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, 2024

The Board is pleased to announce the audited consolidated annual results of the Group for the year ended December 31, 2024, together with the comparative figures of 2023.

BUSINESS HIGHLIGHTS

The Group recorded a surge in our revenue and made significant progress in our product pipeline and business operations during the Reporting Period:

Robust growth in commercialization with total revenue of RMB367.8 million, representing 63.2% revenue surge year-over-year (YoY)

– Commercialization of PUYOUHENG (Pucotenlimab Injection): The Group recorded a revenue of RMB300.3 million for its sales of PUYOUHENG (Pucotenlimab Injection), almost tripling the amount recorded in 2023 (approximately RMB101.4 million).

– Licensing income from BD activity: Approximately RMB22.0 million was recorded by the Group as revenue from the licensing of CMG901, which was mainly contributed by the milestone payment.

– CDMO services income: The Group recorded a revenue of approximately RMB45.5 million for the provision of CDMO services.

ADC pipeline products entering harvest stage and positive results observed in combination therapies

– **MRG003 (EGFR-ADC)**: We have re-submitted the new NDA of MRG003 and received the Acceptance Notice (《受理通知書》) issued by the NMPA in relation to the acceptance of the new NDA in March 2025. MRG003 has also been granted priority review by the CDE of NMPA. The authority is currently proceeding with the clinical and pharmaceutical evaluation of MRG003 in an orderly manner. Encouraging data from the pivotal Phase IIb clinical study has been observed and will be presented at the ASCO Congress 2025. In July 2024, we have obtained BTD for MRG003 from the FDA for the treatment of R/M NPC in the United States.

  MRG003 + PUYOUHENG (Pucotenlimab Injection): We are conducting a Phase I/II trial of the combination therapy with MRG003 and pucotenlimab in the treatment of solid tumors. We are currently conducting the Phase II part of the trial and have observed encouraging data on R/M NPC, which was orally presented at ESMO Asia Congress 2024. In addition, the encouraging data from Phase I and initial Phase II clinical trial has been orally presented at the ASCO Annual Meeting 2024.

– **MRG002 (HER2-ADC):** We have completed a pivotal Phase II clinical trial on HER2 over-expressed BC with liver metastasis in China. The observed encouraging data was presented at the SABCS Congress 2024. Meanwhile, as of December 31, 2024, we are conducting a Phase III clinical study on HER2-positive BC.

  MRG002 + PUYOUHENG (Pucotenlimab Injection): We have completed the 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 was presented at the ESMO Congress 2024.

– **MRG004A (TF-ADC):** We are currently conducting a Phase I clinical study on solid tumors in the United States and China and have observed encouraging data on PC, TNBC and CC. Such preliminary Phase I data on solid tumors was orally presented at the ASCO Annual Meeting 2024. In March 2024, MRG004A was granted FTD from the FDA for the treatment of PC which have relapsed or are refractory to prior approved therapies. The Phase I dose expansion study is being conducted to explore dose optimization of MRG004A on PC.

– **MRG006A (GPC3-ADC):** We have received the IND approval in July 2024 from the NMPA and are currently conducting a Phase I clinical trial. Moreover, IND approval has been received from the FDA in January 2025. In pre-clinical studies, MRG006A demonstrated a robust and dose-dependent tumor growth inhibition on multiple CDX models and HCC PDX models. In the meantime, MRG006A has also demonstrated good tolerability in exploratory toxicology studies. We have presented such encouraging pre-clinical data at the 2024 AACR Annual Meeting.

– **MRG007 (target undisclosed ADC):** MRG007 has shown robust antitumor activity in preclinical models of GI cancers and a favorable therapeutic index based on IND enabling studies. In January 2025, the Company entered into an exclusive licensing agreement with ArriVent, pursuant to which the Company has granted ArriVent exclusive rights to develop, manufacture and commercialize MRG007 outside of Greater China. Under the terms of the agreement, the Company is eligible to receive up to US$1.2 billion in total, including an upfront payment and development, regulatory and sales milestones, and tiered royalties on net sales.

Completion of Phase I patients enrollment of CG0070 in China

– **CG0070 (Oncolytic virus):** CG0070 is currently in a MRCT Phase III clinical study conducted by our U.S. partner, CG Oncology. The latest encouraging data observed has been orally presented at the Society of Urologic Oncology (SUO) 25th Annual Meeting in 2024. We are conducting a Phase I clinical trial in China and have finished patients' enrollment. CG0070 was granted BTD by the CDE in January 2025.

Encouraging pre-clinical data from candidates developed on innovation platforms

We have observed encouraging data in pre-clinical studies of ADC candidate MRG006A and the new-generation T cell agonistic antibody CTM012, which are developed based on our Hi-TOPi and TOPAbody platforms respectively. Besides the abovementioned pre-clinical data of MRG006A, the TOPAbody platform was also presented at the 2024 AACR Annual Meeting. In addition, we filed pre-IND for CTM012 in both China and U.S. in 2024.

FINANCIAL HIGHLIGHTS

– Revenue increased significantly by approximately 63.2% from approximately RMB225.4 million for the year ended December 31, 2023 to approximately RMB367.8 million for the year ended December 31, 2024.

– Research and development expenses decreased by approximately 4.4% from approximately RMB458.1 million for the year ended December 31, 2023 to approximately RMB437.7 million for the year ended December 31, 2024.

– Loss for the year attributable to the owners of the Company increased from approximately RMB22.1 million for the year ended December 31, 2023 to approximately RMB411.4 million for the year ended December 31, 2024.

– Non-IFRS operating loss for the year[1] amounted to RMB429.3 million for the year ended December 31, 2024, remaining a level similar to that of the previous year (2023: RMB425.5 million).

– Cash and cash equivalents remained at a similar level as compared to last year at RMB401.3 million as at December 31, 2024 (2023: RMB426.0 million).

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[1] We define "non-IFRS operating loss for the year" as our loss for the year, deducting certain items as set out in the section headed "Non-IFRS Operating Loss for the Reporting Period". We exclude these items because they are either non-recurring income related to our associate companies that are non-operating in nature or they are not indicative of our core operating results and business outlook.

KEY EVENTS AFTER THE REPORTING PERIOD

– **MRG007:** In January 2025, the Company entered into an exclusive licensing agreement with ArriVent for MRG007. Under the terms of the agreement, the Company has granted ArriVent exclusive rights to develop, manufacture and commercialize MRG007 outside of Greater China. The one-time upfront and near-term milestone payments are US$47 million and the Company is eligible to receive up to US$1.16 billion in development, regulatory and sales milestones and tiered royalties on net sales outside of Greater China.

  MRG007 has shown robust antitumor activity in preclinical models of GI cancers and a favorable therapeutic index based on IND enabling studies. The first IND submission is planned for the first half of 2025 with an initial clinical development focus in colorectal, pancreatic and other GI cancers. Pre-clinical data of MRG007 are expected to be presented at the AACR annual meeting in April 2025.

– **CG0070:** In January 2025, CG0070 was granted BTD by the CDE for the treatment of BCG unresponsive bladder cancer, which signified the innovativeness and efficacy profile of CG0070.

MANAGEMENT DISCUSSION AND ANALYSIS

OVERVIEW

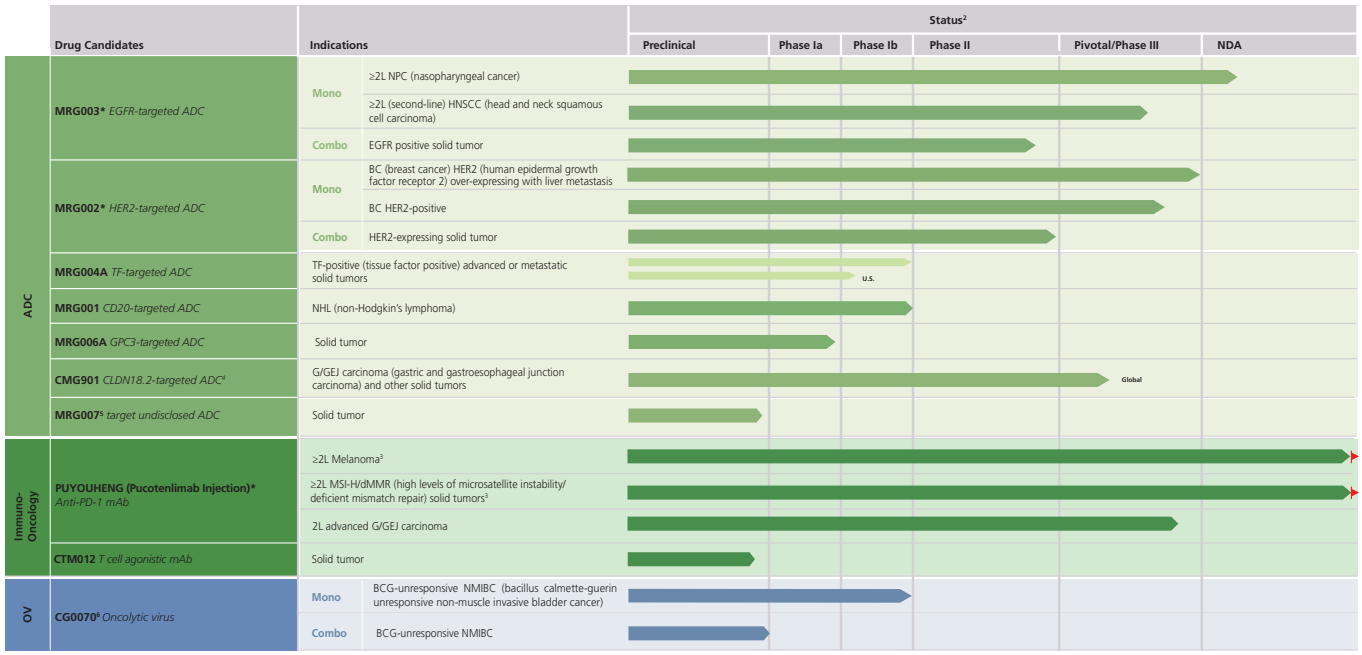
We are an innovation-driven biopharmaceutical company focusing on oncology therapeutics, in particular, targeted therapy and oncology immunotherapy, with a strong China foundation and global vision. Since our establishment, we have been dedicated to developing innovative ADCs through our comprehensive and advanced ADC technology development platform and we aim to develop optimal and innovative drugs to better serve the unmet medical needs of cancer patients. 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. We are committed to continuously developing a market-differentiating pipeline by fully integrating our independent innovation capabilities and strategic collaborations. Concurrently, we are dedicated to exploring synergistic therapeutic approaches on the basis of the continuous enrichment of our product pipeline. We have established and are progressively expanding our internal manufacturing capabilities, driven by the business requirements stemming from the upcoming commercialization of our ADC candidates.

We have strategically designed our pipeline with a range of oncology products. As of the date of this announcement, for clinical-stage candidates, we have (i) one clinical/commercialization-stage drug candidate; (ii) seven clinical-stage drug candidates, including one co-developed through a joint venture; and (iii) three clinical-stage combination therapies of our candidates. One of our drug candidates has obtained marketing approval with respect to two of its targeted indications, with clinical trials for other indications ongoing. Among the seven clinical-stage drug candidates, six are targeted therapeutics and one is an immunotherapeutic, which is an oncolytic virus drug. MRG003 was granted BTD, 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. CG0070 was granted BTD from the CDE. We have continuously striven to build up and develop novel technology platforms as innovative engines for the Company. We have observed encouraging data in pre-clinical studies of MRG006A, MRG007 and CTM012 during the Reporting Period. We have received an IND approval from the CDE for MRG006A and are efficiently progressing our innovative molecules, CTM012 and MRG007, towards the clinical research stage.

We aim to commercialize our pipeline products in China through dedicated sales and marketing forces, while attaining international market reach through strategic partnerships. As of the end of the Reporting Period, the Company has achieved significant milestones in the monetisation of our R&D capabilities through commercialization and BD activities: PUYOUHENG (Pucotenlimab Injection) has completed the full commercialization process and is currently under a rapid sales growth, and two other products, CMG901 and MRG007 have also been licensed out through our BD activities. Notably, CMG901's global rights have been licensed to AstraZeneca, and MRG007's rights for regions outside Greater China have been licensed to ArriVent. These accomplishments have established a solid foundation for the Company's future commercialization of ADC products and global cooperations.

PRODUCT PIPELINE

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



Notes:

1. * denotes the Core Products.

2. Unless otherwise stated, the progress shown under the "Status" column refers to the clinical development progress of the relevant drug candidate and combination therapy in China.

3. In 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.

4. 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 announcements dated February 23, 2023 and April 15, 2024.

5. On January 22, 2025, the Company has entered into an exclusive license agreement with ArriVent to grant an exclusive license to develop and commercialize MRG007, globally excluding the Greater China Region. For details, please refer to the Company's announcement dated January 22, 2025.

6. Apart from the Phase I 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

Commercialization

During the Reporting Period, the Group recorded a total revenue of approximately RMB367.8 million, marking a 63.2% surge YoY. In 2024, the Group recorded a revenue of approximately RMB300.3 million for the sales of PUYOUHENG (Pucotenlimab Injection), tripling the amount recorded in 2023 (approximately RMB101.4 million). For licensing activities, the Group has recognized approximately RMB22.0 million in revenue for the milestone payment and the technology transfer service provided under the License Agreement for CMG901. In addition, the Group recognized approximately RMB45.5 million in revenue for the provision of CDMO services.

- We have built a highly efficient sales and marketing team for 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's.

  In terms of the establishment of sales channels, we actively develop cooperative relationships with various business channel partners. As of December 31, 2024, we have completed the tendering process on the procurement platform in 27 provinces of the PRC. We have covered approximately 81 cities in the PRC through various sales channels, and we will further expand our sales network.

- In 2024, the Group recorded revenue of approximately RMB22.0 million generated though the milestone payment and the technology transfer service provided under the License Agreement for CMG901, which was entered into between KYM, a joint venture formed by us and Keymed, and AstraZeneca on February 23, 2023. We remain committed to advancing our global licensing strategy and actively carry out out-licensing collaborations. In addition, in January 2025, the Company entered into an exclusive licensing agreement with ArriVent, pursuant to which the Company has granted ArriVent exclusive rights to develop, manufacture and commercialize MRG007 outside of Greater China. Under the terms of the agreement, the Company is eligible to receive up to US$1.2 billion in total, including an upfront payment, development, regulatory and sales milestones, and tiered royalties on net sales.

- Furthermore, we have strategically leveraged our surplus capacity to provide CDMO services to Lepu Medical and/or its subsidiaries for their development of GLP-1 and related products. These efforts yielded CDMO services related revenue of approximately RMB45.5 million in 2024. Looking forward to 2025, the Company expects to continue to generate revenue with the annual cap of RMB36.0 million pursuant to the approval granted by the independent shareholders in the 2025 first extraordinary general meeting of the Company held on January 7, 2025.

During the year ended December 31, 2024, 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's 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, 2024 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.

We have received the Acceptance Notice (《受理通知書》) issued by the NMPA in relation to the acceptance of the NDA of MRG003, for the treatment of R/M NPC, and currently the NDA of MRG003 is under the priority review by the CDE of NMPA. Meanwhile, we are concurrently conducting a Phase III clinical study on HNSCC. We are also further exploring the potential of MRG003 through its combination with immuno-oncology which may move forward to become an earlier line treatment therapy and bring clinical benefits to more patients.

– ***Monotherapy***

NPC: We have re-submitted the new NDA of MRG003 and received the the Acceptance Notice (《受理通知書》) issued by the NMPA in relation to the acceptance of the new NDA in March 2025. MRG003 has also been granted priority review by the CDE of NMPA. The authority is currently proceeding with the clinical and pharmaceutical evaluation of MRG003 in an orderly manner. We submitted a BTD application in the U.S. in June 2024, which was granted by the FDA for the treatment of R/M NPC in July 2024. The encouraging data from the pivotal Phase IIb clinical study has been observed and will be presented at the ASCO Congress 2025.

HNSCC: As of December 31, 2024, we are conducting a randomized, open-label, multicenter Phase III clinical study on HNSCC.

– ***Combination Therapy***

MRG003 + PUYOUHENG (Pucotenlimab Injection): We are conducting a Phase I/II trial of combination therapy with MRG003 and pucotenlimab in the treatment of solid tumors and have completed the Phase I part of the trial. We have observed encouraging preliminary data, which were selected to be presented orally at the ASCO Annual Meeting 2024. In addition, the latest encouraging data from the Phase II clinical study on R/M NPC was selected to be presented orally at the ESMO ASIA Congress 2024. As of 30 June 2024, ORR and DCR was 66.7% and 93.3%, respectively. PFS and DoR were immature, with 6-month PFS rate of 76.2% and 6-month DoR rate of 83.3%, respectively.

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

MRG002

MRG002 is an innovative ADC targeting HER2, a molecular target abnormally over-expressed 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. Registrational clinical trials in the aforementioned indications are ongoing. We are constantly exploring the potential of MRG002 through its combination with immuno-oncology by conducting clinical studies which aim to target more patients in early stage and provide more options to fulfill the unmet medical needs.

– ***Monotherapy***

HER2 over-expressing BC: We have completed the pivotal Phase II clinical trial on HER2 over-expressed BC with liver metastasis in China and have observed encouraging data, which was presented at the SABCS Congress 2024. As of July 2024, the ORR and DCR in the pivotal Phase II clinical study was 60.8% and 86.3%, the mPFS was 8.6 months, and the mDoR was 9.4 months. Meanwhile, as of December 31, 2024, we are conducting a Phase III clinical study on HER2-positive BC.

– ***Combination Therapy***

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 data on UC, which was presented at the ESMO Congress 2024. As of April 2024, for all the evaluated patients, the ORR and DCR were 64.0% and 89.0%, respectively. For the patients in MRG002 1.8 mg/kg cohort, the ORR and DCR of evaluable patients were 70.0% and 90.0%. For HER2+ patients, the ORR and DCR of evaluable patients were 70.6% and 94.1%. The patient who has been treated the longest has had a PFS for more than 26.5 months and it is still ongoing.

– **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 and have observed anti-tumor activity signal on PC, TNBC and CC. The preliminary Phase I data on solid tumors were orally presented at the ASCO Annual Meeting 2024. As of December 15, 2023, the ORR and DCR on patients with PC in 2.0 mg/kg dose group was 33.3% and 83.3% respectively. 5 patients with PC of TF expression ≥50% and 3+ intensity and ≤2 prior lines of therapy, the ORR and DCR was 80% and 100% respectively, and the mPFS was 5.5 months. In March 2024, MRG004A was granted FTD from the FDA for the treatment of PC 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. The Phase I dose expansion study is being conducted to explore dose optimization of MRG004A on 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 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 have observed encouraging preliminary data on DLBCL.

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

MRG006A

MRG006A is a novel topoisomerase I inhibitor-based GPC-3 ADC candidate with global first-in-class potential, which has been developed based on our Hi-TOPi platform. We received the IND approval in July 2024 from the NMPA and we are currently conducting a Phase I clinical trial. In pre-clinical studies, MRG006A resulted in a robust and dose-dependent tumor growth inhibition on multiple CDX models and HCC PDX models. In the meantime, MRG006A also demonstrated good tolerability in the exploratory toxicology study. Such pre-clinical data was presented at the AACR Annual Meeting in April 2024.

– **Warning under Rule 18A.08(3) of the Listing Rules:** There is no assurance that the MRG006A will ultimately be successfully developed and marketed by the Company. Shareholders and 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 the 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 co-developed by us and Keymed through a joint venture, KYM. CMG901 showed a favorable safety and tolerability profile in the Phase I trial for the treatment of advanced solid tumors. In June 2024, the latest data from a Phase I clinical study of CMG901 on the treatment of advanced GC/GEJ has been presented by way of oral presentation at the ASCO Annual Meeting 2024. On January 6, 2025, the data from the Phase I clinical study were released on *The Lancet Oncology*, the international authoritative oncology journal. As of February 24, 2024, the ORR is 48% for patients in dose group of 2.2 mg/kg. In the abovementioned dose group, CMG901 presented encouraging mPFS of 4.8 months and mOS of 11.8 months. In connection with the License Agreement, AstraZeneca has been conducting multiple clinical studies regarding CMG901 for the treatment of advanced solid tumors. An international multicenter Phase III study comparing CMG901 monotherapy with regimens selected by the researcher as the second-line or beyond second-line treatment in patients with advanced or metastatic gastric and gastroesophageal junction adenocarcinoma with CLDN18.2-expression was posted on the Drug Clinical Trial Registration and Information Platform (藥物臨床試驗登記與信息公示平台) in March 2024, and the first patient received the first dose in April 2024.

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

MRG007

MRG007 is a novel ADC for the treatment of GI cancers. It has shown robust antitumor activity in preclinical models of GI cancers and a favorable therapeutic index based on IND enabling studies. The first IND submission is planned for the first half of 2025 with an initial clinical development focus in colorectal, pancreatic and other GI cancers. Pre-clinical data of MRG007 are expected to be presented at the AACR annual meeting in April 2025.

– **Warning under Rule 18A.08(3) of the Listing Rules:** There is no assurance that the MRG007 will ultimately be successfully developed and marketed by the Company. Shareholders and 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. Pucotenlimab demonstrated robust antitumor activity in patients (pts) with MSI-H/dMMR, based on findings from the phase II study, and we are expected to present the long-term survival results and the updated safety profile at the ASCO Annual Meeting 2025.

– **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, 2024.

– **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, 2024.

– **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, 2024.

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. The encouraging data observed has been orally presented at the Society of Urologic Oncology (SUO) 25th Annual Meeting in 2024. 74.5% of patients achieved CR at any time, after receiving treatment with CG0070 as a single agent. The median DOR has not been reached but exceeds 27 months as of the data cut-off of September 30, 2024. 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. As of December 31, 2024, we are conducting a Phase I clinical trial in China and have finished Phase I patients enrollment. For the combination therapy of CG0070 with PUYOUHENG (Pucotenlimab Injection), we received an IND approval from the NMPA for its Phase I trial in the treatment of patients with BCG-unresponsive NMIBC.

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

Innovation platforms

We continuously strive to build up and develop novel technology platforms as innovative engines for the Company. Besides the clinical-proven vc-MMAE platform, we have developed multiple innovative linker-payload platforms for ADC drug candidates, including the Hi-TOPi platform and other early-stage platforms. During the Reporting Period, our innovative ADC platforms and T cell engager platform TOPAbody have achieved significant progress. Based on these innovation platforms, we have generated two ADC candidates, which are MRG006A with global first-in-class potential and MRG007 with global best-in-class potential, as well as the new-generation T cell agonistic antibody CTM012. We have observed encouraging data in pre-clinical studies and have received an IND approval for MRG006A in China. Meanwhile, we are advancing MRG007 and CTM012 to clinical research stage efficiently. Pre-clinical data of MRG006A and TOPAbody platforms were presented at the 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.

  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 clinical research stage.

– **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.

  Based on the T cell engager platform, we have developed CTM012, a new-generation T cell agonistic antibody with global best-in-class potential which has entered the IND-enabling study stage during the Reporting Period. We filed pre-IND for CTM012 in both China and U.S. 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. During the Reporting Period, we have recognized RMB45.5 million in revenue from the provision of CDMO services.

In addition, the construction of the Shanghai Biotech Park has been completed. The research and development center in the Shanghai Biotech Park has been put in use, which further enhances our capability to conduct pre-clinical, quality control and CMC research activities. The manufacturing facilities in the Shanghai Biotech Park have a designed total capacity of 12,000L, and has been obtained the environmental impact assessment report for the production of mAb and ADC. Going forward, we will continue to build or expand our manufacturing facilities based on our business needs arising from the commercialization of our ADC candidates.

KEY EVENTS AFTER THE REPORTING PERIOD

Development Progress of our Drug Candidates After the Reporting Period

– ***Exclusive License Agreement with ArriVent for MRG007***

On January 22, 2025, the Company has entered into an exclusive license agreement with ArriVent to develop and commercialize the Group's novel ADC candidate, MRG007. Under the terms of the agreement, the Company has granted ArriVent exclusive rights to develop, manufacture and commercialize MRG007 outside of Greater China. The one-time upfront and near-term milestone payments amount to US$47 million and the Company is eligible to receive up to US$1.16 billion in development, regulatory and sales milestones and tiered royalties on net sales outside of Greater China.

It has shown robust antitumor activity in preclinical models of GI cancers and a favorable therapeutic index based on IND enabling studies. The first IND submission is planned for the first half of 2025 with an initial clinical development focus in colorectal, pancreatic and other GI cancers. Pre-clinical data of MRG007 are expected to be presented at the AACR annual meeting in April 2025.

For details of the License Agreement for MRG007, please refer to the Company's announcement dated January 22, 2025.

– ***CG0070 was granted BTD by the CDE***

In January 2025, CG0070 was granted BTD by the CDE for the treatment of BCG unresponsive bladder cancer patients, which have relapsed or are refractory to prior approved therapies, and this designation signified the innovativeness and the potential of CG0070 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 and related ancillary equipment 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 26, 2024. The annual cap with respect to the provision of CDMO services for the year ending December 31, 2025 is RMB36.0 million. The aforementioned framework agreement (together with the monetary transaction caps therein) was approved by the Independent Shareholders in the 2025 first extraordinary general meeting of the Company held on January 7, 2025. Upon the passing of the relevant resolutions by the Independent Shareholders at the Company's 2025 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.

For further details of the aforementioned continuing connected transaction with Lepu Medical, please refer to the Company's announcement dated November 26, 2024, circular dated December 17, 2024 and poll results announcement dated January 7, 2025.

Change of Auditor

In November 2024, the original auditor of the Company, PricewaterhouseCoopers resigned as the auditor of the Company with effect from November 26, 2024. The Company, with the recommendation from the Audit Committee, proposed to appoint Ernst & Young as the Company's new auditor for the year of 2024 for a term up to the conclusion of the next annual general meeting of the Company and which was approved by Shareholders in the 2025 first extraordinary general meeting of the Company held on January 7, 2025.

For further details of the aforementioned change of auditor of the Company, please refer to the Company's announcement dated November 26, 2024, circular dated December 17, 2024 and poll results announcement dated January 7, 2025.

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. Looking ahead to 2025, We plan to leverage our competitive advantages through the following development strategies:

In respect of drug R&D, we strive to enrich our differentiated marketed product portfolio targeting indications with significant medical needs by combining our independent R&D capability with strategic collaborations. In addition, we are committed to enhancing our ADC platforms and developing novel technologies to support the development of next-generation drugs. For our registrational stage product MRG003, the authority is currently proceeding with the clinical and pharmaceutical evaluation in an orderly manner. We will concentrate our resources and endeavour to expedite the approval process. We will also explore further potential clinical value of our other innovative drug candidates, such as MRG004A and MRG006A. At the same time, we are also constantly exploring the potential efficacy of combination therapies within our pipeline to bring clinical benefits to more patients. For innovation molecules, we will reinforce the establishment of our innovation platforms and advance innovative molecules CTM012 and MRG007 to the clinical research stage efficiently.

In terms of domestic commercialization, we achieved a robust growth in sales revenue in 2024, with sales of PUYOUHENG (Pucotenlimab Injection) tripling compared to the previous year through our own sales channels, which further validates our sales strategy and business model. We will continue to improve our marketing and commercialization teams and take further actions to enhance the market accessibility of PUYOUHENG (Pucotenlimab Injection), accelerating market penetration at all levels to further increase market share. By leveraging the expertise and industry connections of our commercialization team, we will seek to foster our brand's image and market knowledge of our product through various methods, such as marketing and academic activities. At the same time, we will commence the preparation process for the commercial launch of MRG003. 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. Our ADC platform has been endorsed by multinational companies, evidenced by the successful out-licensing of CMG901's global rights to AstraZeneca and MRG007's ex-Greater China rights to ArriVent. We expect our other ADC products to have more promising business development opportunities. Going forward, we will persist in expanding our international network and exploring new business development cooperation opportunities. We remain committed to seeking more strategic partners worldwide to develop our ADC products and other innovative candidates through partnerships, licensing agreements, or joint ventures.

FINANCIAL REVIEW

Revenue

For the year ended December 31, 2024, we have recorded a revenue of RMB367.8 million (2023: RMB225.4 million), representing a significant increase of 63.2%, which consists of (i) RMB300.3 million from the sales of PUYOUHENG (Pucotenlimab Injection), almost tripling the amount in 2023 (RMB101.4 million); (ii) RMB22.0 million from the out-licensing of CMG901 for milestone payment and technology transfer services (2023: RMB124.0 million); and (iii) RMB45.5 million (2023: nil) for the provision of CDMO services.

Cost of sales

For the year ended December 31, 2024, the Group has recorded cost of sales of RMB74.8 million (2023: RMB28.3 million), representing an increase of 164.6%, which was in line with the growth in revenue.

Selling and Marketing Expenses

For the year ended December 31, 2024, the Group has recorded selling and marketing expenses of RMB146.0 million (2023: RMB43.3 million), which was largely in line with the growth in sales revenue of PUYOUHENG (Pucotenlimab Injection) during the year ended December 31, 2024.

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; and (iii) others, mainly representing utilities as well as traveling and transportation expenses.

For the year ended December 31, 2024, the Group has recorded administrative expenses of RMB91.9 million (2023: RMB86.7 million), mainly due to an increase in property taxes following the completion and operation of Shanghai Biotech Park in 2024.

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 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; and (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 RMB458.1 million in 2023 to RMB437.7 million in 2024, representing a decrease of 4.4%.

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

	Year ended 31 December			
	2024		2023	
	RMB'000	***%***	*RMB'000*	*%*
Clinical study related expenses	**184,604**	**42.2**	173,425	37.9
Pre-clinical study costs	**41,688**	**9.5**	34,463	7.5
Raw material and consumables used	**34,689**	**7.9**	26,455	5.8
Employee benefit expenses	**95,698**	**21.9**	120,682	26.3
Depreciation and amortization	**67,475**	**15.4**	88,372	19.3
Others	**13,543**	**3.1**	14,676	3.2
Total	**437,697**	**100**	458,073	100

(i) Clinical study related expenses increased by RMB11.2 million as compared to the year ended December 31, 2023, mainly due to the relatively concentrated CMC expenses incurred during the NDA stage;

(ii) Pre-clinical study costs increased by RMB7.2 million, because the Group has been continuously focusing on the research and development of more innovative molecules;

(iii) Raw material and consumables expenses increased by RMB8.2 million, mainly due to the Company's focus on the research and development of more innovative molecules;

(iv) Employee benefit expense decreased by RMB25.0 million, mainly due to the structural adjustment to meet the current R&D demand of the Group;

(v) Depreciation and amortization costs decreased by RMB20.9 million, mainly because the amortization of leasehold improvement of the Group's Beijing manufacturing plant was completed at the end of 2023, and no further amortization costs were recognized therefrom; and

(vi) Other expenses for the year ended December 31, 2024 decreased by RMB1.1 million.

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

We had fair value gain on financial liabilities at fair value through profit or loss of RMB175.0 million for 2023 and fair value gain of RMB5.1 million for 2024. 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 a certain portion 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	
	2024	2023
	RMB'000	*RMB'000*
Fair value gains on financial liabilities at fair value through profit or loss FVPL	**5,077**	174,976

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 RMB8.3 million in 2023 to RMB6.0 million in 2024, mainly due to a decrease in interest on bank deposits. Our finance costs increased from RMB16.0 million in 2023 to RMB23.0 million in 2024, due to the completion and operation of Shanghai Biotech Park in 2024, which resulted in its loan interest no longer being capitalized.

Income Tax Expenses

For the year ended December 31, 2023 and 2024, the Group's income tax expenses were nil.

Loss for the Reporting Period

Based on the factors described above, the Group's loss increased from RMB30.3 million in 2023 to RMB424.2 million in 2024.

– ***Non-IFRS Operating Loss for the Reporting Period***

To supplement our consolidated financial statements which are presented in accordance with International Financial Reporting Standards ("**IFRS**"), we also use non-IFRS operating loss 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 impacts of items which our management considers not indicative of our core operating performance such as non-recurring items and 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 "non-IFRS operating loss for the year" as loss for the year after deducting (i) net gains on dilution of equity interests in an associate, (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 and (iii) fair value changes on financial liabilities at fair value through profit or loss. For the year ended December 31, 2024, our non-IFRS operating loss for the year was approximately RMB429.3 million (for the year ended December 31, 2023: approximately RMB425.5 million).

The following table sets forth the reconciliations of our non-IFRS financial measure for the years ended December 31, 2023 and 2024 to the nearest measure prepared in accordance with IFRS:

	Year ended 31 December	
	2024	2023
	RMB'000	*RMB'000*
Loss for the year	**(424,193)**	(30,301)
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
Fair value changes on financial liabilities at fair value through profit or loss	**5,077**	174,976
Non-IFRS Operating Loss for the year	**(429,270)**	(425,539)

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

Our cash and cash equivalents remained at a similar level as compared to last year at RMB401.3 million as at December 31, 2024 (2023: RMB426.0 million). 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, 2024, our net cash used in operating activities was RMB196.4 million, a decrease of RMB54.4 million from RMB250.8 million as of December 31, 2023 due to a surge in the revenue for the year ended December 31, 2024.

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

Our bank borrowings are divided into secured loans and unsecured loans. As of December 31, 2024, the Group's bank borrowings amounted to RMB794.4 million (December 31, 2023: RMB694.3 million), among which unsecured and unguaranteed bank borrowings amounted to RMB534.1 million (December 31, 2023: RMB394.0 million) in total with interest at fixed and floating interest rates, among which RMB478.2 million of such borrowing will be repayable within one year.

As of December 31, 2024, the Group's secured and unguaranteed bank borrowings amounted to RMB260.3 million (December 31, 2023: RMB300.3 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, buildings and facilities.

As of December 31, 2024, we had utilized RMB883.6 million from our banking facilities and RMB666.4 million remained unutilized under our banking facilities.

Placing of new Shares under general mandate

References are made to the announcements of the Company dated May 17, 2024 and May 24, 2024, respectively. The Company placed 51,170,000 H Shares to certain places through placing agents at the placing price of HK$4.58 per H Share under its general mandate. Completion of the placing took place on May 24, 2024.

Proceeds from placing and the usage plan

Reference is made to the announcement of the Company dated May 24, 2024. After deducting all applicable costs and expenses, including placing commission, legal fees and levies, the net proceeds raised amounted to approximately HK$229.75 million (equivalent to approximately RMB209.2 million). The net proceeds from the placing will be used as to (i) approximately 70% (being HK$160.83 million or RMB146.4 million) for the research and development, clinical trials, registration filings and other workstreams of the Company's ADC product candidates; (ii) approximately 20% (being HK$45.95 million or RMB41.8 million) for the clinical trials and other workstreams of the Company's oncolytic virus product candidate CG0070; and (iii) approximately 10% (being HK$22.98 million or RMB20.9 million) to replenish the Company's working capital and for general corporate purposes.

As of December 31, 2024, approximately RMB24.6 million of the proceeds has been used for the research and development, clinical trials, registration filings and other workstreams of the Company's ADC product candidates and RMB19.9 million of the proceeds has been used to replenish the Company's working capital and for general corporate purposes.

Gearing Ratio

The gearing ratio is calculated using the Group's liabilities divided by its assets. As of December 31, 2024, the Group's gearing ratio was 70.1% (December 31, 2023: 62.7%).

Significant Investments, Material Acquisitions and Disposals

The Group did not have any significant investments or material acquisitions or disposals of subsidiaries, associates and joint ventures for the year ended December 31, 2024.

Capital Commitments

As of December 31, 2023 and 2024, the Group had capital commitments for property, plant and equipment of RMB456.6 million and RMB456.8 million, respectively, reflecting the capital expenditure our Group contracted at the end of year but not yet incurred.

Contingent Liabilities

As of December 31, 2024, the Group did not have any contingent liabilities.

Charges on Group Assets

Save as disclosed in this announcement, as of December 31, 2024, 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, 2024, the Group had a total of 498 employees. The total remuneration cost for 2024 was RMB211.9 million, as compared to RMB198.9 million for 2023, primarily due to an increase in the expansion of the sales team upon the commercialization of our products.

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, 2024.

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, 2024. 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 (including sale of treasury shares) during the year ended December 31, 2024. As of December 31, 2024, the Company did not hold any of treasury shares.

Final Dividend

The Board does not recommend the payment of a final dividend for the year ended December 31, 2024 (for the year ended December 31, 2023: nil).

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, 2024, reviewed the accounting principles and practices adopted by the Group and discussed auditing, internal controls and financial reporting matters.

Work of Ernst & Young

The figures in respect of the Group's consolidated financial position and consolidated profit or loss and other comprehensive income and the related notes thereto for the year ended December 31, 2024 as set out in this annual results announcement have been agreed by the Group's auditor, Ernst & Young, to the amounts set out in the Group's audited consolidated financial statements for the year. The work performed by Ernst & Young in this respect did not constitute an assurance engagement and consequently no assurance has been expressed by Ernst & Young 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, 2024 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 PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For The Year Ended December 31, 2024

	Notes	Year ended 31 December	
		2024	2023
		RMB'000	*RMB'000*
Revenue	*4*	**367,794**	225,352
Cost of sales		**(74,824)**	(28,277)
Gross profit		**292,970**	197,075
Other income		**8,499**	7,251
Other expenses		**(69)**	(3)
Selling and marketing expenses		**(145,951)**	(43,296)
Administrative expenses		**(91,943)**	(86,657)
Research and development expenses		**(437,697)**	(458,073)
Fair value changes on financial liabilities at fair value through profit or loss ("FVTPL")	*6*	**5,077**	174,976
Other (losses)/gains, net	*7*	**(21,651)**	213,523
Operating (loss)/profit		**(390,765)**	4,796
Finance income		**5,996**	8,261
Finance costs		**(22,985)**	(16,017)
Finance costs, net		**(16,989)**	(7,756)
Share of loss of investments accounted for using the equity method		**(16,439)**	(27,341)
Loss before income tax		**(424,193)**	(30,301)
Income tax expense	*8*	**–**	–
Loss for the year		**(424,193)**	(30,301)
Loss attributable to:			
Owners of the Company		**(411,376)**	(22,096)
Non-controlling interests		**(12,817)**	(8,205)
		(424,193)	(30,301)

	Notes	Year ended 31 December 2024 RMB'000	2023 RMB'000
Other comprehensive income/(loss)			
Items that may be subsequently reclassified to profit or loss			
Currency translation differences		**76**	(331)
Share of other comprehensive income of associates		**901**	–
Total comprehensive loss		**(423,216)**	(30,632)
Total comprehensive loss attributable to:			
Owners of the Company		**(410,399)**	(22,427)
Non-controlling interests		**(12,817)**	(8,205)
		(423,216)	(30,632)
Losses per share for loss attributable to owners of the Company for the year (expressed in RMB per share)			
– Basic losses per share	*9*	**(0.24)**	(0.01)
– Diluted losses per share	*9*	**(0.24)**	(0.01)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As at December 31, 2024

	Notes	As at 31 December	
		2024	2023
		RMB'000	*RMB'000*
Assets			
Non-current assets			
Property, plant and equipment		**930,106**	948,189
Right-of-use assets		**120,932**	139,056
Intangible assets		**435,250**	434,221
Investments accounted for using the equity method		**114,073**	126,685
Other receivables, prepayments and deposits		**34,816**	59,009
Total non-current assets		**1,635,177**	1,707,160
Current assets			
Inventories		**22,787**	29,412
Trade receivables	*10*	**45,821**	37,802
Other receivables, prepayments and deposits		**111,986**	120,289
Financial assets at FVTPL		**63,628**	63,628
Cash and cash equivalents		**401,286**	426,015
Total current assets		**645,508**	677,146
Total assets		**2,280,685**	2,384,306
Equity			
Equity attributable to owners of the Company			
Share capital	*11*	**1,710,615**	1,659,445
Reserves		**1,757,172**	1,591,046
Accumulated losses		**(2,764,962)**	(2,353,586)
		702,825	896,905
Non-controlling interests		**(21,022)**	(8,205)
Total equity		**681,803**	888,700

	Notes	As at 31 December 2024 RMB'000	2023 RMB'000
Liabilities			
Non-current liabilities			
Borrowings		**255,940**	260,000
Lease liabilities		**11,455**	24,184
Deferred government grants		**18,020**	12,000
Deferred tax liabilities		**37,687**	37,687
Financial liabilities at FVTPL	*12*	**232,267**	262,174
Total non-current liabilities		**555,369**	596,045
Current liabilities			
Borrowings		**538,411**	434,299
Trade payables	*13*	**236,135**	207,611
Other payables and accruals		**233,684**	234,380
Lease liabilities		**34,378**	23,271
Contract liabilities		**905**	–
Total current liabilities		**1,043,513**	899,561
Total liabilities		**1,598,882**	1,495,606
Total equity and liabilities		**2,280,685**	2,384,306

1. GENERAL INFORMATION

Lepu Biopharma Co., Ltd. (the "**Company**") was established 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 focused on the discovery, development and commercialisation of drugs for cancer – targeted therapy and immunotherapy globally.

The consolidated financial statements are presented in Renminbi ("**RMB**") and all values are rounded to the nearest thousand except when otherwise indicated.

2. BASIS OF PREPARATION AND CHANGES IN ACCOUNTING POLICIES

2.1 Basis of preparation

(a) Compliance with IFRS Accounting Standards and the disclosure requirements of the Hong Kong Companies Ordinance

The consolidated financial statements of the Group have been prepared in accordance with IFRS Accounting Standards and the disclosure 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 2024, the Group has incurred net losses of approximately RMB424.2 million, while net cash used in operating activities was approximately RMB196.4 million. As at 31 December 2024, the Group had net current liabilities of approximately RMB398.0 million and cash and cash equivalents of approximately RMB401.3 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 equivalents, unutilised bank facilities and 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 31 December 2024. The Group therefore continues to prepare clarify consolidated financial statement on a going concern basis.

(b) Historical cost convention

The financial statements have been prepared on a historical cost basis, except for financial assets and liabilities at FVTPL, which are measured at fair value.

(c) Revised IFRS Accounting Standards adopted by the Group

The Group has applied the following revised IFRS Accounting Standards for the first time for its annual reporting period commencing 1 January 2024:

- Amendments to IFRS 16 – *Lease Liability in a Sale and Leaseback*
- Amendments to IAS 1 – *Classification of Liabilities as Current or Non-current*
- Amendments to IAS 1-*Non-current Liabilities with Covenants*
- Amendments to IAS 7 and IFRS 7 – *Supplier Finance Arrangements*

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

(d) New and revised IFRS Accounting Standards not yet adopted

The following new Accounting Standards have been issued but are not mandatory for the reporting period ending 31 December 2024 and have not been early adopted by the Group:

- IFRS 18-*Presentation and Disclosure in Financial Statements*
- IFRS 19-*Subsidiaries without Public Accountability: Disclosures*
- Amendments to IFRS 9 and IFRS 7-*Amendments to the Classification and Measurement of Financial Instruments*
- Amendments to IFRS 10 and IAS 28-*Sale or Contribution of Assets between an Investor and its Associate or Joint Venture*
- Amendments to IAS 21-*Lack of Exchangeability*
- Annual Improvements to IFRS Accounting Standards – Volume 11-*Amendments to IFRS 1, IFRS 7, IFRS 9, IFRS 10 and IAS 7*
- Amendments to IFRS 9 and IFRS 7- *Contracts Referencing Nature-dependent Electricity*

The application of IFRS 18 will have no impact on the consolidated statements of financial position of the Group, but will have impact on the presentation of the consolidated statements of profit or loss and other comprehensive income. Except for IFRS 18, the directors of the Company anticipate that these new and revised IFRS Accounting Standards are not expected to have a material impact on the Group's financial performance and financial position in the foreseeable future.

3. SEGMENT INFORMATION

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

During the year ended 31 December 2024, the Group has been principally engaged in the sale 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 the allocation of resources. 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 Mainland China. Accordingly, the Group's results were primarily derived in Mainland China during the reporting period, and its non-current assets were also primarily located in Mainland China.

4. REVENUE

	Year ended 31 December	
	2024	2023
	RMB'000	*RMB'000*
Revenue recognised at a point in time		
– Sale of pharmaceutical products	**300,333**	101,385
– Licensing income (a)	**21,964**	123,967
	322,297	225,352
Revenue recognised over time		
– CDMO services (b)	**45,497**	–
Total	**367,794**	225,352

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

	Year ended 31 December	
	2024	2023
	RMB'000	*RMB'000*
Geographical markets		
– Mainland China	**345,830**	101,385
– Overseas	**21,964**	123,967
Total	**367,794**	225,352

For the year ended 31 December 2024, revenue of approximately RMB45,497,000 (2023: Nil) was derived from CDMO services income from Beijing Lepu Pharmaceutical Technology Co., Ltd. ("**Beijing Lepu Pharmaceutical**") and Lepu Pharmaceutical Co., Ltd. ("**Lepu Pharmaceutical**"), both of which are related parties of the Group, ultimately controlled by the same shareholder, which accounted for 12.37% (2023: nil) of the Group's total revenue. Other than the aforementioned customer, the revenue derived from each of the remaining external customers was less than 10% of the Group's total revenue.

(a) Licensing income

On 22 February 2023, KYM Biosciences Inc. (KYM) 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% shares of interest in KYM, respectively.

Upon the execution of the License Agreement and subject to the terms and conditions thereof (including obtaining certain regulatory approvals 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 the 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 of the 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 a 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 2024, the Group has recognised licensing income of approximately RMB21,964,000. (2023: RMB123,967,000) in relation to the abovementioned transaction.

(b) Revenue from CDMO services

The extraordinary general meeting of the Company approved the CDMO services framework Agreement and the supplemental framework agreement in 2024, pursuant to which the Group conditionally agreed to provide Lepu Medical Technology (Beijing) CO., Ltd. ("**Lepu Medical**"), a related party of the group, and/or its subsidiaries with CDMO services.

During the year ended 31 December 2024, the Group has recognised CDMO services income of approximately RMB45,497,000 (2023: Nil) in relation to the abovementioned transaction.

(c) Accounting policies of revenue recognition

(i) Sale 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 orders. The Group adopts advance collection or a credit period of 30 days with 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 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 control of the licences is transferred to the licensee.

The Group recognises revenue for a sales-based or usage-based royalty promised in exchange for a licence 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).

(iii) Revenue from CDMO services

The CDMO services are integrated services including project management, drug manufacturing, development, optimisation, trial production, and other relevant services. The duration of the contracts ranges from months to year. The contracts contain multiple deliverable units, which are generally in the form of technical laboratory reports, samples and/or products for manufacturing, and each deliverable unit has an individual selling price specified within the contract. The Group has assessed whether each deliverable is distinct to determine the performance obligation within the contract. Any deliverable in the contract is identified as a performance obligation if the deliverable is distinct. If the deliverables are highly interdependent or highly interrelated, those deliverables are not separately identifiable, and are combined into a single performance obligation.

The Group satisfies a performance obligation and recognises revenue over time, if one of the following criteria is met:

- the customer simultaneously receives and consumes the benefits provided by the Group's performance as the Group performs;

- the Group's performance creates or enhances an asset that the customer controls as the asset is created or enhanced; or

- the Group's performance does not create an asset with an alternative use to the Group and the Group has an enforceable right to payment for performance completed to date.

If none of the above criteria is met, the Group recognises revenue at the point in time when the customer obtains control of the distinct good or service.

If control of the service transfers over time, revenue is recognised over the period of the contract by reference to the progress towards complete satisfaction of that performance obligation, using the output method. Otherwise, revenue is recognised at the point in time when the customer obtains control of the service.

The transaction price allocated to the remaining performance obligations, all of which pertain to CDMO services, amounts to RMB9,317,000 and is expected to be recognized as revenue over the next five years.

5. LOSS BEFORE TAX

	2024	2023
	RMB'000	*RMB'000*
Cost of sales	**74,824**	28,277
Depreciation of property, plant and equipment	**51,997**	54,268
Depreciation of right-of-use assets	**17,864**	18,515
Amortisation of other intangible assets	**30,318**	29,789
Research and development costs (excluding depreciation, amortisation and employee benefit expense)	**274,524**	249,019
Lease payments not included in the measurement of lease liabilities	**616**	648
Auditors' remuneration	**2,650**	2,850
Employee benefit expense:		
Wages, salaries and welfare	**158,012**	135,986
Share-based payment expenses	**4,402**	18,570
Pension scheme contributions	**18,399**	15,563
Other social security costs, housing benefits and other employee benefits	**31,067**	28,787
Less: Amount capitalised	**(3,129)**	–
Foreign exchange difference, net	**(1,329)**	(212)
Bank interest income	**(4,667)**	(8,049)

6. FAIR VALUE CHANGES ON FINANCIAL LIABILITIES AT FVTPL

	Year ended 31 December	
	2024	2023
	RMB'000	*RMB'000*
Financial liabilities at FVTPL	**5,077**	174,976

7. OTHER GAINS/(LOSSES), NET

	Year ended 31 December	
	2024	2023
	RMB'000	*RMB'000*
Net gains on dilution of equity interests in an associate	**–**	116,388
Net gains on disposal of investments in an associate	**–**	103,874
Net gains on disposal of right-of-use assets	**11**	–
Expected credit losses	**221**	(154)
Donation	**(19,852)**	(3,406)
Others	**(2,031)**	(3,179)
Total	**(21,651)**	213,523

8. INCOME TAX EXPENSE

	Year ended 31 December	
	2024	2023
	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**") renewed its qualification as a High and New Technology Enterprise ("**HNTE**") under the relevant PRC laws and regulations in 2023. Accordingly, it was entitled to a preferential corporate income tax rate of 15% on its estimated assessable profits for a three-year period since then.

Lepu (Beijing) Biopharma Co., Ltd. ("**Lepu Beijing**") was qualified as a HNTE under the relevant PRC laws and regulations on 25 October 2021 and the qualification was renewed in 2024. 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, which was extended to the years ended 31 December 2026.

CtM Bio Co., Ltd. ("**CtM Bio**") was qualified as a 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.

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 the 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	
	2024	2023
Loss for the year attributable to owners of the Company (in RMB'000)	**(411,376)**	(22,096)
Weighted average number of ordinary shares in issue (in thousands)	**1,690,482**	1,659,445
Basic loss per share (in RMB)	**(0.24)**	(0.01)

(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 years ended 31 December 2024 and 2023, the Company had no potential ordinary shares. Accordingly, diluted loss per share for the years ended 31 December 2024 and 2023 is the same as the basic loss per share for the respective years.

10. TRADE RECEIVABLES

	As at 31 December	
	2024	2023
	RMB'000	*RMB'000*
Trade receivables	**46,232**	38,014
Less: Loss allowance	**(411)**	(212)
Total	**45,821**	37,802

The Group allows a credit period of 30 days to its customers. As at 31 December 2024 and 2023, the ageing analysis of the trade receivables (net of loss allowance) based on the invoice date is as follows:

	As at 31 December	
	2024	2023
	RMB'000	*RMB'000*
0 to 30 days	**44,007**	37,802
31 to 60 days	**1,716**	–
61 to 90 days	**98**	–
Total	**45,821**	37,802

11. SHARE CAPITAL

	Number of shares	Nominal value of shares *RMB'000*
Authorised, issued and fully paid		
At 1 January 2023 and 31 December 2023	1,659,444,838	1,659,445
Issuance of shares	51,170,000	51,170
At 31 December 2024	1,710,614,838	1,710,615

On 24 May 2024, the Company completed a placing of 51,170,000 H Shares with a par value of RMB1.00 each at the price of HK$4.58 per H Share (the "**Placing**"). The gross proceeds from the Placing amounted to approximately HK$234 million (equivalent to RMB213,379,000), of which, RMB51,170,000 were credited to the Company's share capital and the remaining proceeds deducting the share issue costs of RMB4,388,000 were credited to the share premium.

12. FINANCIAL LIABILITIES AT FVTPL

	As at 31 December	
	2024	2023
	RMB'000	*RMB'000*
Variable consideration payable arising from the acquisition of 40% equity interests in Taizhou Hanzhong from non-controlling interests	**263,112**	272,625
Less: Current portion	**(30,845)**	(10,451)
Non-current portion	**232,267**	262,174

The movements of financial liabilities at FVTPL for the years ended 31 December 2024 and 2023 are set out below:

	Year ended 31 December	
	2024	2023
	RMB'000	*RMB'000*
Opening balance	**272,625**	448,282
Change in fair value (note 6)	**(5,077)**	(174,976)
Variable consideration paid to Hangzhou HanX Biomedical Co., Ltd.	**(4,436)**	(681)
Closing balance	**263,112**	272,625

13. TRADE PAYABLES

The ageing analysis of the trade payables based on their respective invoice dates is as follows:

	As at 31 December	
	2024	2023
	RMB'000	*RMB'000*
Less than 1 year	**211,469**	196,909
Over 1 year	**24,666**	10,702
Total	**236,135**	207,611

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 2024 and 2023.

15. EVENTS OCCURRING AFTER THE REPORTING PERIOD

In January 2025, the Company entered into an exclusive licensing agreement with ArriVent for MRG007. Under the terms of the agreement, the Company has granted ArriVent exclusive rights to develop, manufacture and commercialize MRG007 outside of Greater China. The one-time upfront and near-term milestone payments are US$47 million and the Company is eligible to receive up to US$1.16 billion in development, regulatory and sales milestones and tiered royalties on net sales outside of Greater China.

"AACR"	American Association for Cancer Research
"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)
"ArriVent"	ArriVent BioPharma, Inc., a clinical-stage biopharmaceutical company listed on the Nasdaq Global Market (ticker symbol: AVBP) 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
"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"	the 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

"CDX"	Cell derived xenograft
"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)
"Core Product(s)"	has the meaning ascribed to it under Chapter 18A of the Listing Rules; for the purposes of this announcement, our core products include MRG003, MRG002 and PUYOUHENG (Pucotenlimab Injection)
"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
"first-line"	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
"FPI"	first-patient-in
"FTD"	Fast Track Designation
"GC"	gastric cancer
"GEJ"	gastroesophageal junction
"G/GEJ carcinoma"	gastric and gastroesophageal junction carcinoma
"GI cancer"	gastrointestinal cancer
"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
"GPC-3"	Glypican-3

"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
"HCC"	hepatocellular carcinoma
"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
"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 for CMG901"	a global exclusive out-license agreement entered into by KYM and AstraZeneca on February 23, 2023
"License Agreement for MRG0007"	an exclusive out-license agreement entered into by the Company and ArriVent on January 22, 2025
"Licensed Region"	licensed region under License Agreement for MRG0007, i.e. worldwide, excluding Mainland China, Hong Kong, Macau and Taiwan.
"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-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, 2024
"R/M"	recurrent/metastatic
"RMB"	Renminbi, the lawful currency of China
"R&D"	research and development
"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
"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
"topoisomerase I inhibitor"	a chemical compound that blocks the action of type I topoisomerases
"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, 2025

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

* *For identification purposes only*