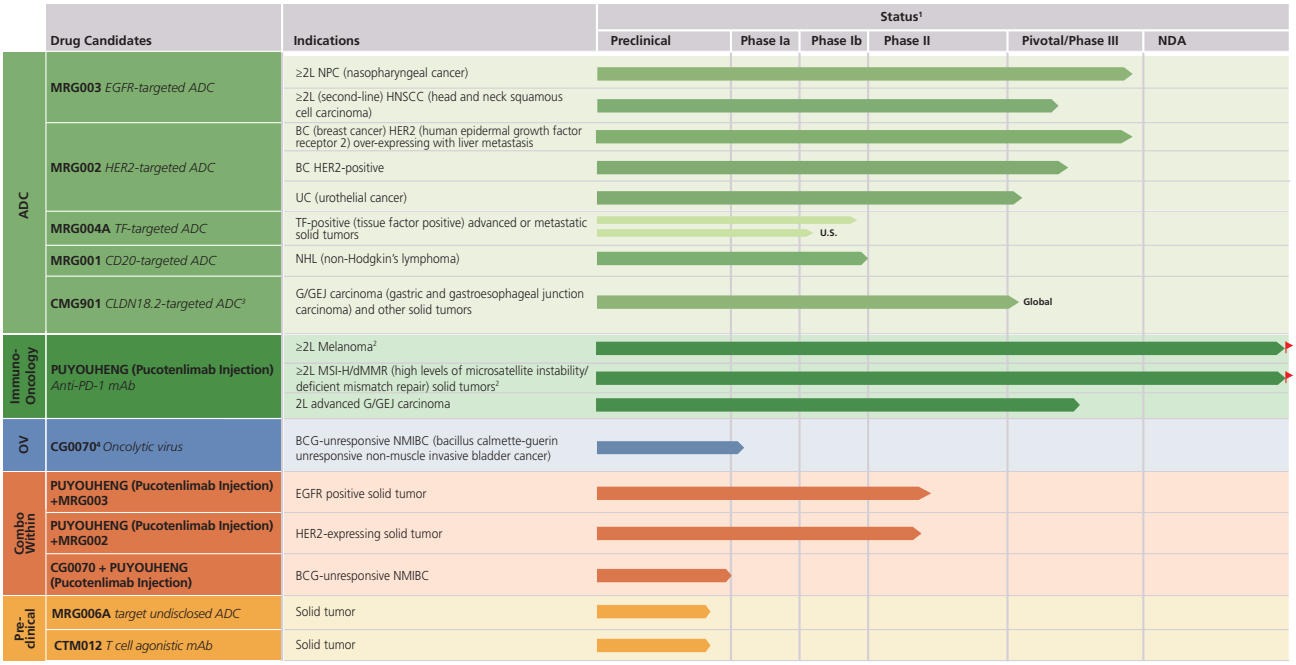
OVERVIEW

We are an innovation-driven biopharmaceutical company focusing on oncology therapeutics, in particular, targeted therapy and oncology immunotherapy, with a strong China foundation and global vision. We are dedicated to developing innovative ADCs through an advanced ADC technology development platform. We aim to develop more optimal and innovative drugs to better serve the unmet medical needs of cancer patients. We endeavor to continuously develop a market-differentiating pipeline by combining in-house research and development with 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. We have an integrated end-to-end capability across drug discovery, clinical development, CMC and GMP-compliant manufacturing, encompassing all critical functions of the biopharmaceutical value chain, and are building dedicated sales and marketing forces.

We have strategically designed our pipeline with a range of oncology products. For clinical-stage candidates, we have (i) one clinical/commercialization-stage drug candidate; (ii) six clinical-stage drug candidates, including one co-developed through a joint venture; and (iii) three clinical-stage combination therapies of our candidates. One of our drug candidates has obtained marketing approval with respect to two of its targeted indications, with clinical trials for other indications ongoing. Among the six clinical-stage drug candidates, five are targeted therapeutics and one is an immunotherapeutic, which is an oncolytic virus drug. We have initiated multiple clinical trials, amongst which one is ongoing in the U.S., and five have entered the stage of registrational trials in the PRC. MRG003 was granted ODD and FTD on NPC from the FDA and BTD from the CDE. MRG002 was granted ODD on GC/GEJ from the FDA. CMG901 was granted FTD and ODD in GC/GEJ from the FDA, and obtained BTD from CDE. MRG004A was granted ODD and FTD by the FDA for the treatment of PC. We have continuously striven to build up and develop novel technology platforms as innovative engines for the Company. Among our pre-clinical-stage candidates, we have observed encouraging data in pre-clinical studies of MRG006A and CTM012 during the Reporting Period, and are advancing these two candidates to enter into the clinical research stage efficiently.

PRODUCT PIPELINE

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



Notes:

1. 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.

2. On July 19, 2022 and September 29, 2022, we obtained from the NMPA conditional marketing approval for PUYOUHENG (Pucotenlimab Injection) on MSI-H/dMMR and inoperable or metastatic melanoma, respectively. We are conducting confirmatory Phase lll clinical studies on the first-line MSI-H/dMMR metastatic colorectal cancer and the first-line stage IV (M1c) melanoma respectively.

3. In February 2023, KYM has entered into a global exclusive out-license agreement with AstraZeneca to grant an exclusive global license for research, development, registration, manufacturing and commercialization of CMG901 to AstraZeneca. For details, please refer to the Company's announcement dated February 23, 2023.

4. Apart from the Phase Ia clinical trial currently conducted in China, the MRCT clinical trial of CG0070 is also being 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, Hong Kong and Macau.

BUSINESS REVIEW

The Group recorded a breakthrough in its revenue and a remarkable decrease in its loss for the year ended December 31, 2023.

During the Reporting Period, the Group recorded a total revenue of RMB225.4 million, which was contributed by the Group's licensing activities and the commercialization of PUYOUHENG (Pucotenlimab Injection). For licensing activities, the Group has recognised approximately RMB124.0 million in total, which was in relation to the License Agreement entered into between KYM, a joint venture formed by us and Keymed, and AstraZeneca on February 23, 2023 to develop and commercialize CMG901. Under the License Agreement, we have received approximately RMB109.5 million from KYM as licensing income, and we have also entered into series of agreements with AstraZeneca to provide services and drug products, which has contributed to the remaining revenue from licensing activities. At the same time, we have also successfully commercialized PUYOUHENG (Pucotenlimab Injection) and recorded a sales revenue of RMB101.4 million during the Reporting Period.

In addition, there was an increase in other gains for the year ended December 31, 2023. On September 28, 2023, the Company has partially disposed of its investment in HealSun Biopharma, which contributed to net gains of RMB103.9 million. During the Reporting Period, the percentage of share of interests held by the Company in Wuhan Binhui was diluted from 20.03 % to 11.84% as the preferred rights granted upon issuance of ordinary shares by Wuhan Binhui to certain investors were terminated, and we have made net gains of RMB116.4 million on the dilution of equity interests. Through these investment activities, the Group recognised other gains of approximately RMB220.3 million for the year ended December 31, 2023.

The significant increase in revenue, together with the increase in other gains recognized from the Group's investment activities, have largely contributed to a remarkable decrease in loss of approximately 95.7% as compared to the year ended December 31, 2022.

During the year ended December 31, 2023, the Group also continued to focus its efforts on the research and development of its drug candidates, while continuously assessing market demand and the competitive landscape relating to the range of oncology therapeutics and the broad spectrum of indications covered by its drug candidates, in order to maximize the competitiveness of its product pipeline. A description of the progress made and the latest status in respect of the Group's drug candidates for the year ended December 31, 2023 and up to the date of this announcement is as follows:

MRG003

– MRG003 is an ADC comprised of an EGFR-targeted mAb conjugated with the potent microtubulin 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.

– As of December 31, 2023, we are conducting a pivotal Phase IIb clinical study on NPC and have completed patients enrollment, and we are concurrently conducting a Phase III clinical study on HNSCC. We are also exploring the potential efficacy of MRG003 in other prevalent cancer types of EGFR over-expression.

  o **NPC**: We have observed encouraging data from the Phase IIa clinical study on NPC, which was presented orally at the ESMO Congress 2023. As of March 15, 2023, the ORR was 47.4% and the DCR was 79.0% on NPC patients previously received PD-1 (L1) and platinum-based therapy. For the 2.0mg/kg dose group, the ORR was 39.3% and the DCR was 71.4%. The mPFS in this group was 7.3 month. For the 2.3mg/kg dose group, the ORR was 55.2% and the DCR was 86.2%. The mPFS in the 2.3mg/kg dose group was immature. Based on the promising data, MRG003 was granted IND approval and FTD from the FDA for the treatment of R/M NPC in October 2023 and November 2023 respectively. We are conducting a pivotal Phase IIb clinical study on NPC and have completed patients enrollment as of December 31, 2023. We expect to file NDA in China in 2024.

  o **HNSCC**: We have observed encouraging data from the Phase II clinical study on HNSCC, which was a poster presentation at the ESMO Congress 2023. As of March 15, 2023, the ORR and DCR was 43% and 86% respectively, and the mOS was 11.3 months on patients who progressed following platinum-based chemotherapy and PD-1 (L1) inhibitors, and prior therapy ≤ 2 lines with 2.3 mg/kg dose. As of December 31, 2023, we are conducting a randomized, open-label, multicenter Phase III clinical study on HNSCC.

– **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 and our 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 and UC. Registrational clinical trials in the aforementioned indications are ongoing.

  o **HER2 over-expressing BC:** We are currently conducting a pivotal Phase II clinical trial on HER2 over-expressed BC with liver metastasis in China and patients enrollment thereof has been completed. We observed encouraging data and are currently making our best efforts on pushing it to the NDA stage. Meanwhile, as of December 31, 2023, we are conducting a Phase III clinical study on HER2-positive BC.

  o **UC**: We are conducting an open-label, randomized, multi-center Phase III clinical study of MRG002 versus investigator's choice of chemotherapy in the treatment of patients with HER2-positive unresectable locally advanced or metastatic UC previously treated with platinum-based chemotherapy and PD-1/PD-L1 inhibitors as of December 31, 2023.

– **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 and our potential investors are advised to exercise caution when dealing in the Shares.

MRG004A

– MRG004A is a novel TF-targeted site-specifically conjugated ADC. We are currently conducting a Phase I clinical study on solid tumors in the United States and China and have observed anti-tumor activity signal on PC, TNBC and CC. The preliminary Phase I data on solid tumors will be presented at the ASCO Annual Meeting 2024. We are expanding sub-group of PC patients in the Phase I clinical trial to explore further potential of MRG004A on PC. In December 2023, MRG004A was granted ODD by the FDA for the treatment of PC.

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

MRG001

– MRG001 is a clinically advancing CD20-targeted ADC which addresses the medical needs of B-cell NHL patients with either primary drug resistance to rituximab or acquired drug resistance to the combination therapy of rituximab and standard chemotherapies. We are conducting a Phase Ib dose expansion study of MRG001 in China and observed encouraging preliminary data on DLBCL. Such data was presented at 65th ASH Annual Meeting as a poster. As of July 28, 2023, the CR rate and ORR was 17.6% and 38.2% respectively on CD20 positive DLBCL patients that failed ≥2L prior therapies, of which a prior anti-CD-20 treatment is necessary. For patients who did not receive prior CAR-T treatment, the CR rate and ORR was 22.2% and 44.4% respectively, and the mPFS was 6.3 months.

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

CMG901

– CMG901 is a CLDN18.2-targeting ADC comprising a CLDN18.2-specific antibody, a cleavable linker and a toxic payload, MMAE. It is the first CLDN18.2 targeting ADC to have received IND clearance both in China and the U.S. CLDN18.2 is selectively and widely expressed in GC, PC and other solid tumors, which makes it an ideal tumor target for therapeutic development. It is being co-developed by us and Keymed through a joint venture, KYM. Phase Ia trial of CMG901 was conducted for advanced solid tumors. CMG901 showed a favorable safety and tolerability profile in this trial. In November 2023, the latest data from a Phase I clinical study of CMG901 in the treatment of advanced GC/GEJ has been presented by way of oral presentation at the ASCO Plenary Series. The clinical study was designed to evaluate the safety and tolerability, pharmacokinetics, immunogenicity, and preliminary efficacy of CMG901 in subjects with advanced solid tumors. As of July 24, 2023, totally 113 patients with GC/GEJ received CMG901 at doses of 2.2, 2.6, and 3.0 mg/kg (n=44, 50, and 19, respectively). All subjects previously received ≥1 line of prior therapy. The median line of prior therapy was two. 74% of subjects previously received PD-1/PD-L1 therapy. In terms of safety, drug-related grade ≥3 TEAEs occurred in 54% of patients, and drug-related serious adverse events were reported in 31% of patients. 8% of patients had discontinued CMG901 treatment due to TEAEs. Among 89 evaluable patients with CLDN18.2-positive GC/GEJ in three cohorts, confirmed ORR and confirmed DCR were 33% and 70%, respectively. Among others, CMG901 showed a 42% confirmed ORR in 2.2 mg/kg dose cohort, with mPFS of 4.8 months, and the median overall survival (mOS) was not reached yet. In this trial, CMG901 had a manageable safety and tolerability profile, and most patients were well-managed by standard treatment management while continuing CMG901 treatment. CMG901 demonstrated promising efficacy in patients with advanced CLDN 18.2-positive GC/GEJ. As of March 26, 2024, AstraZeneca has conducted multiple clinical studies regarding CMG901 for the treatment of advanced solid tumors.

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

PUYOUHENG (Pucotenlimab Injection)

– PUYOUHENG (Pucotenlimab Injection) 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, and which has been commercialized for treating MSI-H/dMMR and inoperable or metastatic melanoma since the second half of 2022. In April 2023, two indications were included into the 2023 CSCO Guideline, which are pucotenlimab as ≥ second-line treatment of MSI-H/dMMR colorectal cancer and solid tumors, and pucotenlimab as second-line treatment of melanoma. Moreover, Pucotenlimab for treatment of advanced and recurrent MSI-H/dMMR gynecological cancer was included into the 2023 CSGO Guideline.

  o **MSI-H/dMMR solid tumors:** We are conducting an open label, multi-center and randomized Phase III clinical trial on the first-line MSI-H/dMMR metastatic colorectal cancer as a confirmatory clinical study for the conditional marketing approval as of December 31, 2023.

  o **Melanoma:** We are conducting an open label, multi-center and randomized Phase III clinical trial on the first-line treatment of subjects with stage IV (M1c) melanoma as a confirmatory clinical study for the conditional marketing approval as of December 31, 2023.

  o **GC/GEJ in second-line therapy:** We are conducting a multi-center, randomized, double-blinded and placebo-controlled Phase III clinical study of pucotenlimab in combination therapy with irinotecan. Patients enrollment is ongoing as of December 31, 2023.

CG0070

– CG0070 is an oncolytic adenovirus for the treatment of BCG unresponsive bladder cancer patients and is currently in a MRCT Phase III clinical study conducted by our U.S. partner, CG Oncology. As of July 2023, patients enrollment has been completed for the MRCT Phase III clinical study. As of October 5, 2023, the overall CR rate was 75.7% on patients with NMIBC who have failed prior BCG therapy. The 3 and 6-month landmark CR rates were 68.2% and 63.6%, respectively. Furthermore, CG0070 was granted FTD and BTD by the FDA in December 2023 in the United States. We in-licensed CG0070 from CG Oncology and were granted the rights to develop, manufacture and commercialize it in Mainland China, Hong Kong and Macau. We are conducting a Phase I clinical trial in China as of December 31, 2023, with patients enrollment ongoing.

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

Combination therapies within pipelines

– **MRG003 + PUYOUHENG (Pucotenlimab Injection):** We have completed a Phase I trial of combination therapy with MRG003 and pucotenlimab in the treatment of solid tumors and have observed encouraging preliminary data, which is anticipated to be showcased at the ASCO Annual Meeting 2024. We are currently conducting a Phase II trial and have observed encouraging data on NPC and HNSCC.

– **MRG002 + PUYOUHENG (Pucotenlimab Injection):** We are conducting a Phase II trial of combination therapy with MRG002 and pucotenlimab in the treatment of HER2-expressing solid tumors and have observed encouraging preliminary data on UC, which is expected to be presented at the ESMO Congress 2024.

– **CG0070 + PUYOUHENG (Pucotenlimab Injection):** We received an IND approval from the NMPA for a Phase I trial of combination therapy with CG0070 and pucotenlimab in the treatment of patients with BCG-unresponsive NMIBC. We plan to initiate a Phase I/II clinical study of CG0070 and pucotenlimab combination therapy on BCG-unresponsive NMIBC.

Innovation platforms

We continuously strive to build up and develop novel technology platforms as innovative engines for the Company. During the Reporting Period, our innovative platforms, being Hi-TOPi platform for ADC and T cell engager platform TOPAbody, have achieved significant progress. Based on these innovation platforms, we have generated ADC candidate MRG006A and the new-generation T cell agonistic antibody CTM012 which have global first-in-class potential. We have observed encouraging data in pre-clinical studies and are advancing these two candidates to enter into clinical research stage efficiently. Pre-clinical data of MRG006A and TOPAbody platforms are also expected to be presented at AACR annual meeting in April 2024.

– **Hi-TOPi platform:** The Hi-TOPi platform for ADC is featured by: (i) Linker, which is highly stable in circulation and effective in releasing payload in cells; (ii) Payload, which has good potency when compared to competitors (it is not a substate for Pgp, and therefore it has a great potential of overcoming drug resistance); (iii) ADCs utilizing the novel linker-payload have demonstrated strong anti-tumor activity in PDX of multiple tumor types and also shown excellent safety profile and good tolerance in monkeys; and (iv) improved therapeutic window.

    o Using the novel linker-payload platform, we have developed MRG006A, which is an ADC candidate with global first-in-class potential and has entered the IND-enabling study stage. We expect to file IND in the second quarter of 2024.

– **T cell engager platform:** Our proprietary T cell engager platform-TOPAbody is featured by (i) simultaneous activation of both TCR signaling and co-stimulatory pathway that intends to unlock the full potential of T cells, and (ii) restricted activity in the tumor microenvironment.

    o Based on the T cell engager platform, we have developed CTM012, a new-generation T cell agonistic antibody with first-in-class potential which has entered the IND-enabling study stage during the Reporting Period. We target to file IND in 2024.

Manufacturing Facilities

We have been operating a 2,000L GMP-compliant bioreactor production line at our Beijing manufacturing plant during the Reporting Period, which mainly supports the production of clinical drug supply and offers CDMO production services.

In addition, the building construction of the Shanghai Biotech Park has been preliminarily completed and accepted during the Reporting Period, and the research and development center in the Shanghai Biotech Park has been put in use. The manufacturing facilities in the Shanghai Biotech Park has a designed total capacity of 12,000L, and it has obtained the environmental impact assessment report for the production of mAb and ADC. Going forward, we will continue to build the manufacturing facilities based on our business needs arising from the commercialization of ADC.

License-out and commercialization

Licensing income from BD activities

For the year ended December 31, 2023, the Group has recorded a total revenue of approximately RMB124.0 million from its licensing activities, which was in relation to the License Agreement entered into between KYM, a joint venture formed by us and Keymed, and AstraZeneca on February 23, 2023 to develop and commercialize CMG901. Under the License Agreement, AstraZeneca has been granted an exclusive global license for the research, development, registration, manufacturing, and commercialization of CMG901, and shall be responsible for all costs and activities associated with the further development and commercialization of CMG901 except as otherwise agreed. According to the License Agreement and subject to the terms and conditions thereof, KYM shall receive an upfront payment of US$63 million with the potential for additional payments up to US$1,125 million subject to achievement of certain development, regulatory and commercial milestones. KYM is also entitled to receive tiered royalties on net sales from AstraZeneca. During the Reporting Period, we have received approximately RMB109.5 million from KYM. Based on the License Agreement, we have also entered into series of agreements with AstraZeneca, pursuant to which we have recognized revenue through providing services and supplying drug products to AstraZeneca.

For details of the License Agreement, please refer to the Company's announcement dated February 23, 2023.

Commercialization of PUYOUHENG (Pucotenlimab injection)

The Company has commercialized its first product, PUYOUHENG (Pucotenlimab Injection), in the second half of 2022, and has since then achieved sales of such product. For the year ended December 31, 2023, PUYOUHENG (Pucotenlimab Injection) recorded a sales revenue exceeding RMB100 million.

We have built a highly efficient sales and marketing team based on our commercialized product, PUYOUHENG (Pucotenlimab Injection). Our commercialization team is mainly responsible for developing strategies for product promotion, product positioning and brand management, establishing a good brand image in the market through academic promotion activities and product education to increase product awareness among leading physicians and the patient population. In April 2023, Pucotenlimab has been successfully included in the 2023 CSCO and CSGO Guidelines for melanoma and MSI-H/dMMR solid tumors, which represents a high degree of recognition from clinical KOL.

In terms of the establishment of sales channels, we actively develop cooperative relationships with various business channel partners. As of December 31, 2023, we have completed the tendering process on the procurement platform in 21 provinces. We have covered approximately 76 cities through various sales channels, and we will further expand our sales network.

KEY EVENTS AFTER THE REPORTING PERIOD

Development Progress of our Drug Candidates After the Reporting Period

- **MRG004A:** In March 2024, MRG004A was granted FTD from the FDA for the treatment of pancreatic cancer which have relapsed or are refractory to prior approved therapies, and this designation signified the innovativeness and the potential of MRG004A to fulfill the unmet medical needs.

Continuing connected transaction with Lepu Medical

The Company has entered into a framework agreement with Lepu Medical in respect of the provision of CDMO technical services by the Company and/or its subsidiaries to Lepu Medical and/or its subsidiaries for their development of GLP-1 and related products on November 13, 2023 (which was subsequently supplemented and amended pursuant to a supplemental framework agreement entered into between the Company and Lepu Medical on December 22, 2023). The aforementioned framework agreement and supplemental framework agreement (together with the monetary transaction caps therein) were approved by the Independent Shareholders in the 2024 first extraordinary general meeting of the Company held on January 31, 2024. Upon the passing of the relevant resolutions by the Independent Shareholders at the Company's 2024 first extraordinary general meeting, the Company has commenced the provision of its CDMO services to Lepu Medical pursuant to the terms and conditions of the aforementioned framework agreement and supplemental framework agreement.

For further details of the aforementioned continuing connected transaction with Lepu Medical, please refer to the Company's announcements dated November 13, 2023 and December 22, 2023, circular dated January 16, 2024 and poll results announcement dated January 31, 2024.

FUTURE DEVELOPMENT

The Company is an innovation-driven biopharmaceutical company focusing on oncology therapeutics, dedicated to promoting the technological advancement of innovative ADCs in China to better serve the unmet medical needs of cancer patients. We strive to develop and broaden our product pipeline by combining our in-house research through development and with strategic collaborations. Looking ahead to 2024, we will accelerate the development of our two key ADC products, MRG003 and MRG002, to the next milestones. We will expedite the NDA submission for MRG003 and expect to file NDA in 2024. We will make every effort to push MRG002 for HER2 over-expressing BC to the NDA stage, and to explore further potential clinical value of our innovative drug candidates, such as MRG004A. We will reinforce the establishment of our innovation platforms and make efforts to file IND for the innovative molecules MRG006A and CTM012.

In 2024, we will work to deepen our efforts on marketing and commercialization and to actively expand our market footprint and product recognition within China. We will expand our commercialization team by recruiting talents with the appropriate skills and expertise in the commercialization of pharmaceutical products. We will take further actions to promote the market accessibility of PUYOUHENG (Pucotenlimab Injection) and continue to accelerate market penetration at all levels, with a view to further increasing market share. By leveraging the expertise and industry connections of our commercialization team and our solid understanding of the Chinese market environment, we will seek to foster our brand's image and market knowledge of our product through various methods. We believe that the enhancement of our efforts in terms of market outreach will translate into better market access, increased market share and increases in the sales of our commercialized product and our brand in general, thereby laying a solid market and channel foundation for the future commercialization of our ADC product pipeline.

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

FINANCIAL REVIEW

Revenue

For the year ended December 31, 2023, we have recorded a revenue of RMB225.4 million (2022: RMB15.6 million), representing an increase of 1,347.2%. During the same period, the Group has recognized revenue of approximately RMB124.0 million from the out-licensing of CMG901 to AstraZeneca. At the same time, after the successful commercialization of PUYOUHENG (Pucotenlimab Injection) in late 2022, the Company has also recognized a revenue of RMB101.4 million from the sale of pharmaceutical products for the year ended December 31, 2023, representing an increase of 551.1% as compared to the relevant amount for the year ended December 31, 2022.

Cost of sales

For the year ended December 31, 2023, the Group has recorded cost of sales of RMB28.3 million (2022: RMB2.0 million), representing an increase of 1,310.3%, which was in line with the growth in revenue.

Selling and Marketing Expenses

For the year ended December 31, 2023, the Group has recorded selling and marketing expenses of RMB43.3 million (2022: RMB1.7 million). This is mainly because the Group had commercialized PUYOUHENG (Pucotenlimab Injection) in late 2022 and has expanded the selling and marketing activities conducted for it during the Reporting Period.

Administrative Expenses

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

Our administrative expenses decreased from RMB138.8 million in 2022 to RMB86.7 million in 2023, primarily due to a decrease in the listing expenses by approximately RMB34.3 million given the Company was listed in February 2022.

Research and Development Expenses

Our research and development expenses primarily consist of (i) clinical study related expenses; (ii) pre-clinical study costs; (iii) raw materials and consumables used, primarily representing expenses for procuring raw materials and consumables used in pre-clinical and clinical studies; (iv) employee benefit expenses (mainly including wages, salaries and bonuses and share-based payment expenses) relating to our research and development staff; (v) depreciation and amortization expenses for property, plant and equipment as well as amortization expenses for intangible assets such as intellectual properties; and (vi) other expenses. Our research and development expenses decreased from RMB524.3 million in 2022 to RMB458.1 million in 2023. The following table sets forth the components of our research and development expenses for the years indicated.

	Year ended 31 December			
	2023		2022	
	RMB'000	***%***	*RMB'000*	*%*
Clinical study related expenses	**173,425**	**37.9**	204,991	39.1
Pre-clinical study costs	**34,463**	**7.5**	71,211	13.6
Raw material and consumables used	**26,455**	**5.8**	34,235	6.5
Employee benefit expenses	**120,682**	**26.3**	127,211	24.3
Depreciation and amortization	**88,372**	**19.3**	72,705	13.9
Others	**14,676**	**3.2**	13,932	2.6
Total	**458,073**	**100**	524,285	100

(i) Clinical study related expenses decreased by RMB31.6 million because the Group has been continuously focusing on the research and development of more advanced pipelines and core products;

(ii) Pre-clinical study costs decreased by RMB36.7 million, mainly because the Group has been focusing more on the research and development of innovative drug candidates based on our advanced technology development platforms;

(iii) Raw material and consumables expenses decreased by RMB7.8 million, mainly due to the capitalisation of the clinical trials expenses on PD-1;

(iv) Employee benefit expense decreased by RMB6.5 million, mainly due to the decrease in employee share incentive expenditures;

(v) Depreciation and amortization costs increased by RMB15.7 million, mainly due to an increase in depreciation of research and development facilities and equipment as a result of the commencement of the first phase of Shanghai Biotech Park in late 2022; and

(vi) Other expenses for the year ended December 31, 2023 stay constant as compared to the year ended December 31, 2022.

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

We had fair value loss on financial liabilities at fair value through profit or loss of RMB62.8 million for 2022 and fair value gain of RMB175.0 million for 2023. Our financial liabilities include financial liabilities at fair value through profit or loss, representing the variable part of the consideration arisen from the acquisition of 40% equity interests of Taizhou Hanzhong from non-controlling interest, being 4.375% of future annual net sales revenue of relevant PD-1 products.

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

	Year ended 31 December	
	2023	2022
	RMB'000	*RMB'000*
Fair value changes on financial liabilities at fair value through profit or loss		
– Fair value changes through profit or loss	**174,976**	(62,816)

Finance Income and Finance Costs

Our finance income primarily represents our bank interest income and foreign exchange gains. Our finance costs primarily consist of interest costs on lease liabilities and borrowings. Our finance income decreased from RMB45.9 million in 2022 to RMB8.3 million in 2023, mainly due to a decrease in foreign currency exchange gain. Our finance costs increased from RMB8.6 million in 2022 to RMB16.0 million in 2023, due to an increase in interest on borrowings.

Income Tax Expenses

For the year ended December 31, 2022 and 2023, the Group's income tax expenses were nil.

Loss for the Reporting Period

Based on the factors described above, the Group's loss decreased from RMB699.4 million in 2022 to RMB30.3 million in 2023.

Adjusted Net Loss (Non-IFRS Measure) for the Reporting Period

To supplement our consolidated financial statements which are presented in accordance with International Financial Reporting Standards ("**IFRS**"), we also use adjusted net loss (non-IFRS measure) for the year (defined below) as an additional financial measure, which is not required by, or presented in accordance with IFRS. We believe that the presentation of this non-IFRS measure facilitates comparisons of operating performance from period to period and company to company by eliminating potential impact of non-recurring income related to our associate companies that are non-operating in nature. We believe that this measure provides useful information to investors in understanding and evaluating the Group's consolidated results of operations in the same manner as they help our management. However, the use of non-IFRS measure has limitations as an analytical tool, and should not be considered in isolation from, or as a substitute for analysis of, our results of operations or financial conditions as reported under IFRS. In addition, the non-IFRS financial measure may be defined differently from similar terms used by other companies.

For the Reporting Period, we define "adjusted net loss (non-IFRS measures) for the year" as loss for the year after deducting (i) net gains on dilution of equity interests in an associate and (ii) net gains on disposal of investments in an associate, which are items that are not in the financial results for the previous financial year. For the year ended December 31, 2023, our adjusted net loss (non-IFRS measure) for the year was approximately RMB250.6 million (for the year ended December 31, 2022: approximately RMB699.4 million).

The following table sets forth the reconciliations of our non-IFRS financial measure for the years ended December 31, 2022 and 2023 to the nearest measure prepared in accordance with IFRS:

	Year ended December 31	
	2023	2022
	RMB'000	*RMB'000*
Loss for the year	**(30,301)**	(699,441)
Deduct:		
Net gains on dilution of equity interests in an associate[(1)]	**116,388**	–
Net gains on disposal of investments in an associate[(2)]	**103,874**	–
Adjusted net loss (non-IFRS measure) for the year	**(250,563)**	(699,441)

Notes:

(1) Net gains on dilution of equity interests in an associate represents the net gains recognized owing to the dilution of the Company's percentage equity interests held in Wuhan Binhui from 20.03% to 11.84% as a result of the preferred rights granted upon issuance of ordinary shares by Wuhan Binhui to certain investors were terminated. Such net gains recognized are non-operating and non-cash in nature.

(2) Net gains on disposal of investments in an associate represents the net gains recognized on the Company's partial disposal of equity interest in HealSun Biopharma. Such net gains recognized are non-operating in nature.

Liquidity and Financial Resources

We have incurred net losses and cash outflows from operations since inception. Our primary use of cash is to fund our research and development activities and the commercialization of our commercialized products. For the year ended December 31, 2023, our net cash used in operating activities was RMB250.8 million, a decrease of RMB230.1 million from RMB480.9 million as of December 31, 2022 due to an increase in the revenue and cash flow following the Group's licensing income and commercialization of PUYOUHENG (Pucotenlimab Injection). As of December 31, 2023, we had cash and cash equivalent of RMB426.0 million, representing a decrease of RMB243.4 million from RMB669.4 million as of December 31, 2022, as a result of the continuous research and development activities carried out by the Company.

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, 2023, the Group's bank borrowings amounted to RMB694.3 million (December 31, 2022: RMB650.0 million), among which unsecured and unguaranteed bank borrowings amounted to RMB394.0 million (December 31, 2022: RMB329.6 million) in total with interest at fixed and floating interest rates. Such borrowing will be repayable within one year.

As of December 31, 2023, the Group's secured and unguaranteed bank borrowings amounted to RMB300.3 million (December 31, 2022: RMB320.4 million) in total which bear interest at floating interest rates. Such bank borrowings are repayable by instalments and will mature in September 2027, and are secured by the Group's land use rights and construction-in-progress.

As of December 31, 2023, we had utilized RMB743.6 million from our banking facilities and RMB706.4 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 December 31, 2023, the Group's gearing ratio was 62.73% (December 31, 2022: 64.39%).

Significant Investments, Material Acquisitions and Disposals

Disposal of 15% equity interests in HealSun Biopharma

The Company (as vendor), Kangzhe Venture Capital (an independent third-party of the Company as the purchaser) and HealSun Biopharma entered into an equity transfer agreement on September 28, 2023, pursuant to which the Company agreed to sell, and Kangzhe Venture Capital agreed to purchase, 15% of the equity interest of HealSun Biopharma, at a consideration of RMB125 million. As at the date of this announcement, the aforementioned disposal has been completed. Upon completion of the disposal, the Company's equity interest in HealSun Biopharma has become 5.68%, and therefore, HealSun Biopharma has ceased to be an associate of the Company.

For further details in respect of the aforementioned disposal of equity interests in HealSun Biopharma, please refer to the Company's announcement dated September 29, 2023.

Save as aforementioned, the Group did not have any other significant investments or material acquisitions or disposals of subsidiaries, associates and joint ventures for the year ended December 31, 2023.

Capital Commitments

As of December 31, 2023 and 2022, the Group had capital commitments for property, plant and equipment of RMB456.6 million and RMB482.0 million, respectively, reflecting the capital expenditure our Group contracted at the end of year but not yet incurred.

Contingent Liabilities

As of December 31, 2023, the Group did not have any contingent liabilities.

Charges on Group Assets

Save as disclosed in this announcement, as of December 31, 2023, 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 risks arising from recognized financial liabilities denominated in foreign currencies. We currently do not have a foreign currency hedging policy. However, our management manages foreign exchange risks by performing regular reviews and will consider hedging significant foreign currency exposure should the need arise.

Employees and Remuneration

As of December 31, 2023, the Group had a total of 429 employees. The total remuneration cost for 2023 was RMB198.9 million, as compared to RMB188.3 million for 2022, primarily due to the expansion of the sales team upon the commercialization of our products, thereby resulting in an increase of total remuneration.

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

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

OTHER INFORMATION

Compliance with the Corporate Governance Code

The Company has adopted the principles and code provisions as set out in the Corporate Governance Code and has complied with all applicable code provisions for the year ended December 31, 2023.

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 year ended December 31, 2023. No incident of non-compliance with 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 year ended December 31, 2023.

Final Dividend

The Board does not recommend the payment of a final dividend for the year ended December 31, 2023.

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 consolidated financial statements and this annual results announcement of the Group for the year ended December 31, 2023, reviewed the accounting principles and practices adopted by the Group and discussed auditing, internal controls and financial reporting matters.

Scope of Work of PricewaterhouseCoopers

The figures in respect of the Group's consolidated balance sheet and consolidated statement of comprehensive loss and the related notes thereto for the year ended December 31, 2023 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.

PUBLICATION OF ANNUAL RESULTS ANNOUNCEMENT AND ANNUAL REPORT

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

The annual report of the Company for the year ended December 31, 2023 containing all the information required by the Listing Rules will be published on the respective websites of the Stock Exchange and the Company in due course.

CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

For The Year Ended December 31, 2023

	Note	Year ended 31 December	
		2023	2022
		RMB'000	*RMB'000*
Revenue	*4*	**225,352**	15,572
Cost of sales	*5*	**(28,277)**	(2,005)
Gross profit		**197,075**	13,567
Other income		**7,251**	11,284
Other expenses	*5*	**(3)**	(729)
Selling and marketing expenses	*5*	**(43,296)**	(1,749)
Administrative expenses	*5*	**(86,657)**	(138,830)
Research and development expenses	*5*	**(458,073)**	(524,285)
Fair value changes on financial liabilities at fair value through profit or loss	*6*	**174,976**	(62,816)
Other gains/(losses), net	*7*	**213,523**	(924)
Operating profit/(loss)		**4,796**	(704,482)
Finance income		**8,261**	45,919
Finance costs		**(16,017)**	(8,647)
Finance (costs)/income, net		**(7,756)**	37,272
Share of loss of investments accounted for using the equity method		**(27,341)**	(32,231)
Loss before income tax		**(30,301)**	(699,441)
Income tax expense	*8*	**–**	–
Loss for the year		**(30,301)**	(699,441)
Loss attributable to:			
Owners of the Company		**(22,096)**	(689,052)
Non-controlling interests		**(8,205)**	(10,389)
		(30,301)	(699,441)

	Note	Year ended 31 December	
		2023	2022
		RMB'000	*RMB'000*
Other comprehensive (loss)/income			
Items that may be subsequently reclassified to profit or loss			
Currency translation differences		**(331)**	109
Total comprehensive loss		**(30,632)**	(699,332)
Total comprehensive loss attributable to:			
Owners of the Company		**(22,427)**	(688,943)
Non-controlling interests		**(8,205)**	(10,389)
		(30,632)	(699,332)
Losses per share for loss attributable to owners of the Company for the year (expressed in RMB per share)			
– Basic losses per share	*9*	**(0.01)**	(0.42)
– Diluted losses per share		**(0.01)**	(0.42)

CONSOLIDATED BALANCE SHEET

As at December 31, 2023

	Note	As at 31 December 2023 RMB'000	2022 RMB'000
Assets			
Non-current assets			
Property, plant and equipment		**948,189**	916,409
Right-of-use assets		**139,056**	122,662
Intangible assets		**434,221**	450,813
Investments accounted for using the equity method		**126,685**	122,392
Other receivables, prepayments and deposits		**59,009**	104,095
Total non-current assets		**1,707,160**	1,716,371
Current assets			
Inventories		**29,412**	24,061
Trade receivables	*10*	**37,802**	–
Notes receivables		**–**	3,040
Other receivables, prepayments and deposits		**120,289**	116,303
Financial assets at fair value through profit or loss		**63,628**	–
Cash and cash equivalents		**426,015**	669,397
Total current assets		**677,146**	812,801
Total assets		**2,384,306**	2,529,172
Equity			
Equity attributable to owners of the Company			
Share capital	*11*	**1,659,445**	1,659,445
Reserves		**1,591,046**	1,572,807
Accumulated losses		**(2,353,586)**	(2,331,490)
		896,905	900,762
Non-controlling interests		**(8,205)**	–
Total equity		**888,700**	900,762

	Note	As at 31 December 2023 RMB'000	2022 RMB'000
Liabilities			
Non-current liabilities			
Borrowings		**260,000**	290,057
Lease liabilities		**24,184**	3,093
Deferred government grants		**12,000**	12,000
Deferred tax liabilities		**37,687**	37,687
Financial liabilities at fair value through profit or loss	*12*	**262,174**	441,787
Total non-current liabilities		**596,045**	784,624
Current liabilities			
Borrowings		**434,299**	359,988
Trade payables	*13*	**207,611**	166,129
Other payables and accruals		**234,380**	287,242
Lease liabilities		**23,271**	30,427
Total current liabilities		**899,561**	843,786
Total liabilities		**1,495,606**	1,628,410
Total equity and liabilities		**2,384,306**	2,529,172

1 GENERAL INFORMATION

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

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

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

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

On 23 February 2022, the Company has completed 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.

The consolidated financial statements are presented in Renminbi ("**RMB**"), unless otherwise stated.

2 BASIS OF PREPARATION AND CHANGES IN ACCOUNTING POLICIES

2.1 Basis of preparation

(a) Compliance with IFRS Accounting Standards and Hong Kong Companies Ordinance

The consolidated financial statements of the Group have been prepared in accordance with IFRS Accounting Standards and requirements of the Hong Kong Companies Ordinance Cap. 622.

IFRS Accounting Standards comprise the following authoritative literature:

- IFRS Accounting Standards
- International Accounting Standards
- Interpretations developed by the IFRS Interpretations Committee or its predecessor body, the Standing Interpretations Committee.

For the year ended 31 December 2023, the Group has incurred net losses of approximately RMB30.3 million, while net cash used in operating activities was approximately RMB250.8 million. As at 31 December 2023, the Group had net current liabilities of approximately RMB222.4 million and cash and cash equivalents of approximately RMB426.0 million. Historically, the Group has relied principally on non-operational sources of financing from investors and banks as well as cash generated from sales activities to fund its operations and business development. The Group's ability to continue as a going concern is dependent on management's ability to successfully execute its business plan. The directors of the Company believes that the cash and cash equivalent, unutilised bank facilities together with the cash generated from operating activities are sufficient to meet the cash requirements to fund planned operations and other commitments for at least the next twelve months from the date of the issuance of this consolidated financial statement. The Group therefore continues to prepare this consolidated financial statements on a going concern basis.

(b) Historical cost convention

The financial statements have been prepared on a historical cost basis, except for the following:

- certain financial assets and liabilities – measured at fair value.

(c) New and amended standards adopted by the Group

The Group has applied the following standards and amendments for the first time for its annual reporting period commencing 1 January 2023:

- IFRS 17 Insurance Contracts
- Definition of Accounting Estimates – amendments to IAS 8
- International Tax Reform – Pillar Two Model Rules – amendments to IAS 12
- Deferred Tax related to Assets and Liabilities arising from a Single Transaction – amendments to IAS 12
- Disclosure of Accounting Policies – Amendments to IAS 1 and IFRS Practice Statement 2.

The amendments listed above did not have material impact on the amounts recognised in prior periods and are not expected to significantly affect the current or future periods.

(d) New standards and interpretations not yet adopted

The following amendments to accounting standards have been published that are not mandatory for 31 December 2023 reporting periods and have not been early adopted by the Group:

- Classification of Liabilities as Current or Non-current – Amendments to IAS 1
- Non-current Liabilities with Covenants – Amendments to IAS 1
- Lease Liability in a Sale and Leaseback – Amendments to IFRS 16
- Supplier finance arrangements – Amendments to IAS 7 and IFRS 7
- Sale or contribution of assets between an investor and its associate or joint venture – Amendments to IFRS 10 and IAS 28

These amendments are not expected to have a material impact on the entity in the current or future reporting periods and on foreseeable future transactions.

3 SEGMENT INFORMATION

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

During the year ended 31 December 2023, the Group has been principally engaged in the sales of pharmaceutical products and research and development of new drugs. Management reviews the operating results of the business as one operating segment to make decisions about resources to be allocated. Therefore, the CODM of the Company regards that there is only one segment which is used to make strategic decisions.

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

4 REVENUE

	Year ended 31 December	
	2023	2022
	RMB'000	*RMB'000*
Revenue recognised at a point in time		
– Sales of pharmaceutical products	**101,385**	15,572
– Licensing income (a)	**123,967**	–
	225,352	15,572

Information about the geographical markets of the Group's revenue is presented based on the locations of the customers.

	Year ended 31 December	
	2023	2022
	RMB'000	*RMB'000*
Geographical markets		
– The PRC	**101,385**	15,572
– Overseas	**123,967**	–
	225,352	15,572

For the year ended 31 December 2023, revenue of approximately RMB109,520,000 (2022: Nil) was derived from licensing income from the Group's associate, KYM Biosciences Inc. ("**KYM**"), which accounted for 48.60% (2022: Nil) of the Group's total revenue. Other than the aforementioned customer, the revenues derived from any of the remaining external customers were less than 10% of the Group's total revenue.

(a) Licensing income

On 22 February 2023, KYM has entered into a global exclusive out-license agreement (the "**License Agreement**") with AstraZeneca AB ("**AstraZeneca**"), an independent global pharmaceutical company, to develop and commercialise CMG901, a drug candidate co-developed by the Group and Keymed Biosciences Inc. ("**Keymed**") through KYM. KYM was established by Keymed and the Group as the platform solely for commercialisation of CMG901. Keymed and the Group held 70% and 30% share of interests in KYM, respectively.

Upon the execution of the License Agreement and subject to terms and conditions thereof (including obtaining certain regulatory approval for the licensing transaction), AstraZeneca would be granted an exclusive global license for research, development, registration, manufacturing, and commercialisation of CMG901, and shall be responsible for all costs and activities associated with the further development and commercialisation of CMG901 in accordance with the License Agreement.

According to the License Agreement and subject to the terms and conditions thereof, KYM shall receive an upfront payment of US$63.0 million with the potential for additional payments up to US$1,125.0 million subject to achievement of certain development, regulatory and commercial milestones. In addition, KYM is entitled to receive tiered royalties on net sales from AstraZeneca. KYM is obliged to provide assistance and staff to facilitate technology and know-how transfer. Except as otherwise agreed, AstraZeneca would be responsible for bearing all costs for activities associated with the development and regulatory affairs on ongoing trial in relation to CMG901.

Concurrently, the Group has entered into a license agreement with KYM, pursuant to which the Group has granted exclusive global license for research, development, registration, manufacturing, and commercialisation of CMG901 to KYM, and KYM shall pay 30% of the amounts received from AstraZeneca after deducting relevant tax and expenses to the Group upon receiving any payment.

Based on the License Agreement, the Group has entered into series of agreements with AstraZeneca pursuant to which the Group would provide services and supply drug products to AstraZeneca.

During the year ended 31 December 2023, the revenue related to the transaction was approximately RMB123,967,000.

(b) Accounting policies of revenue recognition

(i) Sales of goods

The Group produces and sells pharmaceutical products to customers. The Group transports the products to the agreed delivery location in accordance with the sales contract, and the sales are recognised after the customer has accepted the products and both parties have signed the goods delivery order. The Group adopts advance collection and a credit period of 30 days to its customers, and the transaction price does not have a significant financing component.

(ii) Licensing income

The Group generates revenue from licensing of intellectual property ("**IP**") to customers. As the customers are able to direct the use of, and obtain substantially all of the benefits from, the licence at the time that control of the licence is transferred to the licensee, the licences that provide a right to use an entity's IP are performance obligations satisfied at the point in time. Revenue is recognised when or as the control of the licenses is transferred to the licensee.

The Group recognises revenue for a sales-based or usage-based royalty promised in exchange for a license of IP only when (or as) the later of the following events occurs:

- the subsequent sale or usage occurs; and
- the performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied).

5 EXPENSES BY NATURE

	Year ended 31 December	
	2023	2022
	RMB'000	*RMB'000*
Clinical study related expenses	**173,425**	204,991
Employee benefit expenses	**198,906**	188,344
Depreciation and amortisation	**102,572**	95,446
Pre-clinical study costs	**34,463**	71,211
Raw material and consumables used	**32,589**	37,021
Changes in inventories of finished goods and working in progress outsourced for processing	**950**	(1,688)
Entertainment and traveling expenses	**21,149**	5,246
Licensing fee	**6,634**	1,091
Utilities	**6,550**	5,461
Technical service fees	**4,321**	–
Auditors' remuneration		
– Audit services	**2,850**	2,300
– Non-audit services	**–**	–
Listing expenses	**–**	34,334
Others	**31,897**	23,841
Total cost of sales, selling and marketing expenses, administrative expenses, research and development expenses and other expenses	**616,306**	667,598

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

	Year ended 31 December	
	2023	2022
	RMB'000	*RMB'000*
Fair value gains/(losses) on financial liabilities at fair value through profit or loss		
– FVPL	**174,976**	(62,816)

7 OTHER GAINS/(LOSSES), NET

	Year ended 31 December	
	2023	2022
	RMB'000	*RMB'000*
Net gains on dilution of equity interests in an associate (a)	**116,388**	–
Net gains on disposal of investments in an associate (b)	**103,874**	–
Net gains on disposal of right-of-use assets	**–**	608
Expected credit losses	**(154)**	(140)
Donation	**(3,406)**	(1,393)
Others	**(3,179)**	1
	213,523	(924)

(a) Net gains on dilution of equity interests in an associate represents the net gains recognized owing to the dilution of the Company's percentage equity interests held in Wuhan Binhui Biological Technology Co., Ltd. ("Wuhan Binhui") from 20.03% to 11.84% as a result of the preferred rights granted upon issuance of ordinary shares by Wuhan Binhui to certain investors were terminated.

(b) Net gains on disposal of investments in an associate represents the net gains recognized on the Company's partial disposal of equity interest in Hangzhou HealSun Biotechnology Co., Ltd. ("Hangzhou HealSun").

8 INCOME TAX EXPENSE

	Year ended 31 December	
	2023	2022
	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 12 December 2023. Accordingly, it was entitled to a preferential corporate income tax rate of 15% on its estimated assessable profits for the years ended 31 December 2023 to 2025.

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%.

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 financial year.

	Year ended 31 December	
	2023	2022
Loss for the year and attributable to owners of the Company (in RMB'000)	**(22,096)**	(689,052)
Weighted average number of ordinary shares in issue (in thousands)	**1,659,445**	1,640,825
Basic loss per share (in RMB)	**(0.01)**	(0.42)

(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 2023 and 2022, the Company had no potential ordinary share. Accordingly, diluted loss per share for the years ended 31 December 2023 and 2022 are the same as basic loss per share of the respective years.

10 TRADE RECEIVABLES

	As at 31 December	
	2023	2022
	RMB'000	*RMB'000*
Trade receivables	**38,014**	–
Less: Loss allowance	**(212)**	–
	37,802	–

The Group allows a credit period of 30 days to its customers. As at 31 December 2023 and 2022, the ageing analysis of the trade receivables (net of loss allowance) based on invoice date were as follows:

	As at 31 December	
	2023	2022
	RMB'000	*RMB'000*
0 – 30 days	**37,802**	–

11 SHARE CAPITAL

	Number of shares	**Nominal value of shares** *RMB'000*
Authorised issued and fully paid		
At 1 January 2022	1,531,669,838	1,531,670
Issuance of ordinary shares upon global offering (a)	126,876,000	126,876
Exercise of over-allotment option (b)	899,000	899
At 31 December 2022	1,659,444,838	1,659,445
At 1 January 2023 and 31 December 2023	1,659,444,838	1,659,445

(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 issuance.

12 FINANCIAL LIABILITIES AT FAIR VALUE THROUGH PROFIT OR LOSS

	As at 31 December	
	2023	2022
	RMB'000	*RMB'000*
Variable consideration payable arisen from acquisition of 40% equity of Taizhou Hanzhong from non-controlling interests	**272,625**	448,282
Less: current portion	**(10,451)**	(6,495)
Non-current portion	**262,174**	441,787

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 2023 and 2022 was determined by an independent valuer. And the changes in fair value was recognised in the consolidated statements of comprehensive loss.

As at 31 December 2023, the current portion of variable consideration payable consisted of 4.375% of actual net sales of PD-1 products in 2023 accounting to approximately RMB4,436,000 and 4.375% of estimated net sales of PD-1 products in 2024 accounting to approximately RMB6,015,000.

The movements of financial liabilities at fair value through profit or loss for the years ended 31 December 2023 and 2022 are set out below:

	Year ended 31 December	
	2023	2022
	RMB'000	*RMB'000*
Opening balance	**448,282**	385,466
Change in fair value	**(174,976)**	62,816
Variable consideration paid to HanX	**(681)**	–
Closing balance	**272,625**	448,282

13 TRADE PAYABLES

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

	As at 31 December	
	2023	2022
	RMB'000	*RMB'000*
Less than 1 year	**196,909**	154,966
Between 1 and 2 years	**10,702**	11,163
	207,611	166,129

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.

14 DIVIDEND

No dividend has been paid or declared by the Company or companies comprising the Group during the years ended 31 December 2023 and 2022.

15 EVENTS OCCURRING AFTER THE REPORTING PERIOD

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

DEFINITIONS

"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
"ASCO"	American Society of Clinical Oncology
"AstraZeneca"	AstraZeneca AB, a global pharmaceutical company which, to the best knowledge and belief of the Company, is independent of and not connected with the Company and its connected persons (as defined under the Listing Rules)
"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
"BD"	business development
"Board"	the board of Directors of the Company
"BTD"	Breakthrough Therapy Designation
"CAR-T"	chimeric antigen receptor T-cell
"CC"	cervical cancer
"CD20"	a B-lymphocyte antigen that is expressed on the surface of B cells, starting at the pre-B cell stage and also on mature B cells in the bone marrow and in the periphery
"CDE"	藥品審評中心(the Center for Drug Evaluation* 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-stage immuno-oncology company headquartered in the United States, 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 the "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)
"Corporate Governance Code"	the Corporate Governance Code as set out in Appendix C1 to the Listing Rules
"CR"	complete response, the disappearance of all signs of cancer in response to treatment
"CSCO"	Chinese Society of Clinical Oncology
"CSGO"	Chinese Society of Gynecological Oncology
"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
"DLBCL"	diffuse large B cell lymphoma
"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
"ESMO"	European Society for Medical Oncology
"FDA"	Food and Drug Administration of the United States
"FPI"	first-patient-in
"FTD"	Fast Track Designation
"GC"	gastric cancer
"GEJ"	gastroesophageal junction
"G/GEJ carcinoma"	gastric and gastroesophageal junction carcinoma
"GLP-1"	glucagon-like peptide-1
"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 the Company, with a nominal value of RMB1.00 each, listed on the Main Board of the Stock Exchange
"HealSun Biopharma"	Hangzhou HealSun Biopharma Co., Ltd. (杭州皓陽生物技術有限公司), a limited liability company incorporated in the PRC
"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 over-expressing" or "HER2-positive"	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$"	Hong Kong dollars, the lawful currency of Hong Kong
"HNSCC"	head and neck squamous cell carcinoma

"Hong Kong"	the Hong Kong Special Administrative Region of the PRC
"IgG"	human immunoglobulin G, the most common antibody type found in blood circulation that plays an important role in antibody-based immunity against invading pathogens
"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 United States
"Independent Shareholder(s)"	the Shareholders other than Lepu Medical and Ningbo Houde Yimin
"Kangzhe Venture Capital"	海南省康哲創業投資有限公司(Hainan Kangzhe Venture Capital Co. Ltd*), a limited liability company incorporated in the PRC
"Keymed"	康諾亞生物醫藥科技(成都)有限公司(Keymed Bioscience (Chengdu) Co., Ltd.*), 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
"KOL"	key opinion leader, who are professionals that influence their peers' medical practice, including but not limited to prescribing behavior
"KYM"	KYM Biosciences Inc., a Delaware corporation and a joint venture formed in the United States by Keymed and our Group
"Lepu Medical"	樂普(北京)醫療器械股份有限公司(Lepu Medical Technology (Beijing) Co., Ltd.*), a joint stock company incorporated in the PRC on June 11, 1999 and listed on the Shenzhen Stock Exchange (stock code: 300003)
"License Agreement"	a global exclusive out-license agreement entered into by KYM and AstraZeneca on February 23, 2023
"Listing"	the listing of the H Shares of the Company on the Main Board of the Stock Exchange on February 23, 2022
"Listing Rules"	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time
"mAb"	monoclonal antibody, an antibody generated by identical cells that are all clones of the same parent cell

"Macau"	the Macau Special Administrative Region of the PRC
"Main Board"	the Main Board of the Stock Exchange
"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 C3 to the Listing Rules
"mOS"	median overall survival
"mPFS"	median progression free survival
"MRCT"	multi-regional clinical trial
"MSI-H/dMMR"	high levels of microsatellite instability/deficient mismatch repair
"NDA"	new drug application
"NHL"	non-Hodgkin's lymphoma
"Ningbo Houde Yimin"	寧波厚德義民信息科技有限公司(Ningbo Houde Yimin Information Technology Co., Ltd.*), a limited liability company incorporated in the PRC on March 29, 2017
"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"	中國國家藥品監督管理局(National Medical Products Administration of the PRC*)
"NPC"	nasopharyngeal cancer
"ODD"	Orphan-drug Designation
"ORR"	overall response rate
"PC"	pancreatic cancer
"PD-1"	programmed cell death protein 1, an immune checkpoint receptor expressed on T cells, B cells and macrophages
"PD-1 (L1)"	PD-1 or PD-L1

"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
"PD-L2"	PD-1 ligand 2, which is a protein on the surface of a normal cell or a cancer cell that attaches to certain proteins on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell
"PDX"	patient derived xenografts, models of cancer where the tissue or cells from a patient's tumor are implanted into an immunodeficient mouse
"PFS"	progression-free-survival
"Pgp"	a drug transporter which plays important roles in multidrug resistance and drug pharmacokinetics
"Phase I clinical trial(s)" or "Phase I clinical study(ies)"	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 trial(s)" or "Phase II clinical study(ies)"	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 trial(s)" or "Phase III clinical study(ies)"	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, 2023
"R/M"	recurrent/metastatic
"RMB"	Renminbi, the lawful currency of China
"second-line"	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"	深圳證券交易所(Shenzhen Stock Exchange*)
"solid tumors"	an abnormal mass of tissue that usually does not contain cysts or liquid areas. Solid tumors may be benign (not cancer), or malignant (cancer). Different types of solid tumors are named for the type of cells that form them
"Stock Exchange"	The Stock Exchange of Hong Kong Limited
"subsidiaries"	has the meaning ascribed to it in section 15 of the Companies Ordinance (Cap. 622)
"Supervisor(s)"	the supervisor(s) of the Company
"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
"TCR"	a protein complex found on the surface of T cells that is responsible for recognizing fragments of antigen as peptides bound to major histocompatibility complex molecules
"TEAEs"	treatment-emergent adverse events
"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"	urothelial cancer
"United States" or "U.S."	the United States of America, its territories and possessions, any State of the United States, and the District of Columbia
"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$"	United States dollars, the lawful currency of the United States of America
"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
"Wuhan Binhui"	Wuhan Binhui Biological Technology Co., Ltd. (武漢濱會生物科技股份有限公司), a limited liability company incorporated in the PRC
"%"	per cent

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

Shanghai, the PRC
March 27, 2024

As at the date of this announcement, the Board comprises Dr. Pu Zhongjie (chairman) and Dr. Sui Ziye (chief executive officer) as executive Directors; Ms. Pu Jue and Mr. Yang Hongbing as non-executive Directors; and Mr. Zhou Demin, Mr. Yang Haifeng and Mr. Fengmao Hua as independent non-executive Directors.

* *For identification purposes only*