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, 2023

The Board is pleased to announce the unaudited consolidated interim results of the Group for the six months ended June 30, 2023, together with the comparative figures for the same period in 2022.

BUSINESS HIGHLIGHTS

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

Achieving breakthroughs in commercialization with total revenue exceeding RMB150 million

– **Licensing income from BD activity:** On February 23, 2023, KYM, a joint venture formed by us and Keymed, entered into a global exclusive out-license agreement with AstraZeneca to develop and commercialize CMG901, with the upfront payment of US$63 million and the potential for additional payments up to US$1,125 million subject to achievement of certain development, regulatory and commercial milestones. As of June 30, 2023, we have received approximately RMB109.5 million from KYM as licensing income from the abovementioned licensing arrangement.

– **Commercialization of PUYOUHENG (Pucotenlimab Injection):** During the Reporting Period, PUYOUHENG recorded a sales revenue in the amount of RMB44.0 million.

Significant Advancement of ADC Pipeline

– **MRG003:** Two registrational studies on NPC and HNSCC are ongoing, respectively.

  o We observed encouraging data from Phase IIa clinical study on NPC, which will be presented orally at the ESMO Congress 2023. Moreover, in January 2023, based on the encouraging data, we obtained approval for registrational Phase IIb clinical study on NPC from CDE. As of June 30, 2023, the enrollment is ongoing.

  o We observed encouraging data from Phase II clinical study on HNSCC, which will be a poster presentation at the ESMO Congress 2023. As of June 30, 2023, we are conducting a randomized, open-label, multicenter Phase III clinical study on HNSCC.

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

– **MRG004A:** We are conducting a Phase I/II clinical study in solid tumors in US and China. We have observed anti-tumor activity signal on PC, TNBC and CC. The preliminary Phase I data in solid tumors will be presented orally at the 2023 Annual Meeting of CSCO.

Significant synergy observed clinically with ADC+ PD-1 combination therapy

– **Combination Therapy of MRG003 with PUYOUHENG (Pucotenlimab Injection):** We have completed the Phase I trial of combination therapy with MRG003 and pucotenlimab in the treatment of solid tumor and have observed encouraging preliminary data. Such data will be presented orally at the 2023 Annual Meeting of CSCO. We are currently conducting a Phase II trial.

– **Combination Therapy of MRG002 with PUYOUHENG (Pucotenlimab Injection):** We are conducting a Phase I trial of combination therapy with MRG002 and pucotenlimab in the treatment of HER2 expressing solid tumor and have observed encouraging data. The enrollment is ongoing as of June 30, 2023.

FINANCIAL HIGHLIGHTS

– Revenue was approximately RMB153.6 million for the six months ended June 30, 2023 (for six months ended June 30, 2022: nil).

– Loss for the period attributable to the shareholders of the Company decreased by approximately RMB202.4 million, or approximately 58.8%, to approximately RMB141.9 million for the six months ended June 30, 2023 compared to the same period in 2022.

MANAGEMENT DISCUSSION AND ANALYSIS

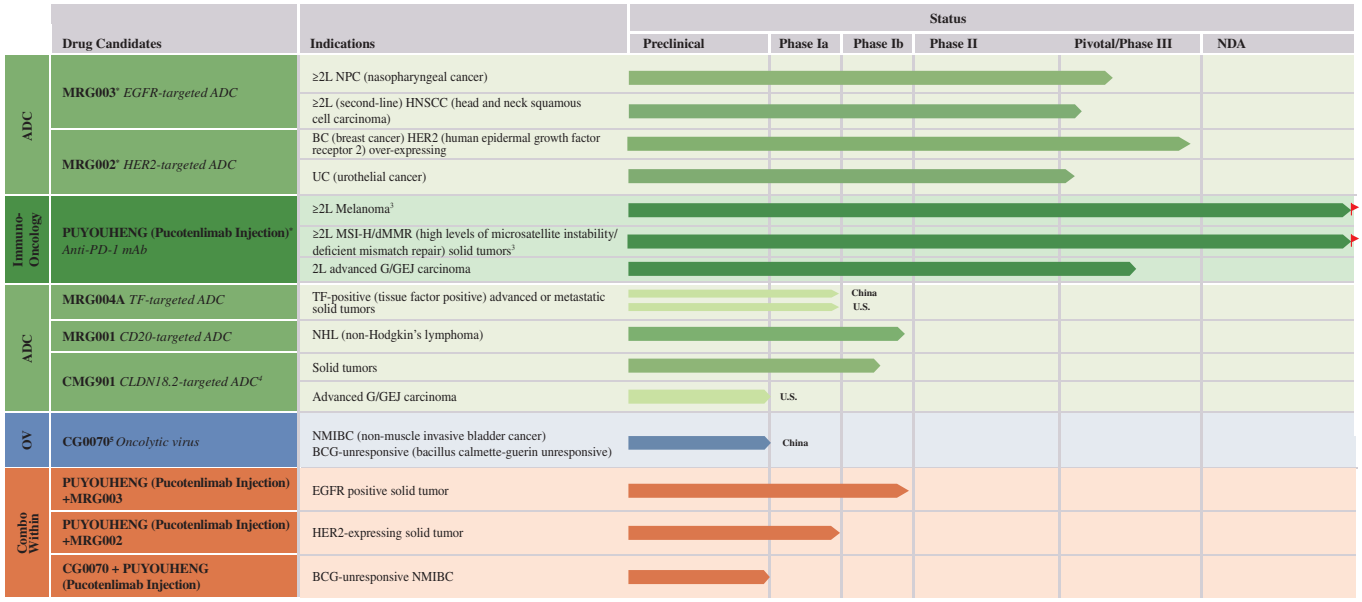
OVERVIEW

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 as well as 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 built our pipeline with a range of oncology products. For clinical-stage candidates, we have (i) one clinical/commercialization-stage drug, pucotenlimab; (ii) six clinical-stage drug candidates, including one co-developed through a joint venture; and (iii) three clinical-stage combination therapies of our own drug candidates. One of our drug candidates has obtained marketing approval with respect to two of its targeted indications, with clinical trials for other indications ongoing. Among the six clinical-stage drug candidates, five are targeted therapeutics and one is an immunotherapeutic, which is an oncolytic virus drug. We have initiated multiple clinical trials, amongst which one is ongoing in the U.S., and five have entered the stage of registrational trials in the PRC. MRG003 was granted ODD on NPC from FDA and BTD from CDE. MRG002 was granted ODD on GC/GEJ from FDA. CMG901 was granted the Fast-Track Designation and ODD in GC/GEJ from FDA, and obtained BTD from CDE.

PRODUCT PIPELINE

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



Notes:

1. * denotes the Core Products.

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

3. On July 19, 2022 and September 29, 2022, we obtained from the NMPA conditional marketing approval for PUYOUHENG (Pucotenlimab Injection) in MSI-H/dMMR and inoperable or metastatic melanoma, respectively.

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

5. Apart from the Phase Ia clinical trial currently conducted in China, the MRCT clinical trial of CG0070 is also being conducted by CG Oncology, a third-party business partner with whom we have a licensed-in arrangement to develop, manufacture and commercialize CG0070 in Mainland China, Hong Kong and Macau.

BUSINESS REVIEW

The Company achieved its listing on the Main Board of the Stock Exchange since February 2022. Since its Listing, the Group has continued to focus its efforts on the research and development of its drug candidates, while continuously assessing the market demand and 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 pipeline. To highlight the progress we have achieved during the Reporting Period, we have received approximately RMB109.5 million from KYM, a joint venture formed by us and Keymed, which entered into a licensing agreement with AstraZeneca for the development and commercialization of CMG901 in February 2023. According to the license agreement and subject to the terms and conditions thereof, KYM shall receive payment of up to US$1,188 million, and KYM is also entitled to receive tiered royalties on net sales from AstraZeneca. We have also successfully commercialized PUYOUHENG (Pucotenlimab Injection) and recorded a sales revenue of approximately RMB44.0 million during the Reporting Period.

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, 2023 and up to the date of this announcement is as follows:

MRG003

- MRG003 is an ADC comprised of an EGFR-targeted mAb conjugated with the potent microtublin disrupting payload MMAE via a vc linker. It binds specifically with high affinity to human EGFR on the surface of tumor cells, releases the potent payload upon internalization and lysosomal protease cleavage of the linker, and results in tumor cell death.

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

    - **NPC:** We have observed encouraging data from Phase IIa clinical study on NPC, which will be presented orally at the ESMO Congress 2023. Moreover, in January 2023, based on the encouraging data, we obtained CDE approval for registrational Phase IIb clinical study for NPC. As of June 30, 2023, we are conducting a randomized, open-label, multicenter Phase IIb clinical study on NPC, and enrollment is ongoing.

    - **HNSCC:** We have observed encouraging data from Phase II clinical study on HNSCC, which will be a poster presentation at the ESMO Congress 2023. As of June 30, 2023, we are conducting a randomized, open-label, multicenter Phase III clinical study on HNSCC.

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

MRG002

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

  o **HER2 over-expressing BC:** We are currently conducting a registrational clinical trial in China and the patient enrollment has been completed. We are currently making our best efforts on pushing it to NDA stage. Meanwhile, we are conducting a Phase III clinical study in HER2-positive BC as of June 30, 2023.

  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, 2023.

– **Warning under Rule 18A.08(3) of the Listing Rules:** There is no assurance that the MRG002 will ultimately be successfully developed and marketed by the Company. Shareholders of the Company 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. In July and September 2022, the NMPA granted marketing approval for PUYOUHENG (Pucotenlimab Injection) in MSI-H/dMMR and inoperable or metastatic melanoma, respectively. In April 2023, two indications were included into the 2023 CSCO Guideline, which are pucotenlimab as ≥second-line treatment of MSI-H/dMMR colorectal cancer and solid tumors, and pucotenlimab as second-line treatment of melanoma. Moreover, Pucotenlimab for treatment of advanced and recurrent MSI-H/dMMR gynecological cancer was included into the 2023 CSGO Guideline.

  o **MSI-H/dMMR solid tumors:** We are conducting an open label, multi-center and randomized Phase III clinical trial in the first-line MSI-H/dMMR metastatic colorectal cancer as a confirmatory clinical study for the conditional marketing approval as of June 30, 2023.

- **Melanoma:** We are conducting an open label, multi-center and randomized Phase III clinical trial in 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, 2023.

- **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. Patient enrollment is ongoing as of June 30, 2023.

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

Combination Therapies Involving our Core Products

– **MRG003 + PUYOUHENG (Pucotenlimab Injection):** We have completed a Phase I trial of combination therapy with MRG003 and pucotenlimab in the treatment of solid tumor and have observed encouraging preliminary data, which will be presented orally at the 2023 Annual Meeting of CSCO. We are currently conducting a Phase II trial.

– **MRG002 + PUYOUHENG (Pucotenlimab Injection):** We are conducting a Phase I trial of combination therapy with MRG002 and pucotenlimab in the treatment of HER2 expressing solid tumor. The enrollment is ongoing as of June 30, 2023.

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

Other Clinical-stage Drug Candidates

– **MRG004A:** MRG004A is a novel TF-targeted site-specifically conjugated ADC. We are currently conducting a Phase I/II clinical study in solid tumors in US and China. We have observed anti-tumor activity signal on PC, TNBC and CC. The preliminary Phase I data in solid tumors will be presented orally at the 2023 Annual Meeting of CSCO.

– **MRG001:** MRG001 is a clinically advancing CD20-targeted ADC to address medical needs of B-cell NHL patients with either primary drug resistance to rituximab or acquired drug resistance to the combination therapy of rituximab and standard chemotherapies. We are conducting the Phase Ib dose expansion study of MRG001 in China.

– **CMG901:** CMG901 is a CLDN18.2-targeting ADC comprising a CLDN18.2-specific antibody, a cleavable linker and a toxic payload, MMAE. It is the first CLDN18.2 targeting ADC to have received IND clearance both in China and the U.S. CLDN18.2 is selectively and widely expressed in GC, PC and other solid tumors, which makes it an ideal tumor target for therapeutic development. It is being co-developed by us and Keymed through a joint venture, KYM. Phase Ia trial of CMG901 was conducted for advanced solid tumors. CMG901 showed a favorable safety and tolerability profile in this trial. In January 2023, Phase Ia trial data has been presented as a poster at 2023 American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO GI 2023). As of August 4, 2022, in CLDN18.2-positive GC/GEJ patients, ORR and DCR were 75.0% and 100%, respectively. Among them, in dose group of 2.6mg/kg, 3.0mg/kg and 3.4 mg/kg, ORR was 100%. Neither the median progression-free survival (mPFS) nor the median overall survival (mOS) has been reached.

– **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 US partner, CG Oncology. We in-licensed CG0070 from CG Oncology and were granted the rights to develop, manufacture and commercialize it in Mainland China, Hong Kong and Macau. We are conducting a Phase I clinical trial in China as of June 30, 2023.

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

Innovation platforms

We continuously strive to build up and develop novel technology platforms as innovative engines for the Company. During the Reporting Period, our innovative platforms, being T cell engager platform and novel linker-payload platform, have achieved significant progress. Based on these innovation platforms, we have generated innovative molecules which possess global first-in-class potential, and we are currently progressing to reach 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 best-in-class potential which has entered the IND-enabling study stage during the Reporting Period.

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

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

Other updates regarding our Product Candidates

As mentioned above, in order to maximize our competitiveness within the oncology therapeutics market, we continuously evaluate our pipeline considering market needs, competitive landscape and the development progress of our existing products.

Notably, during the Reporting Period, our ADC drug candidates gained significant progress. Multiple ADC candidates/indications have initiated registrational clinical trials in the six months ended June 30, 2023 and up to the date of this announcement, including the registrational Phase IIb clinical study in NPC for MRG003, Phase III clinical trial in HNSCC for MRG003, and Phase III clinical study in UC for MRG002. Moreover, we have completed patient enrollment of the registrational clinical trial in patients with HER2 over-expressing BC and are currently making our best efforts on pushing it to NDA stage. Our innovative ADC MRG004A achieved anti-tumor activity signal in PC, TNBC and CC which showed great potential to address the unmet medical needs. Furthermore, we observed preliminary data of ADC and Pucotenlimab combination therapy which encouraged us to further explore and prove the synergy with Immuno-oncology and ADCs. In addition to the significant clinical milestones achieved, MRG003, MRG002 and CMG901 were each granted ODD from the FDA for the treatment of NPC, GC/GEJ and GC/GEJ, respectively, and MRG003 was further granted BTD from the CDE for the treatment of R/M NPC, which demonstrates recognition from regulatory authorities of the innovativeness and efficacy profile of our relevant ADC drug candidates. This signifies that we are well-suited to capture the increasing potential in and demand for ADC drugs that we have observed during the Reporting Period.

Taking into account the factors set out in the above, we decided to focus our resources on the further clinical development of MRG002, MRG003 and other ADC drug candidates, and not further advance the clinical development of LP002 at this stage. We will continue to monitor and evaluate our assets of drug candidates in the future.

Furthermore, the Company also regularly reviews and makes adjustments to the clinical trials of its pipeline products to prioritise resources on indications and drug candidates which the Company considers having the most potential in order to ensure most efficient allocation of resources. Considering the commercial benefits for the Company as a whole, the Board has decided to focus our resources of the Company on the further clinical development of MRG003 for NPC and HNSCC as well as MRG002 for HER2 over-expressing BC and UC, and also on the research and development of PUYOUHENG (Pucotenlimab Injection), including the confirmatory clinical studies for the conditional marketing approval in MSI-H/dMMR solid tumors and melanoma.

For details of the latest pipeline products of the Company, please refer to page 4 of this announcement.

Manufacturing Facilities

We have been operating a 2,000L GMP-compliant bioreactor production line at our Beijing manufacturing plant, and during the Reporting Period, it mainly supports the production of clinical drug supply. We have also been building a manufacturing facility for oncolytic virus products in Beijing with a designed capacity of 200L.

In October 2022, our research and development center in Shanghai Biotech Park was put into operation. During the Reporting Period, we have also been building the phase one of the manufacturing facilities in the Shanghai Biotech Park, which has a designed total capacity of 12,000L and of which the first production line with capacity of 6,000L is under construction.

Commercialization

Licensing income from business development ("BD") activity

On February 23, 2023, KYM, a joint venture formed by us and Keymed, entered into a global exclusive out-license agreement (the "**License Agreement**") with AstraZeneca to develop and commercialize CMG901, pursuant to which AstraZeneca will be granted an exclusive global license for research, development, registration, manufacturing, and commercialization of CMG901, and shall be responsible for all costs and activities associated with the further development and commercialization of CMG901 except as otherwise agreed. According to the License Agreement and subject to the terms and conditions thereof, KYM shall receive an upfront payment of US$63 million with the potential for additional payments up to US$1,125 million subject to achievement of certain development, regulatory and commercial milestones. KYM is also entitled to receive tiered royalties on net sales from AstraZeneca. As of June 30, 2023, we have received approximately RMB109.5 million from KYM as licensing income from the abovementioned licensing arrangement.

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

Commercialization of PUYOUHENG (Pucotenlimab Injection)

After obtaining marketing approval of PUYOUHENG (Pucotenlimab Injection) in the second half of 2022, we have initiated the marketing and commercialization process. For the six months ended June 30, 2023, PUYOUHENG recorded a sales revenue of approximately RMB44.0 million.

We have built up 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 patient population. In April 2023, pucotenlimab have been successfully included in 2023 CSCO and CSGO Guidelines for melanoma and MSI-H/dMMR solid tumors, which represented high recognition from clinical KOL.

On sales channel establishment, we actively develop cooperative relationships with various business channel partners. As of June 30, 2023, we have completed the tendering process on the procurement platform in more than 10 provinces. We have covered approximately 50 cities through various sales channels, and we will further expand our sales network.

Proposed Issue of A Shares and Listing on the Sci-Tech Innovation Board of the Shanghai Stock Exchange

On September 1, 2022, the Company announced that it proposed to apply to the relevant PRC regulatory authorities for the allotment and issuance of not more than 414,861,209 A Shares, and proposed to apply to the Shanghai Stock Exchange for the listing and trading of A Shares on the Sci-Tech Board of the Shanghai Stock Exchange ("**Issue of A Shares**"). On September 23, 2022, the Shareholders considered and approved the issuance of no more than 414,861,209 A Shares and the application to the Shanghai Stock Exchange for the listing of A Shares on the Sci-Tech Board and relevant matters in the 2022 first extraordinary general meeting, the 2022 first class meeting of H Shareholders and the 2022 first class meeting of Domestic Shareholders. The proposed Issue of A Shares is subject to, amongst other things, approval from the Shanghai Stock Exchange and registration with the China Securities Regulatory Commission.

On July 11, 2023, the Company further announced that as the Company is still actively pursuing and preparing for its A Share listing application considering the benefits of an A Share listing, it proposed to extend (i) the validity period of the resolutions in relation to the Issue of A Shares and (ii) the validity period of the resolution authorizing the Board of Directors and persons authorized by it to fully handle the relevant matters in connection with the Issue of A Shares and listing on the Sci-Tech Board, for further 12 months from the date of approval by the Shareholders at the extraordinary general meeting to be held on August 25, 2023. For details, please refer to the Company's announcement dated July 11, 2023 and circular dated August 9, 2023.

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 with development and strategic collaborations. Looking forward to the second half of 2023, we will accelerate the development of our two key ADC products, namely MRG003 and MRG002, to the next milestones. We will make our best efforts on pushing MRG002 for HER2 over-expressing BC to NDA stage and accelerating the MRG003 registrational clinical studies to prepare for NDA application. While we will continue to explore the potential clinical value of MRG004A, we will also enforce the establishment of our innovation platforms and make efforts on progressing these molecules to clinical research stage.

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 expand our commercialization team by recruiting talents with the appropriate skills and expertise in commercialization of pharmaceutical products and 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 these enhancement of our efforts on market outreach would translate into better market access, increased market share and increased 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 step up our efforts for expansion in the global market. As our ADC platform has been endorsed by multi-national companies, we expect our other ADC products to have more promising business development opportunities. We will continue to approach multiple overseas companies and seek the chance for potential business development cooperation.

FINANCIAL REVIEW

Revenue

For the six months ended June 30, 2023, we have recorded revenue of RMB153.6 million (for six months ended June 30, 2022: nil). The Group recognized revenue of approximately RMB109.5 million from the out-licensing of CMG901 for development and commercialization. Also, due to the successful commercialization of PUYOUHENG (Pucotenlimab Injection), the Group recognized approximately RMB44.0 million from its sales.

Selling and Marketing Expenses

For the six months ended June 30, 2023, the Group has recorded selling and marketing expenses of RMB13.9 million (for six months ended June 30, 2022: nil), mainly because the Group had commercialized PUYOUHENG (Pucotenlimab Injection) in late 2022 and has conducted selling and marketing activities for it during the Reporting Period.

Administrative Expenses

Our administrative expenses primarily consist of (i) employee benefit expenses relating to our administrative staff; (ii) depreciation and amortization expenses, primarily representing depreciation expenses for right-of-use assets and property, plant and equipment; and (iii) others, mainly representing utilities as well as traveling and transportation expenses. Our administrative expenses decreased from RMB84.7 million for the six months ended June 30, 2022 to RMB39.1 million for the six months ended June 30, 2023, primarily due to a decrease in the listing expenses by approximately RMB33.5 million.

Research and Development Expenses

Our research and development expenses primarily consist of (i) clinical study related expenses; (ii) pre-clinical study costs; (iii) depreciation and amortization expenses for property, plant and equipment as well as amortization expenses for intangible assets such as intellectual properties; (iv) employee benefit expenses relating to our research and development staff; and (v) raw materials and consumables used, primarily representing expenses for procuring raw materials and consumables used in pre-clinical and clinical studies. Our research and development expenses for the six months ended June 30, 2023 was RMB231.9 million (for six months ended June 30, 2022: RMB230.7 million).

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

	Six months ended 30 June			
	2023		2022	
	RMB'000	***%***	*RMB'000*	*%*
Clinical study related expenses	**85,350**	**36.8**	87,034	37.7
Employee benefit expenses	**62,354**	**26.9**	54,544	23.6
Pre-clinical study costs	**15,606**	**6.7**	37,568	16.3
Depreciation and amortization	**44,703**	**19.3**	34,135	14.8
Raw material and consumables used	**16,282**	**7.0**	9,797	4.2
Others	**7,577**	**3.3**	7,628	3.4
Total	**231,872**	**100**	230,706	100

(i) Employee benefit expenses increased by RMB7.8 million, mainly due to the hiring of more experienced research and development experts;

(ii) Pre-clinical study costs decreased by RMB22.0 million, mainly due to some of our drug candidates progressing beyond pre-clinical study stage, hence lowering pre-clinical study costs;

(iii) Depreciation and amortization costs increased by RMB10.6 million, mainly due to an increase in depreciation of research and development facilities and equipment as a result of the commencement of the first phase of Shanghai Biotech Park in late 2022;

(iv) Raw material and consumables expenses increased by RMB6.5 million, mainly due to an increase in the use of raw materials for our research and development activities; and

(v) Clinical study related expenses and other expenses for the six months ended June 30, 2023 stay constant as compared to the six months ended June 30, 2022.

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

We had fair value loss on financial liabilities at fair value through profit or loss of RMB60.8 million for the six months ended June 30, 2022 and fair value gain of RMB17.7 million for the six months ended June 30, 2023. Our financial liabilities include financial liabilities at fair value through profit or loss, representing the variable part of the consideration arisen from the acquisition of 40% equity interests of Taizhou Hanzhong from non-controlling interest, being 4.375% of future annual net sales revenue of relevant PD-1 products.

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

	Six months ended 30 June	
	2023	2022
	RMB'000	*RMB'000*
Fair value gains/(losses) on financial liabilities at fair value through profit or loss		
– Fair value changes through profit or loss	**17,737**	(60,776)

Finance income and Finance Costs

Our finance income primarily represents our bank interest income and foreign exchange gain. Our finance costs primarily consist of interest costs on lease liabilities and borrowings. Our finance income decreased from RMB36.8 million for the six months ended June 30, 2022 to RMB5.5 million for the six months ended June 30, 2023, mainly due to a decrease in foreign currency exchange gain. Our finance costs increased from RMB2.8 million for the six months ended June 30, 2022 to RMB7.9 million for the six months ended June 30, 2023, due to an increase in interest on borrowings.

Income Tax Expenses

For the six months ended June 30, 2023, the Group's income tax expenses were nil (2022: nil).

Loss for the Reporting Period

Based on the factors described above, the Group's loss decreased from RMB348.4 million for the six months ended June 30, 2022 to RMB141.9 million for the six months ended June 30, 2023.

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. For the six months ended June 30, 2023, our net cash used in operating activities was RMB75.6 million, a decrease of RMB117.2 million from RMB192.8 million as of June 30, 2022. As of June 30, 2023, we had cash and cash equivalent of RMB581.5 million, representing a decrease of RMB87.9 million from RMB669.4 million as of December 31, 2022, as a result of the continuous research and development activities carried out by the Company.

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

Our bank borrowings are divided into secured loans and unsecured loans. As of June 30, 2023, the Group's bank borrowings amounted to RMB749.4 million (December 31, 2022: RMB650.0 million), among which unsecured and unguaranteed bank borrowings amounted to RMB434.1 million in total with interest at fixed and floating interest rates. Such borrowing will be repayable within one year.

As of June 30, 2023, the Group's secured and unguaranteed bank borrowings amounted to RMB315.3 million (December 31, 2022: RMB320.4 million) in total which bear interest at floating interest rates. Such bank borrowings are repayable by instalments and will mature in September 2027 and secured by the Group's land use rights and property, plant and equipment.

As of June 30, 2023, we had utilized RMB783.7 million from our banking facilities and approximately RMB516.3 million remained unutilized under our banking facilities.

Gearing Ratio

The gearing ratio is calculated using the Group's liabilities divided by its assets. As of June 30, 2023, the Group's gearing ratio was 68.24% (December 31, 2022: 64.39%).

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, 2023.

Capital Commitments

As of June 30, 2023, the Group had capital commitments for property, plant and equipment of RMB466.2 million (December 31, 2022: RMB482.0 million), reflecting the capital expenditure of our Group contracted at the end of the Reporting Period/year but not yet incurred.

Contingent Liabilities

As of June 30, 2023 and December 31, 2022, the Group did not have any contingent liabilities.

Charges on Group Assets

Save as disclosed in this announcement, as of June 30, 2023, the Group did not have any charges over its assets.

Foreign Exchange Exposure

Our financial statements are expressed in RMB, but certain of our subsidiaries in the PRC are exposed to foreign exchange risk arising from recognized financial assets and liabilities are denominated in foreign currencies. We currently do not have a foreign currency hedging policy. However, our management manages foreign exchange risk by performing regular reviews and will consider hedging significant foreign currency exposure should the need arise.

Employees and Remuneration

As of June 30, 2023, the Group had a total of 436 employees. The total remuneration cost of the Group for the six months ended June 30, 2023 was RMB89.2 million, as compared to RMB85.6 million for the six months ended June 30, 2022, primarily due to an increase in number of sales and marketing staff to support the commercialization of PUYOUHENG (Pucotenlimab Injection).

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, 2023.

Model Code for Securities Transactions

The Company has adopted the Model Code as its own code of conduct regarding securities transactions by the Directors and Supervisors. Having made specific enquiries with all Directors and Supervisors, each of them has confirmed that he/she has complied with the Model Code for the six months ended June 30, 2023. No incident of non-compliance of the Model Code by the employees who are likely to be in possession of inside information of the Company was noted by the Company.

Purchase, Sale or Redemption of Listed Securities

Neither the Company nor any of its subsidiaries purchased, sold or redeemed any of the Company's listed securities during the six months ended June 30, 2023.

REVIEW OF FINANCIAL INFORMATION

Audit Committee

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

The Audit Committee, together with the management of the Company, has reviewed the unaudited interim condensed consolidated financial information of the Group for the six months ended June 30, 2023, 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, 2023 (June 30, 2022: nil).

PUBLICATION OF INTERIM RESULTS ANNOUNCEMENT AND INTERIM REPORT

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

The interim report of the Company for the six months ended June 30, 2023 containing all the information required by the Listing Rules will be despatched to the Shareholders and will be published on the respective websites of the Stock Exchange and the Company in due course.

INTERIM CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

	Note	Six months ended 30 June	
		2023	2022
		RMB'000	*RMB'000*
		(Unaudited)	(Unaudited)
Revenue	*5*	**153,553**	–
Cost of sales	*6*	**(5,755)**	–
Gross profit		**147,798**	–
Other income		**1,887**	5,162
Other expenses	*6*	**(3)**	(200)
Selling and marketing expenses	*6*	**(13,855)**	–
Administrative expenses	*6*	**(39,073)**	(84,729)
Research and development expenses	*6*	**(231,872)**	(230,706)
Fair value changes on financial assets and liabilities at fair value through profit or loss	*7*	**17,737**	(60,776)
Other (losses)/gains, net		**(614)**	554
Operating loss		**(117,995)**	(370,695)
Finance income		**5,529**	36,754
Finance costs		**(7,937)**	(2,790)
Finance (costs)/income, net		**(2,408)**	33,964
Share of loss of investments accounted for using the equity method		**(21,501)**	(11,643)
Loss before income tax		**(141,904)**	(348,374)
Income tax expense	*8*	**–**	–
Loss for the period		**(141,904)**	(348,374)
Loss attributable to:			
Owners of the Company		**(141,904)**	(344,286)
Non-controlling interests		**–**	(4,088)
		(141,904)	(348,374)

	Note	Six months ended 30 June	
		2023	2022
		RMB'000	*RMB'000*
		(Unaudited)	(Unaudited)
Loss per share for loss attributable to owners of the Company for the period (expressed in RMB per share)			
– Basic	*9*	**(0.09)**	(0.21)
– Diluted	*9*	**(0.09)**	(0.21)
Other comprehensive (loss)/income			
Items that may be subsequently reclassified to profit or loss			
Currency translation differences		**(552)**	132
Total comprehensive loss		**(142,456)**	(348,242)
Total comprehensive loss attributable to:			
Owners of the Company		**(142,456)**	(344,154)
Non-controlling interests		**–**	(4,088)
		(142,456)	(348,242)

INTERIM CONDENSED CONSOLIDATED BALANCE SHEET

	Note	**As at June 30 2023** ***RMB'000*** **(Unaudited)**	As at December 31 2022 *RMB'000* (Audited)
Assets			
Non-current assets			
Property, plant and equipment		**954,946**	916,409
Right-of-use assets		**112,474**	122,662
Intangible assets		**439,993**	450,813
Investments accounted for using the equity method		**100,891**	122,392
Other receivables, prepayments and deposits		**61,666**	104,095
Total non-current assets		**1,669,970**	1,716,371
Current assets			
Inventories		**24,671**	24,061
Notes receivables		**–**	3,040
Other receivables, prepayments and deposits		**123,662**	116,303
Cash and cash equivalents		**581,463**	669,397
Total current assets		**729,796**	812,801
Total assets		**2,399,766**	2,529,172
Equity			
Equity attributable to owners of the Company			
Share capital		**1,659,445**	1,659,445
Reserves		**1,576,181**	1,572,807
Accumulated losses		**(2,473,394)**	(2,331,490)
		762,232	900,762
Non-controlling interests		**–**	–
Total equity		**762,232**	900,762

	Note	**As at June 30 2023** ***RMB'000*** **(Unaudited)**	As at December 31 2022 *RMB'000* (Audited)
Liabilities			
Non-current liabilities			
Borrowings		**280,000**	290,057
Lease liabilities		**1,692**	3,093
Deferred government grants		**12,000**	12,000
Deferred tax liabilities		**37,687**	37,687
Financial liabilities at fair value through profit or loss	*10*	**421,105**	441,787
Total non-current liabilities		**752,484**	784,624
Current liabilities			
Borrowings		**469,365**	359,988
Trade payables	*11*	**176,144**	166,129
Other payables and accruals		**215,091**	287,242
Lease liabilities		**24,450**	30,427
Total current liabilities		**885,050**	843,786
Total liabilities		**1,637,534**	1,628,410
Total equity and liabilities		**2,399,766**	2,529,172

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION FOR THE SIX MONTHS ENDED 30 JUNE 2023

1 GENERAL INFORMATION

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

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

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

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

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

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

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

3 BASIS OF PREPARATION

The Group's interim condensed consolidated financial information for the six months ended 30 June 2023 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 2022 (the "**2022 Annual Financial Statements**"), which have been prepared in accordance with International Financial Reporting Standards ("**IFRSs**"), and any public announcement made by the Company during the interim reporting period.

For the six months period ended 30 June 2023, the Group has incurred net losses of approximately RMB141.9 million, while net cash used in operating activities was approximately RMB75.6 million. As at 30 June 2023, the Group had net current liabilities of approximately RMB155.3 million and cash and cash equivalents of approximately RMB581.5 million. Historically, the Group has relied principally on financing from investors and banks to fund its operations and business development. The Group's ability to continue as a going concern is dependent on management's ability to successfully execute its business plan. The directors of the Company believes that the cash and cash equivalent, unutilised bank facilities together with the cash generated from operating activities are sufficient to meet the cash requirements to fund planned operations and other commitments for at least the next twelve months from the date of the issuance of this consolidated interim financial information. The Group therefore continues to prepare this consolidated interim financial information on a going concern basis.

The accounting policies adopted are consistent with those of 2022 Annual Financial Statements, except for the adoption of new and amended standards as set out below, and accounting policy for revenue from licensing of intellectual property as described in Note 5.

(a) New and amended standards adopted by the Group

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

IFRS 17	Insurance Contracts
Amendments to IAS 1 and IFRS Practice Statement 2	Disclosure of Accounting Policies
Amendments to IAS 8	Definition of Accounting Estimates
Amendments to IAS 12	Deferred Tax related to Assets and Liabilities arising from a Single Transaction

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

(b) New and amended standards not yet adopted

The following new and 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
Amendment to IAS 1	Non-current liabilities with covenants	1 January 2024
Amendment to IAS 1	Classification of Liabilities as Current or Non-current	1 January 2024
Amendments to IFRS 16	Lease liability in sale and leaseback	1 January 2024
Amendments to IAS 7 and IFRS 7	Supplier Finance Arrangements	1 January 2024
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 new and 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 is 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	
	2023	2022
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Revenue recognised at a point in time		
– Licensing income (a)	**109,520**	–
– Sales of pharmaceutical products	**44,033**	–
	153,553	–

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

	Six months ended 30 June	
	2023	2022
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Geographical markets		
– Overseas	**109,520**	–
– The PRC	**44,033**	–
	153,553	–

For the six months ended 30 June 2023, revenue of approximately RMB109,520,000 (six months ended 30 June 2022: Nil) was derived from licensing income with the Group's associate, KYM, which accounted for 71.32% (six months ended 30 June 2022: Nil) of the Group's total revenue. Other than the aforementioned customer, the revenues derived from any of the remaining external customers were less than 10% of the Group's total revenue.

(a) Revenue from licensing of intellectual property

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

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

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

As described in Note 2, during the six months ended 30 June 2023, KYM has received a one-time and non-refundable upfront payment from AstraZeneca, and therefore KYM has paid the one-time and non-refundable upfront payment of approximately RMB109,520,000 to the Group. The Group recognised revenue of RMB109,520,000 accordingly.

6 EXPENSES BY NATURE

	Six months ended 30 June	
	2023	2022
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Employee benefit expenses	**89,193**	85,580
Clinical study related expenses	**85,350**	87,034
Depreciation and amortisation	**51,538**	45,315
Pre-clinical study costs	**15,606**	37,568
Raw material and consumables used	**20,951**	9,797
Changes in inventories of finished goods and working in progress outsourced for processing	**(1,996)**	–
Professional services fees	**4,083**	1,808
Licensing fee	**3,082**	–
Auditors' remuneration	**1,000**	800
Listing expenses	**–**	33,466
Others	**21,751**	14,267
Total cost of sales, selling and marketing expenses, administrative expenses, research and development expenses and other expenses	**290,558**	315,635

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

	Six months ended 30 June	
	2023	2022
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Fair value gains/(losses) on financial liabilities at fair value through profit or loss	**17,737**	(60,776)

8 INCOME TAX EXPENSE

	Six months ended 30 June	
	2023	2022
	RMB'000	*RMB'000*
	(Unaudited)	(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 a High and New Technology Enterprise ("**HNTE**") under the relevant PRC laws and regulations on 18 November 2020. Accordingly, it was entitled to a preferential corporate income tax rate of 15% on its estimated assessable profits for the years ended 31 December 2020 to 2022.

Lepu (Beijing) Biopharma Co., Ltd. ("**Lepu Beijing**") is qualified as a HNTE under the relevant PRC laws and regulations on 25 October 2021. Accordingly, it was entitled to a preferential corporate income tax rate of 15% on its estimated assessable profits for the years ended 31 December 2021 to 2023.

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

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	
	2023	2022
	(Unaudited)	(Unaudited)
Loss for the period and attributable to owners of the Company (in RMB'000)	**(141,904)**	(344,286)
Weighted average number of ordinary shares in issue (in thousands)	**1,659,445**	1,621,896
Basic loss per share (in RMB)	**(0.09)**	(0.21)

(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 2023 and 2022.

10 FINANCIAL LIABILITIES AT FAIR VALUE THROUGH PROFIT OR LOSS

	As at 30 June 2023 ***RMB'000*** **(Unaudited)**	As at 31 December 2022 *RMB'000* (Audited)
Variable consideration payable arisen from acquisition of 40% equity of Taizhou Hanzhong Biotechnology Co., Ltd. from non-controlling interests	**430,545**	448,282
Less: current portion	**(9,440)**	(6,495)
Non-current portion	**421,105**	441,787

The movements of financial liabilities at fair value through profit or loss for the six months ended 30 June 2023 and 2022 are set out below:

	Six months ended 30 June	
	2023 ***RMB'000*** **(Unaudited)**	2022 *RMB'000* (Unaudited)
Opening balance	**448,282**	385,466
Change in fair value	**(17,737)**	60,776
Closing balance	**430,545**	446,242

11 TRADE PAYABLES

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

	As at 30 June 2023 ***RMB'000*** **(Unaudited)**	As at 31 December 2022 *RMB'000* (Audited)
Less than 1 year	**161,421**	154,966
Between 1 and 2 years	**14,723**	11,163
	176,144	166,129

12 DIVIDEND

No dividend has been paid or declared by the Company or companies comprising the Group during the six months ended 30 June 2023 and 2022.

13 EVENTS OCCURRING AFTER THE REPORTING PERIOD

There was not any significant event occurred after 30 June 2023 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 2023.

"A Share(s)"	the ordinary Share(s) with a nominal value of RMB1.00 each in the share capital of the Company proposed to be allotted, issued and listed on the Sci-Tech Board
"ADC"	antibody drug conjugate, a class of biopharmaceutical drugs that combine monoclonal antibodies specific to surface antigens present on particular tumor cells with highly potent antitumor small molecule agents linked via a chemical linker
"Audit Committee"	the audit committee of the Board
"AstraZeneca"	AstraZeneca AB, a global pharmaceutical company who to the best knowledge and belief of the Company, is independent of and not connected with the Company and its connected persons (as defined in the Listing Rules)
"BC"	breast cancer
"B-cell"	a type of white blood cell that differs from other types of lymphocytes by expressing B-cell receptors on its surface, and responsible for producing antibodies
"Bacillus Calmette-Guerin" or "BCG"	a type of bacteria that causes a reaction in a patient's immune system that can destroy cancer cells located in the lining of the bladder. It is also widely used as a vaccine against tuberculosis
"Board"	the board of Directors of the Company
"BTD"	Breakthrough Therapy Designation
"CC"	cervical cancer
"CD20"	a B-lynphocyte 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
"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 "PRC"	the People's Republic of China excluding, for the purpose of this announcement, Hong Kong, Macau Special Administrative Region and Taiwan
"CLDN18.2"	Claudin 18.2, a highly specific tissue junction protein for gastric tissue
"CMC"	chemistry, manufacturing, and controls processes in the development, licensure, manufacturing, and ongoing marketing of pharmaceutical products
"combination therapy"	a treatment modality that combines two or more therapeutic agents
"Company" or "our Company"	Lepu Biopharma Co., Ltd. (樂普生物科技股份有限公司), a joint stock company incorporated in the PRC with limited liability, the H Shares of which are listed on the Stock Exchange (Stock code: 2157)
"Company Law"	the Company Law of the PRC (《中華人民共和國公司法》), enacted by the Standing Committee of the Eighth National People' Congress on December 29, 1993 and effective on July 1, 1994, and subsequently amended on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013 and October 26, 2018, as amended, supplemented or otherwise modified from time to time
"Core Product(s)"	has the meaning ascribed to it in Chapter 18A of the Listing Rules; for purposes of this announcement, our core products include MRG003, MRG002 and PUYOUHENG (Pucotenlimab Injection)
"Corporate Governance Code"	the Corporate Governance Code as set out in Appendix 14 to the Listing Rules
"CR"	complete response, the disappearance of all signs of cancer in response to treatment
"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

"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
"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
"Group", "we", "us" or "our"	the Company and its subsidiaries
"H Share(s)"	overseas listed foreign invested ordinary share(s) in the ordinary share capital of our Company, with a nominal value of RMB1.00 each, which are listed on the Main Board of the Stock Exchange
"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
"IC50"	half maximal inhibitory concentration
"IgG"	human immunoglobulin G, the most common antibody type found in blood circulation that plays an important role in antibody-based immunity against invading pathogens
"IHC"	immunohistochemistry, the most common application of immunostaining. It involves the process of selectively identifying antigens in cells of a tissue section by exploiting the principle of antibodies binding specifically to antigens in biological tissues
"IND"	investigational new drug or investigational new drug application, also known as clinical trial application in China or the US
"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 ChiNext Board of the Shenzhen Stock Exchange (stock code: 300003), and the promoter of the Company
"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
"metastatic"	in reference to any disease, including cancer, disease producing organisms or of malignant or cancerous cells transferred to other parts of the body by way of the blood or lymphatic vessels or membranous surfaces
"MMAE"	monomethyl auristatin E, a potent tubulin binder with a half maximal inhibitory concentration (IC50) in the subnanomolar range
"Model Code"	the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix 10 to the Listing Rules
"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
"NPC"	nasopharyngeal cancer
"ODD"	orphan drug designation
"ORR"	objective response rate, which is equal to the sum of CR and PR
"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
"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"	study in which a drug is introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion, and if possible, to gain an early indication of its effectiveness
"Phase II clinical trials"	study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases, and to determine dosage tolerance and optimal dosage
"Phase III clinical trials"	study in which a drug is administered to an expanded patient population generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to provide adequate information for the labeling of the product
"placebo"	any dummy medical treatment administered to the control group in a controlled clinical trial in order that the specific and non-specific effects of the experimental treatment can be distinguished
"PR"	partial response, refers to an at least 30% but below 100% decrease in the size of a tumor or in the extent of cancer in the body in response to treatment, according to RECIST
"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, 2023
"R/M"	recurrent/metastatic
"RMB" or "Renminbi"	Renminbi, the lawful currency of China
"Sci-Tech Board"	the Sci-Tech Innovation Board of the Shanghai Stock Exchange
"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
"Shanghai Stock Exchange"	the Shanghai Stock Exchange
"Shenzhen Stock Exchange"	the Shenzhen Stock Exchange
"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
"Supervisor(s)"	supervisor(s) of the Company
"Taizhou Hanzhong"	Taizhou Hanzhong Biotechnology Co., Ltd. (泰州翰中生物醫藥有限公司), a limited liability company incorporated in the PRC on November 25, 2016, and our non-wholly owned subsidiary
"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
"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
"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
"%"	per cent

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

Shanghai, the PRC
August 25, 2023

As at the date of this announcement, the Board comprises Dr. Pu Zhongjie (Chairman), Dr. Sui Ziye (Chief Executive Officer) and Dr. Hu Chaohong (Co-Chief Executive Officer) as executive Directors; Mr. Lin Xianghong, 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.