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Lepu Biopharma Co., Ltd.
樂普生物科技股份有限公司

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

(Stock Code: 2157)

INTERIM RESULTS ANNOUNCEMENT
FOR THE SIX MONTHS ENDED JUNE 30, 2024

The Board is pleased to announce the unaudited consolidated interim results of the Group for the six months ended June 30, 2024, together with the comparative figures for the same period in 2023.

BUSINESS HIGHLIGHTS

During the Reporting Period and up to the date of this announcement, we have made significant progress in advancing our product pipeline as well as business operations:

Sales revenue of PUYOUHENG (Pucotenlimab Injection) totalling RMB94.8 million, doubling that of the same period in 2023.

During the Reporting Period, the Group recorded a total revenue of RMB133.3 million, which was mainly contributed by the sales of PUYOUHENG (Pucotenlimab Injection). In the first half of 2024, the Group recorded a revenue of RMB94.8 million for the sales of PUYOUHENG (Pucotenlimab Injection), doubling that recorded in the same period in 2023, which was approximately RMB44.0 million.

Significant advancement of ADC pipelines and their combination therapies with immunoncology

– **MRG003:** We have completed patients enrollment of the registrational Phase IIb clinical study on NPC and expect to file NDA in China in the second half of 2024. In July 2024, we have obtained BTD for MRG003 from the FDA for the treatment of R/M NPC in the United States.

Combination therapy of MRG003 with 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 was orally presented at the ASCO Annual Meeting 2024. We are currently conducting the Phase II part of the trial and have observed encouraging data, which is planned to be presented at ESMO Asia Congress 2024.

– **MRG002:** We have completed patients enrollment of the pivotal Phase II clinical trial on HER2 over-expressing BC with liver metastasis in China and observed encouraging data, which is expected to be presented at the 2024 CSCO. Meanwhile, we are conducting a Phase III clinical trial on HER2 positive BC.

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

- **MRG004A:** 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. We are expanding the subgroup of PC patients in the Phase I clinical trial to explore further potential of MRG004A on PC.
- **MRG006A:** We have presented encouraging pre-clinical data at the 2024 AACR Annual Meeting. 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 has also demonstrated good tolerability in exploratory toxicology study. Following the encouraging pre-clinical performance, we have received the IND approval in China and are currently conducting a Phase I clinical study, with the FPI achievement in August 2024.

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.

FINANCIAL HIGHLIGHTS

- Revenue for the six months ended June 30, 2024 was approximately RMB133.3 million (for six months ended June 30, 2023: RMB153.6 million).
- Administrative expenses decreased for 21.1% from approximately RMB39.1 million for the six months ended June 30, 2023 to approximately RMB30.8 million for the same period this year.
- Research and development expenses for the six months ended June 30, 2024 were approximately RMB216.6 million, which was 6.6% lower than the same period in 2023 (six months ended June 30, 2023: RMB231.9 million).
- Loss for the period attributable to the Shareholders was approximately RMB192.4 million for the six months ended June 30, 2024 (for the six months ended June 30, 2023: RMB141.9 million).
- Cash and cash equivalents increased from approximately RMB426.0 million as of December 31, 2023 to approximately RMB513.6 million as of June 30, 2024, signifying an increase of 20.6%.

KEY EVENTS AFTER THE REPORTING PERIOD

- **MRG003:** Owing to the encouraging clinical data, MRG003 was granted BTM by the FDA in July 2024.
- **MRG006A:** We have received an IND approval in July 2024. Whereafter, we are conducting a Phase I clinical study, with the FPI achievement in August 2024.

MANAGEMENT DISCUSSION AND ANALYSIS

OVERVIEW

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

We have strategically designed our pipeline with a range of oncology products. 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. We have initiated multiple clinical trials, amongst which one is ongoing in the U.S., and five have entered the stage of registrational trials in the PRC. MRG003 was granted BTM, ODD and FTD on NPC from the FDA and BTM 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 BTM from CDE. MRG004A was granted ODD and FTD by the FDA for the treatment of PC. We have continuously striven to build up and develop novel technology platforms as innovative engines for the Company. 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 advancing innovative molecules CTM012 and MRG007 to enter into the clinical research stage efficiently.

PRODUCT PIPELINE

The following chart illustrates our pipeline and summarizes the development status of our drug candidates:

Drug Candidates	Indications	Status ²						
		Preclinical	Phase Ia	Phase Ib	Phase II	Pivotal/Phase III	NDA	
ADC	MRG003* <i>EGFR</i> -targeted ADC	≥2L NPC (nasopharyngeal cancer)	[Progress bar from Preclinical to Pivotal/Phase III]					
		≥2L (second-line) HNSCC (head and neck squamous cell carcinoma)	[Progress bar from Preclinical to Pivotal/Phase III]					
	MRG002* <i>HER2</i> -targeted ADC	BC (breast cancer) <i>HER2</i> (human epidermal growth factor receptor 2) over-expressing with liver metastasis	[Progress bar from Preclinical to Pivotal/Phase III]					
		BC <i>HER2</i> -positive	[Progress bar from Preclinical to Pivotal/Phase III]					
	MRG004A <i>TF</i> -targeted ADC	UC (urothelial cancer)	[Progress bar from Preclinical to Pivotal/Phase III]					
			[Progress bar from Preclinical to Pivotal/Phase III]					
	MRG001 <i>CD20</i> -targeted ADC	NHL (non-Hodgkin's lymphoma)	[Progress bar from Preclinical to Phase II]					
	MRG006A <i>GPC3</i> -targeted ADC	Solid tumor	[Progress bar from Preclinical to Phase Ia]					
CMG901 <i>CLDN18.2</i> -targeted ADC ⁴	G/GEJ carcinoma (gastric and gastroesophageal junction carcinoma) and other solid tumors	[Progress bar from Preclinical to Pivotal/Phase III] Global						
MRG007 target undisclosed ADC	Solid tumor	[Progress bar from Preclinical to Phase Ia]						
Immunology	PUYOUHENG (Pucotenlimab Injection)* <i>Anti-PD-1 mAb</i>	≥2L Melanoma ³	[Progress bar from Preclinical to Pivotal/Phase III] →					
		≥2L MSI-H/dMMR (high levels of microsatellite instability/deficient mismatch repair) solid tumors ³	[Progress bar from Preclinical to Pivotal/Phase III] →					
		2L advanced G/GEJ carcinoma	[Progress bar from Preclinical to Pivotal/Phase III]					
CTM012 <i>T cell agonistic mAb</i>	Solid tumor	[Progress bar from Preclinical to Phase Ia]						
OV	CG0070* <i>Oncolytic virus</i>	BCG-unresponsive NMIBC (bacillus calmette-guerin unresponsive non-muscle invasive bladder cancer)	[Progress bar from Preclinical to Phase Ia]					
Combo Within Pipeline	PUYOUHENG (Pucotenlimab Injection) + MRG003	EGFR positive solid tumor	[Progress bar from Preclinical to Pivotal/Phase III]					
		HER2-expressing solid tumor	[Progress bar from Preclinical to Pivotal/Phase III]					
	CG0070 + PUYOUHENG (Pucotenlimab Injection)	BCG-unresponsive NMIBC	[Progress bar from Preclinical to Phase Ia]					

Notes:

- * denotes the Core Products.
- 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.
- On July 19, 2022 and September 29, 2022, we obtained from the NMPA conditional marketing approval for PUYOUHENG (Pucotenlimab Injection) on MSI-H/dMMR and inoperable or metastatic melanoma, respectively. We are conducting confirmatory Phase III clinical studies on the first-line MSI-H/dMMR metastatic colorectal cancer and the first-line stage IV (M1c) melanoma respectively.
- 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.
- Apart from the Phase Ia clinical trial currently conducted in China, the MRCT clinical trial of CG0070 is also being conducted by CG Oncology, a third-party business partner with whom we have a licensed-in arrangement to develop, manufacture and commercialize CG0070 in Mainland China, Hong Kong and Macau.

BUSINESS REVIEW

Commercialization

During the Reporting Period, the Group recorded a total revenue of approximately RMB133.3 million, which was mainly contributed by the sales of PUYOUHENG (Pucotenlimab Injection), licensing activities and CDMO services. In the first half of 2024, the Group recorded a revenue of approximately RMB94.8 million for the sales of PUYOUHENG (Pucotenlimab Injection), doubling that recorded in the same period in 2023, which was approximately RMB44.0 million. For licensing activities, the Group has recognized approximately RMB20.7 million in revenue, which was attributable to the milestone payment and the technology transfer service provided under the License Agreement of CMG901 entered into between KYM, a joint venture formed by us and Keymed, and AstraZeneca on February 23, 2023 to develop and commercialize CMG901. In addition, the Group recognized approximately RMB17.8 million in revenue for the provision of CDMO services.

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

In terms of the establishment of sales channels, we actively develop cooperative relationships with various business channel partners. As of June 30, 2024, we have completed the tendering process on the procurement platform in 26 provinces. We have covered approximately 78 cities through various sales channels, and we will further expand our sales network.

During the six months ended June 30, 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 pipeline. A description of the progress made and the latest status in respect of the Group's drug candidates for the six months ended June 30, 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.

As of June 30, 2024, we have completed patients enrollment of a pivotal Phase IIb clinical study on NPC in preparation of the NDA filing, and 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**

- o **NPC:** We have observed encouraging data from the Phase IIa clinical study on NPC. We submitted a BTM application in the US in June 2024, and the FDA granted it for the treatment of R/M NPC in July 2024. As of June 30, 2024, we have completed patients enrollment of a pivotal Phase IIb clinical study on NPC, and we expect to file NDA in China in the second half of 2024.
- o **HNSCC:** As of June 30, 2024, we are conducting a randomized, open-label, multicenter Phase III clinical study on HNSCC.

– **Combination Therapy**

- o **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. As of January 30, 2024, the ORR and DCR in the Phase I study was 53.8% and 84.7% respectively. On NPC and HNSCC patients with at least one tumor assessment in Phase II, the ORR was 77.8% and 60% and the DCR was 100% and 80%, respectively. We are currently conducting the Phase II part of the trial and have observed encouraging data, which is planned to be presented at ESMO Asia Congress 2024.
- **Warning under Rule 18A.08(3) of the Listing Rules:** There is no assurance that MRG003 will ultimately be successfully developed and marketed by the Company. Shareholders and our potential investors are advised to exercise caution when dealing in the Shares.

MRG002

MRG002 is an innovative ADC targeting HER2, a molecular target abnormally overexpressed in many cancer types including BC, UC and GC/GEJ. Our clinical development strategy for MRG002 in China aims at realizing the efficacy potential of MRG002 in various prevalent malignancies, especially for second- or later-line systemic therapy of BC and UC. Registrational clinical trials in the aforementioned indications are ongoing. 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**

- o **HER2 over-expressing BC:** We have completed patients enrollment of a pivotal Phase II clinical trial on HER2 over-expressed BC with liver metastasis in China. We observed encouraging data, which is expected to be presented at the 2024 CSCO. Meanwhile, as of June 30, 2024, we are conducting a Phase III clinical study on HER2-positive BC.
- o **UC:** We are conducting an open-label, randomized, multi-center Phase III clinical study of MRG002 versus investigator's choice of chemotherapy in the treatment of patients with HER2-positive unresectable locally advanced or metastatic UC previously treated with platinum-based chemotherapy and PD-1/PD-L1 inhibitors as of June 30, 2024.

– **Combination Therapy**

- o **MRG002 + PUYOUHENG (Pucotenlimab Injection):** We are conducting a Phase II trial of combination therapy with MRG002 and pucotenlimab in the treatment of HER2-expressing solid tumors and have observed encouraging preliminary data on UC, which is expected to be presented at the ESMO Congress 2024. The enrollment is ongoing as of June 30, 2024.

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

MRG004A

MRG004A is a novel TF-targeted site-specifically conjugated ADC. We are currently conducting a Phase I clinical study on solid tumors in the United States and China and have observed anti-tumor activity signal on PC, TNBC and CC. The preliminary Phase I data on solid tumors were selected to be 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. On 5 patients with PC of TF expression $\geq 50\%$ 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. We are expanding the subgroup of PC patients in the Phase I clinical trial to explore further potential of MRG004A on PC.

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

MRG001

MRG001 is a clinically advancing CD20-targeted ADC which addresses the medical needs of B cell NHL patients with either primary drug resistance to rituximab or acquired drug resistance to the combination therapy of rituximab and standard chemotherapies. We are conducting a Phase Ib dose expansion study of MRG001 in China and observed encouraging preliminary data on DLBCL.

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

MRG006A

MRG006A is a novel topoisomerase I inhibitor-based GPC3 ADC candidate with global first-in-class potential, which is developed based on our Hi-TOPi platform. 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. Following the encouraging pre-clinical performance, we have received the IND approval in July 2024 and we are currently conducting a Phase I clinical trial, with the FPI achievement in August 2024.

- **Warning under Rule 18A.08(3) of the Listing Rules:** There is no assurance that MRG006A will ultimately be successfully developed and marketed by the Company. Shareholders and our potential investors are advised to exercise caution when dealing in the Shares.

CMG901

CMG901 is a CLDN18.2-targeting ADC comprising a CLDN18.2-specific antibody, a cleavable linker and a toxic payload, MMAE. It is the first CLDN18.2 targeting ADC to have received 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. Phase Ia trial of CMG901 was conducted for advanced solid tumors, and CMG901 showed a favorable safety and tolerability profile in this trial. In May 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. 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 CMG901 will ultimately be successfully developed and marketed by the Company. Shareholders and our potential investors are advised to exercise caution when dealing in the Shares.

PUYOUHENG (Pucotenlimab Injection)

PUYOUHENG (Pucotenlimab Injection) is a humanized IgG4 mAb against human PD-1, which can antagonize the PD-1 signal to restore the capability of the immune cells to kill cancer cells through blocking PD-1 binding to their ligands PD-L1 and PD-L2, and which has been commercialized for treating MSI-H/dMMR and inoperable or metastatic melanoma since the second half of 2022. In April 2023, two indications were included into the 2023 CSCO Guideline, which are pucotenlimab as \geq 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.

- **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 June 30, 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 June 30, 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 June 30, 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. As of April 1, 2024, patients enrollment was completed with the observation of 75.2% CR in patients and 92.4% cystectomy-free survival. The encouraging interim data observed has been orally presented at the 2024 American Urological Association (AUA) Annual Meeting. Furthermore, CG0070 was granted FTD and BTD by the FDA in December 2023 in the United States. We in-licensed CG0070 from CG Oncology and were granted the rights to develop, manufacture and commercialize it in Mainland China, Hong Kong and Macau. As of June 30, 2024, we are conducting a Phase I clinical trial in China and have finished Phase Ia 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 CG0070 will ultimately be successfully developed and marketed by the Company. Shareholders and our potential investors are advised to exercise caution when dealing in the Shares.

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.
 - o Using the novel linker-payload platform, we have developed MRG006A, which is an ADC candidate with global first-in-class potential and has entered the 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.
 - o 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 target to file IND in 2024.

Manufacturing Facilities

We have been operating a 2,000L GMP-compliant bioreactor production line at our Beijing manufacturing plant during the Reporting Period, which mainly supports the production of clinical drug supply and offers CDMO production services. During the Reporting Period, we have recognized RMB17.8 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 has a designed total capacity of 12,000L, and it has obtained the environmental impact assessment report for the production of mAb and ADC. Going forward, we will continue to build or expand our manufacturing facilities based on our business needs arising from the commercialization of our ADC candidates.

KEY EVENTS AFTER THE REPORTING PERIOD

Key Developments of our Drug Candidates

- **MRG003:** Owing to the encouraging clinical data, MRG003 was granted BTB by the FDA in July 2024.
- **MRG006A:** We have received an IND approval in July 2024. Whereafter, we are currently conducting a Phase I clinical study, with the FPI achievement in August 2024.

FUTURE DEVELOPMENT

The Company is an innovation-driven biopharmaceutical company focusing on oncology therapeutics, dedicated to promoting the technological advancement of innovative ADCs in China to better serve the unmet medical needs of cancer patients. We strive to develop and broaden our product pipeline by combining our in-house research through development and with strategic collaborations. In the second half of 2024, we will continue to accelerate the development of our two key ADC products, MRG003 and MRG002, to the next milestones. We expect to file the NDA for MRG003 in China in the second half of 2024 and will 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 pipelines 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 enter into the clinical research stage efficiently.

We will be working to deepen our efforts on marketing and commercialization and to actively expand our market footprint and product recognition within China. We will enhance the ability of our commercialization team by internal training and recruiting talents with the appropriate skills and expertise in the commercialization of pharmaceutical products. We will take further actions to promote the market accessibility of PUYOUHENG (Pucotenlimab Injection) and continue to accelerate market penetration at all levels, with a view to further increasing market share. By leveraging the expertise and industry connections of our commercialization team and our solid understanding of the Chinese market environment, we will seek to foster our brand's image and market knowledge of our product through various methods. We believe that the enhancement of our efforts in terms of market outreach will translate into better market access, increased market share and increases in the sales of our commercialized product and our brand in general, thereby laying a solid market and channel foundation for the future commercialization of our ADC product pipeline. At the same time, we will get ready for the commercial launch of MRG003.

On the international front, we will ramp up our efforts to expand into the global market. As our ADC platform has been endorsed by multinational companies, we expect our other ADC products to have more promising business development opportunities. Going forward, we will persist in expanding our international network and exploring new BD cooperation opportunities that contribute to our growth and success through multiple strategies.

FINANCIAL REVIEW

Revenue

For the six months ended June 30, 2024, we have recorded revenue of approximately RMB133.3 million (for six months ended June 30, 2023: approximately RMB153.6 million). A major part of the revenue was contributed by the Company's sales of PUYOUHENG (Pucotenlimab Injection) during the Reporting Period, which amounted to approximately RMB94.8 million and represented a remarkable increase of approximately 115.4% from sales revenue of approximately RMB44.0 million for the same period in 2023. For the six months ended June 30, 2024, the Group also recognized revenue of approximately RMB20.7 million from the licensing activities of CMG901 attributable to the milestone payment and the technology transfer service. Lastly, the Group recognized approximately RMB17.8 million in revenue for the provision of CDMO services.

The decrease in revenue for the six months ended June 30, 2024 was due to the recognition of licensing income of approximately RMB109.5 million (including a one-time up-front payment) for the same period in 2023 in relation to the out-licensing of CMG901 under the Licensing Agreement, as compared with a recognized revenue of approximately RMB20.7 million in milestone payment and technology transfer service for the Reporting Period, which was partially offset by the doubled revenue from sales of PUYOUHENG (Pucotenlimab Injection) as aforementioned and the recognition of approximately RMB17.8 million in revenue from the provision of CDMO services during the Reporting Period (for the six months ended June 30, 2023: nil).

Cost of Sales

For the six months ended June 30, 2024, the Group has recorded cost of sales of approximately RMB21.0 million (for six months ended June 30, 2023: approximately RMB5.8 million).

The increase in cost of sales was in conformity with the growth of sales revenue of PUYOUHENG (Pucotenlimab Injection) during the Reporting Period and the change in the Group's revenue structure as compared to the same period in 2023. As disclosed above, a major portion of the Group's revenue during the Reporting Period was contributed by the sales of PUYOUHENG (Pucotenlimab Injection), whereas over 70% of the revenue of the Group during the same period in 2023 was contributed by licensing income under the Licensing Agreement. The shift in the revenue structure, coupling with the increase of sales revenue of PUYOUHENG (Pucotenlimab Injection) during the Reporting Period, resulted in the increase in cost of sales for the six months ended June 30, 2024.

Selling and Marketing Expenses

For the six months ended June 30, 2024, the Group has recorded selling and marketing expenses of approximately RMB43.8 million (for six months ended June 30, 2023: approximately RMB13.9 million), which was largely in line with the growth in sales revenue of PUYOUHENG (Pucotenlimab Injection) during the Reporting Period.

Administrative Expenses

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

Our administrative expenses decreased by approximately 21.1%, from approximately RMB39.1 million for the six months ended June 30, 2023 to RMB30.8 million for the six months ended June 30, 2024, primarily due to a decrease in the amount of remuneration paid to administrative management employees.

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; (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 for the six months ended June 30, 2024 was RMB216.6 million, signifying a decrease of 6.6% as compared to the same period in 2023 (for six months ended June 30, 2023: RMB231.9 million).

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

	Six months ended 30 June			
	2024		2023	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%
Clinical study related expenses	84,670	39.1	85,350	36.8
Pre-clinical study costs	12,564	5.8	15,606	6.7
Raw material and consumables used	25,439	11.7	16,282	7.0
Employee benefit expenses	49,533	22.9	62,354	26.9
Depreciation and amortization	38,061	17.6	44,703	19.3
Others	6,343	2.9	7,577	3.3
Total	216,610	100	231,872	100

- (i) Clinical study related expenses, which consisted of expenses associated with conducting clinical trials and CMC, for the six months ended June 30, 2024 stayed largely constant as compared to the six months ended June 30, 2023.
- (ii) Pre-clinical study costs decreased by RMB3.0 million, mainly because the Group has continuously refined its focus on the R&D of its innovative drug candidates;
- (iii) Raw material and consumables expenses increased by RMB9.2 million, mainly due to an increase in the procurement and consumption of raw materials for the CMC research of the Group's core ADC products in relation to the NDA filing;
- (iv) Employee benefit expenses decreased by RMB12.8 million, mainly due to the structural adjustment in the R&D team of the Group;
- (v) Depreciation and amortization costs decreased by RMB6.6 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 six months ended June 30, 2024 decreased by RMB1.23 million as compared to the six months ended June 30, 2023.

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 RMB17.7 million for the six months ended June 30, 2023 and fair value loss of RMB0.1 million for the six months ended June 30, 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 the non-controlling shareholder, being 4.375% of the 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.

	Six months ended 30 June	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Fair value (losses)/gains on financial liabilities at fair value through profit or loss		
– Fair value changes through profit or loss	<u>(124)</u>	<u>17,737</u>

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 RMB5.5 million for the six months ended June 30, 2023 to RMB2.6 million for the six months ended June 30, 2024, mainly due to a decrease in interest on bank deposits. Our finance costs remained largely constant as compared to the six months ended June 30, 2023 to RMB8.5 million for the six months ended June 30, 2024.

Income Tax Expenses

For the six months ended June 30, 2024, the Group's income tax expenses were nil (2023: nil).

Loss for the Reporting Period

Based on the factors described above, the Group's loss increased from RMB141.9 million for the six months ended June 30, 2023 to RMB197.0 million for the six months ended June 30, 2024.

Liquidity and Financial Resources

We have incurred net losses and cash outflows from operations since inception. Our primary use of cash is to fund our research and development activities and the commercialization of our commercialized products. For the six months ended June 30, 2024, our net cash used in operating activities was RMB115.1 million, representing an increase of RMB39.5 million from RMB75.6 million for the six months ended June 30, 2023 due to an increase in operating costs. As of June 30, 2024, we had cash and cash equivalent of RMB513.6 million, representing an increase of RMB87.6 million from RMB426.0 million as of December 31, 2023, as a result of cash inflow brought by the placing activity carried out by the Company during the Reporting Period.

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 June 30, 2024, the Group's bank borrowings amounted to RMB729.6 million (December 31, 2023: RMB694.3 million), among which unsecured and unguaranteed bank borrowings amounted to RMB449.3 million (December 31, 2023: RMB394.0 million) in total with interest at fixed and floating interest rates. Such borrowing will be repayable within one year.

As of June 30, 2024, the Group's secured and unguaranteed bank borrowings amounted to RMB280.3 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 secured by the Group's land use rights and buildings and facilities.

As of June 30, 2024, we had utilized RMB798.9 million from our banking facilities and approximately RMB651.1 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 June 30, 2024, approximately RMB0.22 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 June 30, 2024, the Group's gearing ratio was 63.05% (December 31, 2023: 62.73%).

Significant Investments, Material Acquisitions and Disposal

The Group did not have any significant investments or material acquisitions or disposals of subsidiaries, associates and joint ventures for the six months ended June 30, 2024.

Capital Commitments

As of June 30, 2024, the Group had capital commitments for property, plant and equipment of RMB452.8 million (December 31, 2023: RMB456.6 million), reflecting the capital expenditure of the Group contracted at the end of the Reporting Period but not yet incurred.

Contingent Liabilities

As of June 30, 2024 and December 31, 2023, the Group did not have any contingent liabilities.

Charges on Group Assets

Save as disclosed in this announcement, as of June 30, 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 subsidiaries in the PRC are exposed to foreign exchange risks arising from recognized financial assets and 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 June 30, 2024, the Group had a total of 491 employees. The total remuneration cost of the Group for the six months ended June 30, 2024 was RMB92.9 million, as compared to RMB89.2 million for the six months ended June 30, 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 during the six months ended June 30, 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 six months ended June 30, 2024. No incident of non-compliance of the Model Code by the employees who are likely to be in possession of inside information of the Company was noted by the Company.

Purchase, Sale or Redemption of Listed Securities

Neither the Company nor any of its subsidiaries has made any purchase, sale or redemption of the listed securities of the Company (including sale of treasury shares) during the Reporting Period.

As at 30 June 2024, the Company did not hold any treasury shares.

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 a non-executive Director. The primary duties of the Audit Committee are to review and supervise the Company's financial reporting process and internal controls.

The Audit Committee, together with the management of the Company, has reviewed the unaudited interim condensed consolidated financial information of the Group for the six months ended June 30, 2024, and has discussed with the management the accounting principles and practices adopted by the Group and its internal controls and financial reporting matters.

Interim Dividend

The Board does not recommend the payment of an interim dividend for the six months ended June 30, 2024 (June 30, 2023: nil).

PUBLICATION OF INTERIM RESULTS ANNOUNCEMENT AND INTERIM REPORT

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

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

INTERIM CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

	<i>Note</i>	Six months ended 30 June	
		2024 <i>RMB'000</i> (Unaudited)	2023 <i>RMB'000</i> (Unaudited)
Revenue	5	133,283	153,553
Cost of sales		<u>(21,042)</u>	<u>(5,755)</u>
Gross profit		112,241	147,798
Other income		651	1,887
Other expenses	6	–	(3)
Selling and marketing expenses	6	(43,789)	(13,855)
Administrative expenses	6	(30,844)	(39,073)
Research and development expenses	6	(216,610)	(231,872)
Fair value changes on financial liabilities at fair value through profit or loss	7	(124)	17,737
Other losses, net		<u>(5,561)</u>	<u>(614)</u>
Operating loss		(184,036)	(117,995)
Finance income		2,572	5,529
Finance costs		<u>(8,465)</u>	<u>(7,937)</u>
Finance costs, net		(5,893)	(2,408)
Share of loss of investments accounted for using the equity method		<u>(7,037)</u>	<u>(21,501)</u>
Loss before income tax		(196,966)	(141,904)
Income tax expense	8	<u>–</u>	<u>–</u>
Loss for the period		<u>(196,966)</u>	<u>(141,904)</u>
Other comprehensive income/(loss)			
<i>Items that may be subsequently reclassified to profit or loss</i>			
Currency translation differences		<u>85</u>	<u>(552)</u>
Total comprehensive loss		<u>(196,881)</u>	<u>(142,456)</u>

		Six months ended 30 June	
	<i>Note</i>	2024	2023
		RMB'000	RMB'000
		(Unaudited)	(Unaudited)
Loss attributable to:			
Owners of the Company		(192,430)	(141,904)
Non-controlling interests		(4,536)	–
		<u>(196,966)</u>	<u>(141,904)</u>
Total comprehensive loss attributable to:			
Owners of the Company		(192,345)	(142,456)
Non-controlling interests		(4,536)	–
		<u>(196,881)</u>	<u>(142,456)</u>
Loss per share for loss attributable to owners of the Company for the period (expressed in RMB per share)			
– Basic	9	<u>(0.12)</u>	<u>(0.09)</u>
– Diluted	9	<u>(0.12)</u>	<u>(0.09)</u>

INTERIM CONDENSED CONSOLIDATED BALANCE SHEET

	<i>Note</i>	As at June 30 2024 RMB'000 (Unaudited)	As at December 31 2023 RMB'000 (Audited)
Assets			
Non-current assets			
Property, plant and equipment		946,443	948,189
Right-of-use assets		131,255	139,056
Intangible assets		432,902	434,221
Investments accounted for using the equity method		122,652	126,685
Other receivables, prepayments and deposits		63,676	59,009
		<u>1,696,928</u>	<u>1,707,160</u>
Total non-current assets			
Current assets			
Inventories		22,275	29,412
Trade receivables	10	26,662	37,802
Other receivables, prepayments and deposits		117,876	120,289
Financial assets at fair value through profit or loss		63,628	63,628
Cash and cash equivalents		513,640	426,015
		<u>744,081</u>	<u>677,146</u>
Total current assets			
		<u>744,081</u>	<u>677,146</u>
Total assets			
		<u><u>2,441,009</u></u>	<u><u>2,384,306</u></u>
Equity			
Equity attributable to owners of the Company			
Share capital	11	1,710,615	1,659,445
Reserves		1,750,152	1,591,046
Accumulated losses		(2,546,016)	(2,353,586)
		<u>914,751</u>	<u>896,905</u>
Non-controlling interests			
		<u>(12,741)</u>	<u>(8,205)</u>
Total equity			
		<u><u>902,010</u></u>	<u><u>888,700</u></u>

	<i>Note</i>	As at June 30 2024 RMB'000 (Unaudited)	As at December 31 2023 RMB'000 (Audited)
Liabilities			
Non-current liabilities			
Borrowings		230,000	260,000
Lease liabilities		18,801	24,184
Deferred government grants		12,000	12,000
Deferred tax liabilities		37,687	37,687
Financial liabilities at fair value through profit or loss	12	<u>254,700</u>	<u>262,174</u>
Total non-current liabilities		<u>553,188</u>	<u>596,045</u>
Current liabilities			
Borrowings		499,610	434,299
Trade payables	13	228,048	207,611
Other payables and accruals		231,680	234,380
Lease liabilities		<u>26,473</u>	<u>23,271</u>
Total current liabilities		<u>985,811</u>	<u>899,561</u>
Total liabilities		<u>1,538,999</u>	<u>1,495,606</u>
Total equity and liabilities		<u>2,441,009</u>	<u>2,384,306</u>

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION FOR THE SIX MONTHS ENDED 30 JUNE 2024

1 GENERAL INFORMATION

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

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

This interim condensed consolidated financial information is presented in Renminbi (“**RMB**”), unless otherwise stated.

The interim condensed consolidated financial information for the six months ended 30 June 2024 has been reviewed by the Company’s auditor in accordance with International Standard on Review Engagements 2410 “Review of Interim Financial Information Performed by the Independent Auditor of the Entity”. The independent auditor’s review report to the Directors is included in the interim report to be sent to the shareholders.

2 SIGNIFICANT EVENT

On 24 May 2024, the Company has completed a placing of 51,170,000 new H shares at the price of HK\$4.58 per H Share (the “**Placing**”). The gross proceeds from the Placing amounted to approximately HK\$234,359,000 (equivalent of RMB213,379,000). The number of total issued shares of the Company has increased from 1,659,444,838 shares to 1,710,614,838 shares upon completion of the Placing.

3 BASIS OF PREPARATION

The Group’s interim condensed consolidated financial information for the six months ended 30 June 2024 has been prepared in accordance with International Accounting Standard 34 “Interim Financial Reporting” (“**IAS 34**”) issued by the International Accounting Standards Board (“**IASB**”).

The interim condensed consolidated financial information should be read in conjunction with the annual financial statements of the Company for the year ended 31 December 2023 (the “**2023 Annual Financial Statements**”), which have been prepared in accordance with International Financial Reporting Standards (“**IFRS Accounting Standards**”), and any public announcement made by the Company during the interim reporting period.

For the six months period ended 30 June 2024, the Group has incurred net losses of approximately RMB197 million, while net cash used in operating activities was approximately RMB115 million. As at 30 June 2024, the Group had net current liabilities of approximately RMB242 million and cash and cash equivalents of approximately RMB514 million. Historically, the Group has relied principally on non-operational sources of financing from investors and banks as well as cash generated from sales activities to fund its operations and business development. The Group’s ability to continue as a going concern is dependent on management’s ability to successfully execute its business plan. The directors of the Company believes that the cash and cash equivalent, unutilised bank facilities together with the cash generated from operating activities are sufficient to meet the cash requirements to fund planned operations and other commitments for at least the next twelve months from the date of the issuance of this interim condensed consolidated financial information. The Group therefore continues to prepare this interim condensed consolidated financial information on a going concern basis.

The accounting policies adopted are consistent with those of 2023 Annual Financial Statements, except for the adoption of new and amended standards as set out below, and accounting policy for revenue from contract development and manufacturing organization (“**CDMO**”) services as described in Note 5.

(a) Amended standards adopted by the Group

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

Amendments to IAS 1	Classification of Liabilities as Current or Non-current
Amendment to IAS 1	Non-current liabilities with covenants
Amendments to IAS 7 and IFRS 7	Supplier Finance Arrangements
Amendments to IFRS 16	Lease liability in sale and leaseback

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

(b) Amended standards not yet adopted

The following amended standards have been published (which may be applicable to the Group) but not mandatory for the year ended on 31 December 2023 and have not been early adopted by the Group:

		Effective for annual periods beginning on or after
Amendments to IAS 21	Lack of Exchangeability	1 January 2025
Amendments to IFRS 10 and IAS 28	Sale or contribution of assets between an investor and its associate or joint venture	To be determined

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

4 SEGMENT INFORMATION

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

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

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

5 REVENUE

	Six months ended 30 June	
	2024	2023
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Revenue recognised at a point in time		
– Sales of pharmaceutical products	94,836	44,033
– Licensing income	20,678	109,520
	<u>115,514</u>	<u>153,553</u>
Revenue recognised over time		
– CDMO services (a)	<u>17,769</u>	–
	<u>133,283</u>	<u>153,553</u>

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

	Six months ended 30 June	
	2024	2023
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Geographical markets		
– The PRC	112,605	44,033
– Overseas	20,678	109,520
	<u>133,283</u>	<u>153,553</u>

For the six months ended 30 June 2024, revenue of approximately RMB20,678,000 (six months ended 30 June 2023: RMB109,520,000) was derived from licensing income from the Group's associate, KYM, which accounted for 15.51% (six months ended 30 June 2023: 71.32%) of the Group's total revenue. Revenue of approximately RMB16,181,000 (six months ended 30 June 2023: nil) was derived from CDMO services income from Beijing Lepu Pharmaceutical Technology Co., Ltd. ("**Beijing Lepu Pharmaceutical**"), the Group's related parties, which accounted for 12.14% (six months ended 30 June 2023: nil) of the Group's total revenue. Other than the aforementioned customers, the revenues derived from any of the remaining external customers were less than 10% of the Group's total revenue.

(a) Revenue from CDMO services

The extraordinary general meeting of the Company approved the CDMO Services Framework Agreement and the supplemental framework agreement in 2024, which provided that the Group and Lepu Medical Technology (Beijing) CO., Ltd. (“**Lepu Medical**”), the Group’s related party, conditionally entered into the CDMO Services Framework Agreement, pursuant to which the Group conditionally agreed to provide Lepu Medical and/or its subsidiaries with CDMO services.

The CDMO services are integrated services including project management, drug manufacturing, development, optimization and trial production, and other relevant services. The duration of the contracts ranged months to year. The contracts contained multiple deliverable units, which are generally in the form of technical laboratory reports, samples and/or products for manufacturing, each of deliverable units is with 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 performance obligation when 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 has satisfied a performance obligation and recognises revenue over time, if one of the following criteria is met:

- (a) The customer simultaneously receives and consumes the benefits provided by the Group’s performance as the Group performs
- (b) The Group’s performance creates or enhances an asset that the customer controls as the asset is created or enhanced
- (c) 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 conditions 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. Otherwise, revenue is recognised at the point in time when the customer obtains control of the service.

During the six months ended 30 June 2024, the Group has recognised CDMO services income in relation to abovementioned transaction approximately RMB17,769,000 (six months ended 30 June 2023: nil).

6 EXPENSES BY NATURE

	Six months ended 30 June	
	2024 RMB'000 (Unaudited)	2023 RMB'000 (Unaudited)
Employee benefit expenses	92,943	89,193
Clinical study related expenses	84,670	85,350
Depreciation and amortisation	47,135	51,538
Pre-clinical study costs	12,564	15,606
Raw material and consumables used	28,822	20,951
Changes in inventories of finished goods and working in progress outsourced for processing	4,640	(1,996)
Entertainment and traveling expenses	19,178	8,066
Licensing fee	6,263	3,082
Auditors' remuneration	1,000	1,000
Professional services fees	658	4,083
Others	14,412	13,685
Total cost of sales, selling and marketing expenses, administrative expenses, research and development expenses and other expenses	312,285	290,558

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

	Six months ended 30 June	
	2024 RMB'000 (Unaudited)	2023 RMB'000 (Unaudited)
Fair value (losses)/gains on financial liabilities at fair value through profit or loss (Note 12)	(124)	17,737

8 INCOME TAX EXPENSE

	Six months ended 30 June	
	2024 RMB'000 (Unaudited)	2023 RMB'000 (Unaudited)
Current income tax expense	–	–
Deferred income tax expense	–	–
Income tax expense	–	–

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

Shanghai Miracogen Inc. (“**Miracogen Shanghai**”) is qualified as High and New Technology Enterprise (“**HNTE**”) under the relevant PRC laws and regulations and is entitled to a preferential corporate income tax rate of 15% on its estimated assessable profits for the years ended 31 December 2023 to 2025.

Concept to Medicine Biotech Co., Ltd. (“**CtM Biotech**”) is qualified as HNTE under the relevant PRC laws and regulations and is entitled to a preferential corporate income tax rate of 15% on its estimated assessable profits for the years ended 31 December 2023 to 2025.

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

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

9 LOSS PER SHARE

(a) Basic loss per share

Basic loss per share is calculated by dividing:

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

	Six months ended 30 June	
	2024	2023
	(Unaudited)	(Unaudited)
Loss for the period and attributable to owners of the Company (in RMB’000)	(192,430)	(141,904)
Weighted average number of ordinary shares in issue (in thousands)	1,670,129	1,659,445
Basic loss per share (in RMB)	<u>(0.12)</u>	<u>(0.09)</u>

(b) Diluted loss per share

Diluted earnings per share presented is the same as the basic earnings per share as there were no potentially dilutive ordinary shares issued during the six months ended 30 June 2024 and 2023.

10 TRADE RECEIVABLES

The Group allows a credit period of 3 to 60 days to its customers. At 30 June 2024 and 31 December 2023, the ageing analysis of the trade receivables (net of loss allowance) based on the goods delivery dates, which approximated to their invoice date were as follows

	As at 30 June 2024 RMB’000 (Unaudited)	As at 31 December 2023 RMB’000 (Audited)
0 to 30 days	23,324	37,802
31 to 60 days	253	–
61 to 90 days	1,681	–
Over 90 days	1,404	–
	<u>26,662</u>	<u>37,802</u>

11 SHARE CAPITAL

	Number of shares	Nominal value of shares <i>RMB'000</i>
Authorised issued and fully paid		
At 1 January 2024	1,659,444,838	1,659,445
Issuance of shares (a)	51,170,000	51,170
At 30 June 2024 (Unaudited)	1,710,614,838	1,710,615
At 1 January 2023 and 30 June 2023 (Unaudited)	1,659,444,838	1,659,445

- (a) As described in Note 2, the Company has completed the placing of 51,170,000 new H shares at the price of HK\$4.58 per H Share on 24 May 2024. The gross proceeds from the Placing amounted to approximately HK\$234,359,000 (equivalent of RMB213,379,000).

Share issuance costs related to the Placing mainly include share underwriting commissions, lawyers' fee and other costs. Incremental costs that are directly attributable to the Placing amounting to approximately RMB4,388,000 was treated as a deduction against the share premium arising from the issuance.

12 FINANCIAL LIABILITIES AT FAIR VALUE THROUGH PROFIT OR LOSS

	As at 30 June 2024 <i>RMB'000</i> (Unaudited)	As at 31 December 2023 <i>RMB'000</i> (Audited)
Variable consideration payable arisen from acquisition of 40% equity of Taizhou Hanzhong Biotechnology Co., Ltd. from non-controlling interests	268,313	272,625
Less: current portion	(13,613)	(10,451)
Non-current portion	254,700	262,174

The movements of financial liabilities at fair value through profit or loss for the six months ended 30 June 2024 and 2023 are set out below:

	Six months ended 30 June 2024 <i>RMB'000</i> (Unaudited)	2023 <i>RMB'000</i> (Unaudited)
Opening balance	272,625	448,282
Change in fair value (<i>Note 7</i>)	124	(17,737)
Confirm but not paid	(4,436)	(681)
Closing balance	268,313	429,864

13 TRADE PAYABLES

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

	As at 30 June 2024 RMB'000 (Unaudited)	As at 31 December 2023 RMB'000 (Audited)
Less than 1 year	221,381	196,909
Between 1 and 2 years	<u>6,667</u>	<u>10,702</u>
	<u>228,048</u>	<u>207,611</u>

14 DIVIDEND

No dividend has been paid or declared by the Company or companies comprising the Group during the six months ended 30 June 2024 and 2023.

15 EVENTS OCCURRING AFTER THE REPORTING PERIOD

There was not any significant event occurred after 30 June 2024 which needs to be disclosed in this interim condensed consolidated financial information.

The unaudited interim condensed consolidated statement of comprehensive loss, the unaudited interim condensed consolidated balance sheet of the Group and its explanatory notes as presented above are extracted from the unaudited interim condensed consolidated financial information of the Group for the six months ended 30 June 2024.

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

“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)
“Audit Committee”	the audit committee of the Board
“B cell”	a type of white blood cell that differs from other types of lymphocytes by expressing B cell receptors on its surface, and responsible for producing antibodies
“Bacillus Calmette-Guerin” or “BCG”	a type of bacteria that causes a reaction in a patient’s immune system that can destroy cancer cells located in the lining of the bladder. It is also widely used as a vaccine against tuberculosis
“BC”	breast cancer
“BD”	business development
“Board”	the board of Directors of the Company
“BTD”	Breakthrough Therapy Designation
“CAR-T”	chimeric antigen receptor T-cell
“CC”	cervical cancer
“CD20”	a B-lymphocyte antigen that is expressed on the surface of B cells, starting at the per-B cell stage and also on mature B cells in the bone marrow and in the periphery
“CDE”	Center for Drug Evaluation* (藥品審評中心) of the NMPA
“CDMO”	Contract development and manufacturing organization, a pharmaceutical company that develops and manufactures drugs for other pharmaceutical companies on a contractual basis
“CDX”	cell derived xenograft

“CG Oncology”	CG Oncology, Inc. (previously known as Cold Genesys, Inc.), a clinical-stage immuno-oncology company headquartered in the US, of which Lepu Medical holds approximately 7.73% equity interest through Lepu Holdings Limited, a company wholly-owned by Lepu Medical, and Ms. Pu Jue (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 in Chapter 18A of the Listing Rules; for 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” or “1L”	with respect to any disease, the first line therapy, which is the treatment regimen or regimens that are generally accepted by the medical establishment for initial treatment. It is also called primary treatment or therapy
“FISH”	fluorescence in situ hybridization, a test that maps the genetic material in human cells, including specific genes or portions of genes
“FPI”	first patient in
“FTD”	Fast Track Designation
“GC”	gastric cancer
“GEJ”	gastroesophageal junction
“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
“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-positive” or “HER2 over-expressing”	HER2 status of tumor cells identified with a test score of either IHC 3+ or IHC 2+/FISH (or ISH) + (IHC 2+ plus FISH (or ISH)+)
“HK\$” or “Hong Kong dollars”	Hong Kong dollars, the lawful currency of Hong Kong

“HNSCC”	head and neck squamous cell carcinoma
“Hong Kong”	the Hong Kong Special Administrative Region of the PRC
“IgG”	human immunoglobulin G, the most common antibody type found in blood circulation that plays an important role in antibody-based immunity against invading pathogens
“IHC”	immunohistochemistry, the most common application of immunostaining. It involves the process of selectively identifying antigens in cells of a tissue section by exploiting the principle of antibodies binding specifically to antigens in biological tissues
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China or the US
“Keymed”	Keymed Bioscience (Chengdu) Co., Ltd. (康諾亞生物醫藥科技(成都)有限公司), a limited liability company incorporated in the PRC on September 1, 2016, which is a third-party biotechnology company focusing on the in-house discovery and development of innovative biological therapies in the autoimmune and oncology therapeutic areas
“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 US by Keymed and the Group
“Lepu Medical”	Lepu Medical Technology (Beijing) Co., Ltd. (樂普(北京)醫療器械股份有限公司), a joint stock company incorporated in the PRC on June 11, 1999 and listed on the Shenzhen Stock Exchange (stock code: 300003), and the promoter of the Company
“License Agreement”	a global exclusive out-license agreement entered into by KYM and AstraZeneca on February 23, 2023
“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 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
“NK cell”	natural killer cell, a kind of cells that play important roles in immunity against viruses and in the immune surveillance of tumors
“NMIBC”	non-muscle invasive bladder cancer
“NMPA”	the National Medical Products Administration of the PRC* (中國國家藥品監督管理局)
“NPC”	nasopharyngeal cancer
“ODD”	Orphan-drug Designation
“ORR”	objective response rate
“PC”	pancreatic cancer
“PD-1”	programmed cell death protein 1, an immune checkpoint receptor expressed on T cells, B cells and macrophages
“PD-1 (L1)”	PD-1 or PD-L1
“PD-L1”	PD-1 ligand 1, which is a protein on the surface of a normal cell or a cancer cell that binds to its receptor, PD-1, on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell
“PD-L2”	PD-1 ligand 2, which is a protein on the surface of a normal cell or a cancer cell that attaches to certain proteins on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell
“PDX”	patient derived xenografts, models of cancer where the tissue or cells from a patient’s tumor are implanted into an immunodeficient mouse

“Pgp”	a drug transporter which plays important roles in multidrug resistance and drug pharmacokinetics
“pre-clinical studies”	studies or programs testing a drug on non-human subjects, to gather efficacy, toxicity, pharmacokinetic and safety information and to decide whether the drug is ready for clinical trials
“Phase I clinical trials” 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 trials” 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 trials” 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
“PR”	partial response, refers to an at least 30% but below 100% decrease in the size of a tumor or in the extent of cancer in the body in response to treatment, according to RECIST
“R&D”	research and development
“registrational trial”	a clinical trial or study intended to provide evidence for a drug marketing approval
“RECIST”	Response Evaluation Criteria in Solid Tumors, a set of published rules that define when tumors in cancer patients improve (“ respond ”), stay the same (“ stabilize ”), or worsen (“ progress ”) during treatment. The criteria were published in February 2000 by an international collaboration including the European Organisation for Research and Treatment of Cancer (EORTC), National Cancer Institute of the United States, and the National Cancer Institute of Canada Clinical Trials Group. Now the majority of clinical trials evaluating cancer treatments for objective response in solid tumors use RECIST. These criteria were developed and published in February 2000, and subsequently updated in 2009

“Reporting Period”	the six months ended June 30, 2024
“R/M”	recurrent/metastatic
“RMB” or “Renminbi”	Renminbi, the lawful currency of China
“SD”	stable disease. In oncology, it refers to cancer that is neither decreasing at least 30% nor increasing at least 20% in the size of a tumor or in the extent of cancer in the body in response to treatment, according to RECIST
“second-line” or “2L”	with respect to any disease, the therapy or therapies that are tried when the first-line treatments do not work adequately
“Share(s)”	shares in the share capital of the Company, with a nominal value of RMB1.00 each, comprising the Domestic Shares, Unlisted Foreign Shares and H Shares
“Shareholder(s)”	holder(s) of the Shares
“SMO”	site management organization, an organization that provides clinical trial related services to medical device companies having adequate infrastructure and staff to meet the requirements of the clinical trial protocol
“solid tumors”	an abnormal mass of tissue that usually does not contain cysts or liquid areas. Solid tumors may be benign (not cancer), or malignant (cancer). Different types of solid tumors are named for the type of cells that form them
“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)
“Taizhou Hanzhong”	Taizhou Hanzhong Biotechnology Co., Ltd., (泰州翰中生物醫藥有限公司), a limited liability company incorporated in the PRC on November 25, 2016, and the non-wholly owned subsidiary of the Company
“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
“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
“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
“Unlisted Foreign Shares”	ordinary shares issued by the Company with a nominal value of RMB1.00 each and are held by foreign investors and are not listed on any stock exchange
“US” or “United States” or “the U.S.”	the United States of America, its territories and possessions, any State of the United States, and the District of Columbia
“vc linker”	valine-citrulline linker, which is adequately stable in blood circulation and cleaved effectively by the lysosomal cathepsin enzyme after the ADC is internalized and enters lysosome
“%”	per cent

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

Shanghai, the PRC
August 21, 2024

As at the date of this announcement, the Board comprises Dr. Pu Zhongjie (chairman) and Dr. Sui Ziyue (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*