



樂普生物科技股份有限公司
LEPU BIOPHARMA CO.,LTD.

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

Stock Code: 2157

INTERIM REPORT 2022

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CORPORATE INFORMATION

EXECUTIVE DIRECTORS

Dr. Pu Zhongjie (蒲忠傑) (*Chairman*)
Dr. Sui Ziyi (隋滋野) (*Chief Executive Officer*)
Dr. Hu Chaohong (胡朝紅) (*Co-Chief Executive Officer*)

NON-EXECUTIVE DIRECTORS

Ms. Pu Jue (蒲珏)
Mr. Yang Hongbing (楊紅冰)
Mr. Lin Xianghong (林向紅)

INDEPENDENT NON-EXECUTIVE DIRECTORS

Mr. Zhou Demin (周德敏)
Mr. Yang Haifeng (楊海峰)
Mr. Fengmao Hua (華風茂)

SUPERVISORS

Mr. Xu Yang (徐揚)
Mr. Yang Ming (楊明)
Mr. Wang Jiwei (王倚緯)

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Mr. Fengmao Hua (華風茂) (*Chairman*)
Mr. Yang Haifeng (楊海峰)
Ms. Pu Jue (蒲珏)

REMUNERATION AND APPRAISAL COMMITTEE

Mr. Yang Haifeng (楊海峰) (*Chairman*)
Mr. Fengmao Hua (華風茂)
Dr. Pu Zhongjie (蒲忠傑)

NOMINATION COMMITTEE

Mr. Zhou Demin (周德敏) (*Chairman*)
Mr. Yang Haifeng (楊海峰)
Dr. Pu Zhongjie (蒲忠傑)

STRATEGY COMMITTEE

Dr. Pu Zhongjie (蒲忠傑) (*Chairman*)
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Mr. Zhou Demin (周德敏)

JOINT COMPANY SECRETARIES

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Ms. Lai Siu Kuen (黎少娟) (*FCG, HKFCG*)

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Ms. Lai Siu Kuen (黎少娟) (*FCG, HKFCG*)

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FINANCIAL SUMMARY

	As at June 30, 2022 (Unaudited) RMB'000	As at December 31, 2021 (Audited) RMB'000
Total assets	2,642,963	2,082,061
Total liabilities	1,430,712	1,234,978
Total equity	1,212,251	847,083
	As at June 30, 2022 (Unaudited) RMB'000	As at June 30, 2021 (Unaudited) RMB'000
Other income	5,162	4,113
Other expenses	(200)	(530)
Administrative expenses	(84,729)	(77,755)
Research and development expenses	(230,706)	(412,667)
Fair value changes on financial assets and liabilities at fair value through profit and loss	(60,776)	(34,279)
Other gains/(losses), net	554	(954)
Operating loss	(370,695)	(522,072)
Finance income, net	33,964	600
Share of loss of investments accounted for using the equity method	(11,643)	(1,251)
LOSS BEFORE TAX	(348,374)	(522,723)

MANAGEMENT DISCUSSION AND ANALYSIS

OVERVIEW

We are an innovation-driven biopharmaceutical company focusing on oncology therapeutics with a strong China foundation and global vision. Our mission is to become a leading innovative platform serving the unmet medical needs of cancer patients with first-in-class and best-in-class drugs. We endeavor to continuously develop a market-differentiating pipeline by combining in-house research and development and strategic collaborations, strengthen our in-house manufacturing capabilities and commercialize our pipeline products in China through dedicated sales and marketing forces and internationally via partnerships. Since our inception, we have established an integrated end-to-end platform across drug discovery, clinical development, CMC and GMP-compliant manufacturing, encompassing all critical functions of the biopharmaceutical value chain, and are building dedicated sales and marketing forces.

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

PRODUCT PIPELINE

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

Drug Candidates	Indications	Status						
		Preclinical	Phase Ia	Phase Ib	Phase II	Pivotal/Phase III	NDA	
ADC	MRG003* EGFR-targeted ADC	>2L (second-line) HNSCC (head and neck squamous cell carcinoma)	U.S.					
		>2L NPC (nasopharyngeal cancer)						
	MRG002* HER2-targeted ADC	Advanced NSCLC (non-small cell lung cancer)						
		BC (breast cancer) HER2 (human epidermal growth factor receptor 2) over-expressing						
Immuno-Oncology	HX008* Anti-PD-1 mAb	>2L Gastric or gastroesophageal junction carcinoma			China and U.S.			
		UC (urothelial cancer)						
	LP002* Anti-PD-L1 mAb	BC HER2 low-expressing						
		>2L Melanoma						
	ADC	MRG001 CD20-targeted ADC	>2L MSI-H/dMMR (high levels of microsatellite instability/deficient mismatch repair) solid tumors*					
			2L advanced G/GEJ carcinoma					
		MRG004A TF-targeted ADC	1L (first-line) NSCLC					
			1L TNBC (triple-negative breast cancer)					
		CMG901 CLDN18.2-targeted ADC	1L advanced G/GEJ carcinoma					
			HCC (hepatocellular carcinoma)					
OV	CG0070* Oncolytic virus	1L ES-SCLC (extensive stage small-cell lung cancer)						
		NMIBC (non-muscle invasive bladder cancer) BC G-unresponsive (bacillus calmette-guerin unresponsive)		China				
Combo Pipeline	HX008+MRG002	HER2-expressing solid tumor						
		EGFR positive solid tumor						
Pre-clinical Drug Candidates	LP007 CD47 mAb	Solid tumors/Blood tumor						
	LP010 Tigit mAb	PD1A.1 relapsed/refractory solid tumor						
	LP008 PDL1-TGFR/III	PD1A.1 relapsed/refractory solid tumor						

MANAGEMENT DISCUSSION AND ANALYSIS

Notes:

1. * denotes the Core Products.
2. Unless otherwise stated, the progress shown under the “Status” column refers to the clinical development progress of the relevant drug candidate and combination therapy in China.
3. On July 19, 2022, we obtained conditional marketing approval for PUYOUHENG (Pucotenlimab Injection) (HX008) with the NMPA in MSI-H/dMMR solid tumors.

BUSINESS REVIEW

As at the date of this report, the Company has made significant progress in its pipeline products and business operations to meet investors’ expectations. The following sets out the progress the Company has made during the Reporting Period.

MRG003

- MRG003 is an ADC comprised of an EGFR-targeted mAb conjugated with the potent microtubulin disrupting payload MMAE via a vc linker. It binds specifically with high affinity to human EGFR on the surface of tumor cells, releases the potent payload upon internalization and lysosomal protease cleavage of the linker and results in tumor cell death.
- We have initiated Phase II clinical trials of MRG003 in a variety of EGFR expressing cancer types in China. Currently, we are strategically focusing on clinical investigations for HNSCC and NPC, which have demonstrated promising efficacy and indicated potential to meet these particularly significant unmet medical needs. We are currently communicating with the CDE for the possibility of conducting registrational trials. We are also exploring the potential efficacy of MRG003 in other prevalent cancer types with EGFR over-expression such as NSCLC.
 - o **HNSCC:** We are conducting an open-label, single-arm, multicenter Phase II clinical study of MRG003. Patient enrollment was completed in February 2022 and have entered into the follow-up period, and encouraging data have been observed.
 - o **NPC:** We are conducting an open-label, single-arm, multicenter Phase II clinical study of MRG003. Patient enrollment was completed in March 2022. It has entered the follow-up period and encouraging data have been observed.
 - o **NSCLC:** We are conducting Phase II clinical trials in patients with advanced NSCLC.
- **Warning under Rule 18A.08(3) of the Listing Rules:** There is no assurance that the MRG003 will ultimately be successfully developed and marketed by the Company. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the Shares.

MRG002

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

MANAGEMENT DISCUSSION AND ANALYSIS

- o **HER2 over-expressing BC:** We achieved first-patient-in in March 2022. We are currently conducting a registrational Phase II clinical trial in China and we are enrolling patients during the Reporting Period. We have observed encouraging data.
 - o **UC:** We are conducting an open label, single-arm, multicenter Phase II trial of MRG002 in HER2-positive inoperable locally advanced or metastatic HER2-expressing UC (including bladder, renal pelvis, ureter and urethral orifice) with prior treatment of first-line systemic chemotherapy. We have completed enrollment in February 2022 and have entered the follow-up period with encouraging data being observed. As of April 1, 2022, for the ITT population, the investigator-assessed ORR rate was 55%, CR was 8%, and DCR was 89%, with a median PFS of 5.8 months. On the other hand, the ORR rate in the subgroup that failed platinum-containing chemotherapy and PD-(L)1 treatment was 63% and the CR rate was 10%. The median PFS in this subgroup was 6.4 months.
 - o **HER2 low-expressing BC:** We are conducting an open-label, multicenter Phase II clinical trial in HER2 low-expressing BC with patient enrollment completed and which has entered the follow-up period.
 - o **GC/GEJ:** We are conducting an open-label, multicenter Phase II study of MRG002 in HER2-positive/low-expressing GC/GEJ patients in China with enrollment ongoing as of June 30, 2022. In the US, the patient enrollment for Phase I/II clinical trials for MRG002 in HER2-positive, locally advanced or metastatic GC/GEJ is ongoing as of June 30, 2022.
- **Warning under Rule 18A.08(3) of the Listing Rules:** There is no assurance that the MRG002 will ultimately be successfully developed and marketed by the Company. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the Shares.

HX008

- HX008 is a humanized IgG4 mAb against human PD-1, which can antagonize the PD-1 signal to restore the capability of the immune cells to kill cancer cells through blocking PD-1 binding to their ligands PD-L1 and PD-L2. In January 2022, we obtained IND clearance for HX008 in the US.
- o **MSI-H/dMMR solid tumors:** We filed an NDA of HX008 in MSI-H/dMMR solid tumors to the NMPA and it was granted priority review in October 2021, which could expedite the review and marketing approval process in China. For further development, please refer to the section “Key Events after the Reporting Period” below.
- o **Melanoma:** We filed an NDA of HX008 in melanoma to the NMPA in June 2021.
- o **GC/GEJ in second-line therapy:** We are conducting a multi-center, randomized, double-blinded and placebo-controlled Phase III clinical study of HX008 in combination therapy with irinotecan. Patient enrollment is ongoing as of June 30, 2022.
- o **Other indications:** We are in the follow-up period for Phase Ib clinical trial of HX008 in advanced solid tumors and for various Phase II clinical trials of HX008 in NSCLC, TNBC, and first-line GC/GEJ.

MANAGEMENT DISCUSSION AND ANALYSIS

- **Warning under Rule 18A.08(3) of the Listing Rules:** There is no assurance that the HX008 will ultimately be successfully developed and marketed by the Company. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the Shares.

LP002

- LP002 is a humanized anti-PD-L1 mAb with unique targeted epitope, which employs IgG1 isotype with aglycosylated mutation. It has demonstrated favorable safety and efficacy in clinical trials, which serves as the basis for the further development of combination therapies with standard of care chemotherapies.
 - o **ES-SCLC:** We have completed the patient enrollment for the single-arm, open-label Phase II clinical study of LP002 in combination therapy with carboplatin and etoposide in July 2022. It has entered the follow-up period with encouraging data being observed. Based on the encouraging efficacy data in ES-SCLC clinical study, we obtained approval from the NMPA in December 2021 regarding potentially initiating a Phase III clinical trial.
- **Warning under Rule 18A.08(3) of the Listing Rules:** There is no assurance that the LP002 will ultimately be successfully developed and marketed by the Company. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the Shares.

Combination Therapies Involving our Core Products

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

Other Clinical-stage Drug Candidates

- **MRG001:** MRG001 is a clinically advancing CD20-targeted ADC to address medical needs of B-cell NHL patients with either primary drug resistance to rituximab or acquired drug resistance to the combination therapy of rituximab and standard chemotherapies. We are conducting the Phase Ib dose expansion study of MRG001 in China.
- **MRG004A:** MRG004A is a novel TF-targeted site-specifically conjugated ADC. We are currently conducting the dose escalation trial in the US. We are initiating Phase I/II clinical trials in China as of June 30, 2022.
- **CG0070:** CG0070 is an oncolytic adenovirus for the treatment of BCG failed bladder cancer patients. We in-licensed CG0070 from CG Oncology and were granted the rights to develop, manufacture and commercialize it in greater China including Mainland China, Hong Kong and Macau. We are initiating Phase I clinical trial as of June 30, 2022 in China.

MANAGEMENT DISCUSSION AND ANALYSIS

- **CMG901:** CMG901 is a CLDN 18.2-targeting ADC comprising a CLDN 18.2-specific antibody, a cleavable linker and a toxic payload, MMAE. It is the first CLDN 18.2 ADC to have received IND clearance both in China and the U.S. CLDN 18.2 is selectively and widely expressed in GC, pancreatic cancer and other solid tumors, which makes it an ideal tumor target for therapeutic development. It is being co-developed by us and Keymed through a joint venture, KYM. We have completed the patient enrollment of dose-escalation stage of Phase I clinical trial of CMG901 in subjects with solid tumors in the first half of 2022, and plan to present and disclose the data from the Phase I clinical trial in academic papers/conferences in the future. Furthermore, we also initiated the dose-expansion stage of Phase I clinical trial of CMG901 in subjects with solid tumors in China in the second quarter of 2022. In April 2022, CMG901 for the treatment of relapsed/refractory GC and GEJ adenocarcinoma has been granted the Fast Track Designation by the FDA. Previously, we have received the Orphan-drug Designation for this indication from the FDA.
- **Warning under Rule 18A.08(3) of the Listing Rules:** There is no assurance that the MRG001, MRG004A, CG0070 and CMG901 will ultimately be successfully developed and marketed by the Company. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the Shares.

Other updates on Pipeline Products

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

Manufacturing Facilities

We are operating a 2,000L bioreactor production line at our Beijing GMP-compliant manufacturing plant, and during the Reporting Period, given all of our products remained in the research and development stage, our manufacturing activities are mainly conducted in support of our clinical trials.

During the Reporting Period, we have been building (i) the phase one of the manufacturing facilities in the Shanghai Biotech Park with a designed total capacity of 12,000L and of which the first production line with a capacity of 6,000L is under construction, and (ii) a manufacturing facility for oncolytic virus products in Beijing with a designed capacity of 200L.

Commercialization

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

With our team’s expertise and rich networks, we will mainly rely on face-to-face and onsite marketing strategy focusing on direct and interactive communication with KOLs and doctors in the respective areas to promote the differentiating clinical aspects of our products. We expect the marketing efforts will commence before the expected approval for the commercialization of a drug candidate. For HX008, we have already contacted several cancer centers, hospitals, clinics, and doctors specializing in the relevant treatment and have started to visit the sites and medical professionals in person for pre-launch training and communication.

MANAGEMENT DISCUSSION AND ANALYSIS

KEY EVENTS AFTER THE REPORTING PERIOD

Key developments of our Drug Candidates

We will continue to advance both our ongoing and planned clinical programs and trials for our pipeline products in the PRC and globally to prepare for the commercialization of our pipeline products. In particular, subsequent to the Reporting Period, on July 19, 2022, the Company obtained conditional marketing approval for PUYOUHENG (Pucotenlimab Injection) (HX008) with the NMPA in MSI-H/dMMR solid tumors. Please refer to the announcement of the Company dated July 22, 2022 for details. No material unexpected or adverse change has occurred in respect thereof since the issuance of the conditional marketing approval. Furthermore, on August 29, 2022, the FDA granted Orphan-drug Designation for MRG002 for GC/GEJ. On September 17, 2022, the CDE granted CMG901 breakthrough therapy designation for the treatment of CLDN18.2 advanced GC that was resistant/refractory or intolerant to prior systemic therapy. Furthermore, on September 20, 2022, the FDA granted Orphan-drug Designation for MRG003 for NPC.

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

Proposed issue of A Shares and listing on the Sci-Tech 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. 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 issuance of A Shares is subject to, amongst other things, approval from the Shanghai Stock Exchange and registration with the China Securities Regulatory Commission.

Proposed amendments to the Articles and relevant constitutional documents in respect of the proposed issue of A Shares

On September 1, 2022, the Company announced that it proposed to amend the Articles and relevant constitutional documents in view of the proposed issue of A Shares and listing on the Sci-Tech Board of the Shanghai Stock Exchange in accordance with relevant requirements of laws, regulations and regulatory documents. The proposed amendments to the Articles would form part of the listing application materials to be submitted to the CSRC and the Shanghai Stock Exchange for the proposed issue of A Shares and listing on the Sci-Tech Board. On September 23, 2022, the Shareholders considered and approved the amendment to the Articles and relevant constitutional documents 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 amendments to the Articles and relevant constitutional documents would come into effect after the completion of the issue of A Shares and listing on the Sci-Tech Board, and the Company will make consequential change to the number of the relevant articles as a result of the adoption of the amendments.

MANAGEMENT DISCUSSION AND ANALYSIS

Please refer to the announcement and circular of the Company both dated September 1, 2022, the supplemental announcement and circular of the Company dated September 8, 2022 and the poll results announcement of the Company dated 23 September, 2022, for further details on the proposed issue of A Shares and listing on the Sci-Tech Board of the Shanghai Stock Exchange and the proposed amendments to the Articles and relevant constitutional documents in respect of the proposed issue of A Shares.

Other key developments

The Company has been selected as a constituent stock of Hang Seng Composite Index and Hang Seng Healthcare Index by Hang Seng Indexes Company Limited, and as an eligible stock of the Shenzhen-Hong Kong Stock Connect, both with effect from September 5, 2022.

THE IMPACT OF COVID-19

The outbreak of COVID-19 and its Omicron variant continued during the Reporting Period. In particular, different cities (such as Shanghai) in the PRC implemented control measures in response to the increasing number of cases of COVID-19 infection. However, the management of the Company expected that the business operations of the Company had not been significantly affected. As our clinical trial sites are geographically dispersed, the control measures in certain cities had not significantly affected the progress of clinical trials in and outside Mainland China. Based on the information available as of the Latest Practicable Date, the Company believes that the outbreak of COVID-19 would not result in a material disruption to the Group's business operations or cause a material impact on the financial position or financial performance of the Group.

In response to the outbreak of COVID-19, we continue to take various measures, including but not limited to reducing face-to-face meetings by means of telephone or video conferences, avoiding unnecessary travels and trips for interviews as well as providing face masks, hand sanitizers and other sanitation supplies to minimise the chance of the COVID-19 infection.

FUTURE DEVELOPMENT

The Company is an innovation-driven biopharmaceutical company with a strong Chinese root and global vision. We are dedicated to discovering, developing, and commercializing first-in-class and best-in-class drug candidates in anti-tumor targeted therapy and oncology immunotherapy in the US and PRC. The mission and goal of the Company are to develop the safest, most effective, and most readily available drugs to enhance the life quality of patients and address unmet significant clinical needs in the medical system. The Company also values the continuing build-out of our own commercialization capabilities, and is determined to pursue the goal towards strong transformation from core technology to commercialized drugs.

Looking forward to the second half of 2022, we will endeavour to accelerate the commercialization of our products pipeline. Meanwhile, we will accelerate the development of two of our ADC products, being MRG002 and MRG003. On the international front, we will step up our efforts for expansion in the global market and actively seek collaboration partners.

While the establishment of our sales and marketing team in China remains one of our key focuses, we will also keep up with formulating clear business strategies. With our solid understanding of the Chinese market environment, we expect that our market access strategies will be able to meet the market demand successfully.

MANAGEMENT DISCUSSION AND ANALYSIS

FINANCIAL REVIEW

Revenue

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

Other Income

The Group's other income primarily consists of (i) investment income on financial assets at fair value through profit or loss, representing the interest we earn from structured deposits; (ii) government grants to support our research and development activities; and (iii) rental and related income.

Our other income increased from RMB4.1 million for the six months ended June 30, 2021 by RMB1.1 million to RMB5.2 million for the six months ended June 30, 2022, primarily due to an increase in subsidies received from the government.

Administrative Expenses

Our administrative expenses primarily consist of (i) employee benefit expenses (mainly including wages, salaries and bonuses and share-based payment expenses) relating to our administrative staff; (ii) depreciation and amortization expenses, primarily representing depreciation expenses for right-of-use assets and property, plant and equipment; (iii) listing expenses; and (iv) others, mainly representing utilities as well as traveling and transportation expenses. Our administrative expenses increased from RMB77.8 million for the six months ended June 30, 2021 to RMB84.7 million for the six months ended June 30, 2022, primarily due to increase in listing expenses and professional service fees by RMB12.1 million and depreciation and amortization expenses by RMB3.7 million, net off by a decrease in the employee benefit expenses in relation to our administrative staff by RMB8.6 million.

Research and Development Expenses

Our research and development expenses primarily consist of (i) clinical trial expenses, mainly in relation to our engagement of CROs, SMOs, CDMOs and hospitals; (ii) pre-clinical study costs; (iii) depreciation and amortization expenses for property, plant and equipment as well as amortization expenses for intangible assets such as intellectual properties; (iv) employee benefit expenses (mainly including wages, salaries and bonuses and share-based payment expenses) relating to our research and development staff; and (v) raw materials and consumables used, primarily representing expenses for procuring raw materials and consumables used in pre-clinical studies and clinical trials. Our research and development expenses decreased from RMB412.7 million for the six months ended June 30, 2021 to RMB230.7 million for the six months ended June 30, 2022.

MANAGEMENT DISCUSSION AND ANALYSIS

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

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

- (i) Clinical trial expenses decreased by RMB100.8 million, mainly due to a decrease in the number of enrolled patients.
- (ii) Employee benefit expenses decreased by RMB42.6 million, mainly due to a decrease in the share-based payment expenses.
- (iii) Pre-clinical study costs decreased by RMB13.9 million, mainly due to the prioritization of resources on indications and drug candidates which the Company considers have the most potential.
- (iv) Depreciation and amortization costs decreased by RMB5.7 million, mainly due to the derecognition of certain right-of-use assets.
- (v) Raw material and consumables expenses decreased by RMB18.9 million, mainly due to a decrease in the use of raw materials for our research and development activities.
- (vi) Other expenses decreased by RMB0.03 million, mainly due to a decrease in utilities and other expenses.

Other Expenses

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

MANAGEMENT DISCUSSION AND ANALYSIS

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

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

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

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

Finance Income and Finance Costs

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

Income Tax Expenses

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

Loss for the Period

Based on the factors described above, the Group's loss decreased from RMB522.7 million for the six months ended June 30, 2021 to RMB384.4 million for the six months ended June 30, 2022.

Liquidity and Financial Resources

We have incurred net losses and negative cash flows from operations since inception. Our primary use of cash is to fund our research and development activities. For the six months ended June 30, 2022, our net cash used in operating activities was RMB192.8 million, a decrease of RMB161.5 million from RMB354.3 million as of June 30, 2021. As of June 30, 2022, we had cash and cash equivalent of RMB814.5 million, an increase of RMB659.3 million from RMB155.2 million as of December 31, 2021, primarily due to the receipt of the proceeds from the Global Offering.

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

MANAGEMENT DISCUSSION AND ANALYSIS

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

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

As at 30 June 2022, approximately 21.7% (31 December 2021: 13.8%) of the Group's total bank and other borrowings carried at fixed interest rates.

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

The Group adopts conservative treasury policies in cash and financial management and a centralized treasury management system to achieve better risk control and minimize cost of funds. We review our liquidity and financing requirements regularly.

Gearing Ratio

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

Significant Investments, Material Acquisitions and Disposal

The Group did not have any significant investments or material acquisitions or disposals of subsidiaries, associates and joint ventures for the six months ended June 30, 2022.

Future Plans for Material Investments or Capital Assets

As of the date of this report, the Group did not have any concrete future plans for material capital expenditure, investments or capital assets. The Company will make further announcement(s) in accordance with the Listing Rules, where applicable, if any investments and acquisition opportunities materialize.

Capital Commitments

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

Contingent Liabilities

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

MANAGEMENT DISCUSSION AND ANALYSIS

Charges on Group Assets

As at June 30, 2022, the Group has pledged its land use rights and construction-in-progress with carrying amounts of approximately RMB59,702,000 and RMB622,574,000 respectively (31 December 2021: RMB61,559,000 and RMB562,232,000 respectively) to bank as the security for certain of the Group's bank borrowings.

Foreign Exchange Exposure

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

Employees and Remuneration

As of June 30, 2022, the Group had a total of 371 employees. The total remuneration cost of the Group for the six months ended June 30, 2022 was RMB85.6 million, as compared to RMB136.8 million for the six months ended June 30, 2021, primarily due to a decrease in the share-based payment expenses.

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

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

USE OF PROCEEDS FROM THE LISTING

On the Listing Date, the Company's shares were listed on the Stock Exchange, and on March 17, 2022, the Over-allotment Option granted as part of the Global Offering was partially exercised and the Company has allotted and issued 899,000 H Shares. The net proceeds received by the Group from the initial public offering of the Company (after deducting underwriting fee and relevant listing expenses and taking into account the net proceeds from the Over-allotment Option) amounted to approximately HK\$810.42 million (equivalent to approximately RMB657.61 million).

MANAGEMENT DISCUSSION AND ANALYSIS

The net proceeds from the Listing (pro-rata adjustment based on the actual net proceeds) have been and will be used in accordance with the purposes set out in the Prospectus. The following table sets forth the planned use of the net proceeds and the actual use as of June 30, 2022:

Proposed use	Percentage of total net proceeds	Allocation of net proceeds (RMB million)	Utilized amount	Unutilized amount
			as at June 30, 2022 (RMB million)	as at June 30, 2022 (RMB million)
a) To fund our Core Products	68.51%	450.57	20.82	429.75
• To be used for MRG003	23.00%	151.28	5.80	145.48
– To fund the clinical development and preparation for registration filings of MRG003, including the ongoing and planned clinical trials	19.27%	126.75	3.57	123.18
– To fund the manufacturing of MRG003	3.73%	24.53	2.23	22.30
• To be used for MRG002	22.01%	144.74	7.45	137.29
– To fund the clinical development and preparation for registration filings of MRG002, including the ongoing and planned clinical trials	18.65%	122.66	7.38	115.28
– To fund the manufacturing of MRG002	3.36%	22.08	0.07	22.01
• To be used for HX008	16.17%	106.30	6.79	99.51
– To fund the clinical development and preparation for registration filings of HX008, including the ongoing and planned clinical trials	7.46%	49.06	5.86	43.20
– To fund the manufacturing of HX008	6.22%	40.89	0.93	39.96
– To fund the commercialization of HX008, including marketing and sales activities	2.49%	16.35	–	16.35
• To fund the clinical development and preparation for registration filings of LP002, including the ongoing and planned clinical trials	1.24%	8.18	0.43	7.75
• To be used to fund the planned clinical development and other development activities of the combination therapies of HX008 and LP002 with our other products including MRG003, MRG002 and CG0070	6.09%	40.07	0.35	39.72

MANAGEMENT DISCUSSION AND ANALYSIS

Proposed use	Percentage of total net proceeds	Allocation of net proceeds (RMB million)	Utilized amount as at June 30, 2022 (RMB million)	Unutilized amount as at June 30, 2022 (RMB million)
b) To fund our other key clinical-stage drug candidates and our key pre-clinical drug candidates	6.35%	41.70	4.06	37.64
<ul style="list-style-type: none"> • To ongoing pre-clinical studies and planned clinical trials for the pre-clinical drug candidates in our pipeline 	0.62%	4.09	1.15	2.94
<ul style="list-style-type: none"> • To fund the clinical development and preparation for registration filings of CG0070, including ongoing and planned clinical trials and milestone payments 	1.87%	12.27	–	12.27
<ul style="list-style-type: none"> • To fund the clinical development and preparation for registration filings of MRG001, including ongoing and planned clinical trials 	1.87%	12.27	0.28	11.99
<ul style="list-style-type: none"> • To fund the clinical development and preparation for registration filings of MRG004A, including ongoing and planned clinical trials 	1.87%	12.27	2.63	9.64
<ul style="list-style-type: none"> • To fund, through our contribution to KYM, the clinical development and preparation for registration filings of CMG901, including ongoing and planned clinical trials 	0.12%	0.80	–	0.80
c) To acquire potential technologies and assets and expand our pipeline of drug candidates, including discovery of new drug candidates and business development activities and to fulfill our continuous payment obligation under our acquisition of HX008 from HanX	15.79%	103.85	–	103.85
d) For general corporate purposes	9.35%	61.49	20.26	41.23
Total	100.00%	657.61	45.14	612.47

The unutilized amount of net proceeds from the Listing is expected to be used by December 31, 2023.

OTHER INFORMATION

INTERESTS AND SHORT POSITIONS OF DIRECTORS, SUPERVISORS AND CHIEF EXECUTIVE IN SHARES, UNDERLYING SHARES AND DEBENTURES OF THE COMPANY AND ITS ASSOCIATED CORPORATIONS

As at June 30, 2022, the interests and short positions of the Directors, Supervisors and the chief executives of the Company in the Shares, underlying Shares and debentures of the Company or its associated corporation (within the meaning of Part XV of the SFO) which were required to be recorded in the register kept by the Company pursuant to section 352 of the SFO, or which were otherwise required, to be notified to the Company and the Stock Exchange pursuant to the Model Code, are set out below:

Interests of our Directors in the Shares or Underlying Shares of the Company

Long position in the Shares as at June 30, 2022

Name of Director	Class of Shares	Nature of Interest	Number of Shares or underlying Shares	Approximate percentage in relevant class of Shares ⁽¹⁾	Approximate percentage in the total registered share capital ⁽¹⁾
Dr. Pu Zhongjie ⁽²⁾	H Shares	Interests in controlled corporation	658,591,549	41.03%	39.69%
Dr. Hu Chaohong ⁽³⁾	H Shares	Interests in controlled corporation	138,978,106	8.66%	8.37%
Ms. Pu Jue ⁽⁴⁾	H Shares	Interests in controlled corporation	90,000,000	5.61%	5.42%
Mr. Lin Xianghong ⁽⁵⁾	H Shares	Beneficiary of a discretionary trust	21,859,000	1.36%	1.32%

Notes:

- (1) The calculation is based on the total number of 1,659,444,838 Shares, including 1,605,176,474 H Shares and 54,268,364 Domestic Shares, issued as at June 30, 2022.
- (2) Ningbo Houde Yimin directly holds 433,239,436 H Shares as beneficial owner, and Ningbo Houde Yimin is held as to 100% by Beijing Houde Yimin, which is in turn held as to 100% by Dr. Pu Zhongjie, one of the executive Directors and the chairman of the Board. In addition, Lepu Medical directly holds 225,352,113 H Shares as beneficial owner, and Dr. Pu Zhongjie is the actual controller of Lepu Medical. Dr. Pu Zhongjie is therefore deemed to be interested in the 433,239,436 H Shares and the 225,352,113 H Shares held by Ningbo Houde Yimin and Lepu Medical, respectively.
- (3) Miracogen HK directly holds 138,978,106 H Shares as beneficial owner, and Miracogen HK is held as to 100% by Miracogen Inc., which is in turn held as to 100% by Dr. Hu Chaohong, one of the executive Directors and a co-chief executive officer of the Company. Dr. Hu Chaohong is therefore deemed to be interested in the 138,978,106 H Shares held by Miracogen HK.
- (4) Shanghai Lvyan directly holds 90,000,000 H Shares as beneficial owner, and Shanghai Lvyan is held as to 100% by Cereblue Limited, which is in turn held as to 100% by Ms. Pu Jue, one of the non-executive Directors. Ms. Pu Jue is therefore deemed to be interested in the 90,000,000 H Shares held by Shanghai Lvyan.
- (5) King Star Med LP directly holds 21,859,000 H Shares as beneficial owner, and the general partner and manager of King Star Med LP, namely King Star Med Management Limited and King Star Consulting Limited, are both indirectly held by Ace Treasure Trust and Superb Outcome Trust (the "Trusts") as to 40% and 30%, respectively. Mr. Lin Xianghong, a non-executive Director, is the settlor, the protector and one of the beneficiaries of the Trusts. Under the SFO, as settlor and beneficiary of such Trusts, Mr. Lin Xianghong is deemed to be interested in the H Shares held by King Star Med LP.

OTHER INFORMATION

Interests of our Directors in the Shares or Underlying Shares of Associated Corporations

Hangzhou Healsun Biopharma Co., Ltd.

Long position in the shares as at June 30, 2022

Name of Director	Class of Shares	Nature of Interest	Amount of registered capital subscribed (RMB)	Approximate percentage of shareholding
Mr. Lin Xianghong ⁽⁶⁾	Domestic Shares	Interests in controlled corporation	933,333	5.41%

Notes:

- (6) Suzhou Yipu No. 2 Venture Investment Limited Partnership* 蘇州翼樸二號創業投資合夥企業(有限合夥) (“Yipu LP”) directly holds 5.41% interests in Hangzhou Healsun Biopharma Co., Ltd., a company owned by us as to 23.2% and is an associated corporation of the Company under Part XV of the SFO. The general partner of Yipu LP is Suzhou Yipu No. 2 Zhechuang Management Consultation Limited Partnership* (蘇州翼樸二號諮詢管理諮詢合夥企業(有限合夥)), in which Mr. Lin Xianghong, one of the non-executive Directors, holds 50% interests in. Mr. Lin Xianghong is therefore deemed to be interested in the shares in Hangzhou Healsun Biopharma Co., Ltd. held by Yipu LP.

Save as disclosed above, so far as the Directors are aware, as at June 30, 2022, none of the Directors, Supervisors or chief executives of the Company had any interests and/or short positions in the Shares, underlying Shares and debentures of the Company or its associated corporations, recorded in the register required to be kept under section 352 of the SFO or required to be notified to the Company and the Stock Exchange pursuant to the Model Code.

INTERESTS AND SHORT POSITIONS OF SUBSTANTIAL SHAREHOLDERS IN SHARES AND UNDERLYING SHARES OF THE COMPANY

So far as is known to the Company, as at June 30, 2022, the following persons, other than a Director, Supervisor or chief executive of the Company, had an interest of 5% or more in the Shares or underlying Shares which were required to be disclosed to the Company pursuant to the provisions of Divisions 2 and 3 of Part XV of the SFO and recorded in the register required to be kept pursuant to Section 336 of the SFO:

OTHER INFORMATION

Long position in the Shares as at June 30, 2022

Name of Shareholder	Class of Shares	Nature of Interest	Number of Shares or underlying Shares	Approximate percentage in relevant class of Shares ⁽¹⁾	Approximate percentage in the total registered share capital ⁽¹⁾
Mr. Su Rongyu	H Shares	Beneficial interest	100,000,000	6.23%	6.03%
Ms. Hao Chunmei ⁽²⁾	H Shares	Interests of spouse	100,000,000	6.23%	6.03%
Kington Capital No. 1 Equity Investment Partnership (Limited Partnership)* 蘇州翼樸一號股權投資合夥企業 (有限合夥) ("Kington Capital")	H Shares	Beneficial interest	39,436,621	2.46%	2.38%
	Domestic Shares	Beneficial interest	39,436,620	72.67%	2.38%
Suzhou Yipu No. 1 Chuangzhe Management Consultation Limited Partnership* 蘇州翼樸一號創喆管理諮詢合夥企業 (有限合夥) ⁽³⁾	H Shares	Interest in controlled corporation	39,436,621	2.46%	2.38%
	Domestic Shares	Interest in controlled corporation	39,436,620	72.67%	2.38%
Suzhou Suzi Investment Limited Partnership* 蘇州蘇梓投資合夥企業 (有限合夥) ("Suzhou Suzi")	H Shares	Beneficial interest	9,859,155	0.61%	0.59%
	Domestic Shares	Beneficial interest	9,859,155	18.17%	0.59%
Suzhou Zisu Investment Consultation Limited Partnership* 蘇州梓蘇投資諮詢合夥企業 (有限合夥) ⁽⁴⁾	H Shares	Interest in controlled corporation	9,859,155	0.61%	0.59%
	Domestic Shares	Interest in controlled corporation	9,859,155	18.17%	0.59%
Shanghai Qianyu Equity Investment Fund Management Co., Ltd.* 上海前宇股權投資基金管理 有限公司 ⁽⁴⁾	H Shares	Interest in controlled corporation	9,859,155	0.61%	0.59%
	Domestic Shares	Interest in controlled corporation	9,859,155	18.17%	0.59%
Suzhou Yumeng Investment Management Co., Ltd.* 蘇州宇夢投資管理有限公司 ⁽⁴⁾	H Shares	Interest in controlled corporation	9,859,155	0.61%	0.59%
	Domestic Shares	Interest in controlled corporation	9,859,155	18.17%	0.59%

OTHER INFORMATION

Name of Shareholder	Class of Shares	Nature of Interest	Number of Shares or underlying Shares	Approximate percentage in relevant class of Shares ⁽¹⁾	Approximate percentage in the total registered share capital ⁽¹⁾
Qian Xin (錢鑫) ⁽⁴⁾	H Shares	Interest in controlled corporation	9,859,155	0.61%	0.59%
	Domestic Shares	Interest in controlled corporation	9,859,155	18.17%	0.59%
Yinhua Changan Capital Management (Beijing) Co., Ltd.* 銀華長安資本管理(北京)有限公司 ⁽⁴⁾	H Shares	Interest in controlled corporation	9,859,155	0.61%	0.59%
	Domestic Shares	Interest in controlled corporation	9,859,155	18.17%	0.59%
Yinhua Fund Management Co., Ltd.* 銀華基金管理股份有限公司 ⁽⁴⁾	H Shares	Interest in controlled corporation	9,859,155	0.61%	0.59%
	Domestic Shares	Interest in controlled corporation	9,859,155	18.17%	0.59%
Southwest Securities Co., Ltd. (西南證券有限責任公司) ⁽⁴⁾	H Shares	Interest in controlled corporation	9,859,155	0.61%	0.59%
	Domestic Shares	Interest in controlled corporation	9,859,155	18.17%	0.59%
Chongqing Yufu Capital Management Group Co., Ltd.* 重慶渝富資本運營集團有限公司 ⁽⁴⁾	H Shares	Interest in controlled corporation	9,859,155	0.61%	0.59%
	Domestic Shares	Interest in controlled corporation	9,859,155	18.17%	0.59%

OTHER INFORMATION

Name of Shareholder	Class of Shares	Nature of Interest	Number of Shares or underlying Shares	Approximate percentage in relevant class of Shares ⁽¹⁾	Approximate percentage in the total registered share capital ⁽¹⁾
Chongqing Yufu Holding Group Co., Ltd.* 重慶渝富控股集團有限公司 ⁽⁴⁾	H Shares	Interest in controlled corporation	9,859,155	0.61%	0.59%
	Domestic Shares	Interest in controlled corporation	9,859,155	18.17%	0.59%
State-Owned Assets Supervision and Administration Commission of Chongqing Municipal Government ⁽⁴⁾	H Shares	Interest in controlled corporation	9,859,155	0.61%	0.59%
	Domestic Shares	Interest in controlled corporation	9,859,155	18.17%	0.59%
Suzhou Kington Equity Investment Fund Management Co., Ltd. (蘇州翼樸股權投資基金管理有限公司) ⁽⁵⁾	H Shares	Interest in controlled corporation	49,295,776	3.07%	2.97%
	Domestic Shares	Interest in controlled corporation	49,295,775	90.84%	2.97%
Suzhou Private Capital Investment Holdings Co., Ltd. (蘇州民營資本投資控股有限公司) ⁽⁶⁾	H Shares	Interest in controlled corporation	49,295,776	3.07%	2.97%
	Domestic Shares	Interest in controlled corporation	49,295,775	90.84%	2.97%
Shanghai Healthcare Capital Partnership (Limited Partnership) (上海生物醫藥產業股權投資基金合夥企業(有限合夥)) (“SHC”)	H Shares	Beneficial interest	10,962,335	0.68%	0.66%
	Domestic Shares	Beneficial interest	3,654,111	6.73%	0.22%
Shanghai Healthcare Capital Investment Fund Co., Ltd. (上海生物醫藥產業股權投資基金管理有限公司) ⁽⁷⁾	H Shares	Interest in controlled corporation	10,962,335	0.68%	0.66%
	Domestic Shares	Interest in controlled corporation	3,654,111	6.73%	0.22%

OTHER INFORMATION

Notes:

- (1) The calculation is based on the total number of 1,659,444,838 Shares, including 1,605,176,474 H Shares and 54,268,364 Domestic Shares, issued as at June 30, 2022.
- (2) Ms. Hao Chunmei is the spouse of Mr. Su Rongyu, and is therefore deemed to be interested in the H Shares beneficially held by Mr. Su Rongyu.
- (3) Suzhou Yipu No. 1 Chuangzhe Management Consultation Limited Partnership is the general manager of Kington Capital and therefore is deemed to be interested in our Shares held by Kington Capital.
- (4) Suzhou Zisu Investment Consultation Limited Partnership is the general partner of Suzhou Suzi, with Suzhou Kington Equity Investment Fund Management Co., Ltd. being its general partner and Shanghai Qianyu Equity Investment Fund Management Co., Ltd. being its limited partners holding 50% partnership interest. Suzhou Kington Equity Investment Fund Management Co., Ltd. is wholly owned by Suzhou Private Capital Investment Holdings Co., Ltd. Shanghai Qianyu Equity Investment Fund Management Co., Ltd. is owned as to 60% by Suzhou Yumeng Investment Management Co., Ltd., a company owned by Qian Xin as to 99.50%.

Yinhua Changan Capital Management (Beijing) Co., Ltd. is the limited partner of Suzhou Suzi holding 69.47% partnership interest, which in turn is wholly owned by Yinhua Fund Management Co., Ltd. Southwest Securities Co., Ltd. owns 49% equity interest in Yinhua Fund Management Co., Ltd. and is owned by Chongqing Yufu Capital Management Group Co., Ltd. as to 56.63%. Chongqing Yufu Capital Management Group Co., Ltd. is a wholly owned subsidiary of Chongqing Yufu Holding Group Co., Ltd., a company wholly owned by the State-Owned Assets Supervision and Administration Commission of Chongqing Municipal Government.

Therefore, each of Suzhou Zisu Investment Consultation Limited Partnership, Suzhou Kington Equity Investment Fund Management Co., Ltd., Shanghai Qianyu Equity Investment Fund Management Co., Ltd., Suzhou Yumeng Investment Management Co., Ltd., Qian Xin, Yinhua Changan Capital Management (Beijing) Co., Ltd., Yinhua Fund Management Co., Ltd., Southwest Securities Co., Ltd., Chongqing Yufu Capital Management Group Co., Ltd., Chongqing Yufu Holding Group Co., Ltd. and the State-Owned Assets Supervision and Administration Commission of Chongqing Municipal Government is deemed to be interested in our Shares held by Suzhou Suzi.
- (5) Suzhou Kington Equity Investment Fund Management Co., Ltd. is the general partner of Suzhou Yipu No. 1 Chuangzhe Management Consultation Limited Partnership and Suzhou Zisu Investment Consultation Limited Partnership, therefore deemed to be interested in our Shares held by Kington Capital and Suzhou Suzi.
- (6) Suzhou Private Capital Investment Holdings Co., Ltd. holds 100% equity interest in Suzhou Kington Equity Investment Fund Management Co., Ltd. and is therefore deemed to be interested in our Shares held by Kington Capital and Suzhou Suzi.
- (7) Shanghai Healthcare Capital Investment Fund Co., Ltd. is the general partner of SHC and therefore is deemed to be interested in our Shares held by SHC.

Save as disclosed above, as at June 30, 2022, the Company had not been notified of any persons (other than a Director, Supervisor or chief executive of the Company) who had an interest or short position in the Shares or underlying Shares that were recorded in the register required to be kept under section 336 of the SFO.

ARRANGEMENTS TO PURCHASE SHARES OR DEBENTURES

At no time during the Reporting Period was the Company or any of its subsidiaries a party to any arrangements to enable the Directors to acquire benefits by means of the acquisition of shares in, or debentures of, the Company or any other body corporate; and none of the Directors, or any of their spouse or children under the age of 18, had any right to subscribe for equity or debt securities of the Company or any other body corporate, or had exercised any such right.

PURCHASE, SALE AND REDEMPTION OF LISTED SECURITIES OF THE COMPANY

Neither the Company nor any of its subsidiaries had purchased, sold or redeemed any of the listed securities of the Company since the Listing Date and up to June 30, 2022.

COMPLIANCE WITH THE CORPORATE GOVERNANCE CODE

As the Company was not a listed company until the Listing Date, the Corporate Governance Code was not applicable to the Company before the Listing Date. Since the Listing Date and up to June 30, 2022, 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.

CHANGES IN DIRECTORS' AND SUPERVISORS' INFORMATION

On August 24, 2022, Dr. Sui Ziyi ceased to be a non-executive director of Star Combo Pharma Limited, a company listed on the Australian Stock Exchange (stock code: 566).

Save as disclosed above, there are no material changes in Directors, Supervisors and senior management of the Company and their respective biographies during the Reporting Period and up to the Latest Practicable Date that need to be disclosed pursuant to Rule 13.51B(1) of the Listing Rules.

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 since the Listing Date and up to June 30, 2022. No incident of non-compliance of the Model Code by the employees who are likely to be in possession of inside information of the Company was noted by the Company.

REVIEW OF INTERIM REPORT

The independent auditor of the Company, namely, PricewaterhouseCoopers, has carried out a review of the interim financial information in accordance with the International Standard on Review Engagements 2410, "Review of Interim Financial Information Performed by the Independent Auditor of the Entity" issued by the Hong Kong Institute of Certified Public Accountants. The Audit Committee has jointly reviewed with the management and the independent auditor of the Company the accounting principles and policies adopted by the Group and the Group's financial reporting matters (including the review of the unaudited condensed consolidated interim financial statements for the six months ended June 30, 2022 and this interim report). The Audit Committee considered that the interim results are in compliance with the applicable accounting standards, laws and regulations, and the Company has made appropriate disclosures thereof.

INTERIM DIVIDEND

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

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

Shanghai, the PRC
September 27, 2022

REPORT ON REVIEW OF INTERIM FINANCIAL INFORMATION

To the Board of Directors of Lepu Biopharma Co., Ltd.

(incorporated in the People's Republic of China with limited liability)

INTRODUCTION

We have reviewed the interim financial information set out on pages 27 to 52, which comprises the interim condensed consolidated balance sheet of Lepu Biopharma Co., Ltd. (the “**Company**”) and its subsidiaries (together, the “**Group**”) as at 30 June 2022 and the interim condensed consolidated statement of comprehensive loss, the interim condensed consolidated statement of changes in equity and the interim condensed consolidated statement of cash flows for the six-month period then ended, and notes, comprising significant accounting policies and other explanatory information. The Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited require the preparation of a report on interim financial information to be in compliance with the relevant provisions thereof and International Accounting Standard 34 “Interim Financial Reporting”. The directors of the Company are responsible for the preparation and presentation of this interim financial information in accordance with International Accounting Standard 34 “Interim Financial Reporting”. Our responsibility is to express a conclusion on this interim financial information based on our review and to report our conclusion solely to you, as a body, in accordance with our agreed terms of engagement and for no other purpose. We do not assume responsibility towards or accept liability to any other person for the contents of this report.

SCOPE OF REVIEW

We conducted our review in accordance with International Standard on Review Engagements 2410, “Review of Interim Financial Information Performed by the Independent Auditor of the Entity”. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

CONCLUSION

Based on our review, nothing has come to our attention that causes us to believe that the interim financial information of the Group is not prepared, in all material respects, in accordance with International Accounting Standard 34 “Interim Financial Reporting”.

OTHER MATTER

The comparative information for the interim condensed consolidated balance sheet is based on the audited financial statements as at 31 December 2021. The comparative information for the interim condensed consolidated statements of comprehensive loss, the interim condensed consolidated statement of changes in equity and the interim condensed consolidated statement of cash flows, and related explanatory notes, for the six-month period ended 30 June 2021 has not been audited or reviewed.

PricewaterhouseCoopers

Certified Public Accountants

Hong Kong, 25 August 2022

INTERIM CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

	Note	Six months ended 30 June	
		2022 RMB'000 (Unaudited)	2021 RMB'000 (Unaudited)
Other income	8	5,162	4,113
Other expenses	9	(200)	(530)
Administrative expenses	9	(84,729)	(77,755)
Research and development expenses	9	(230,706)	(412,667)
Fair value changes on financial assets and liabilities at fair value through profit or loss	10	(60,776)	(34,279)
Other gains/(losses), net	11	554	(954)
Operating loss		(370,695)	(522,072)
Finance income		36,754	3,216
Finance costs		(2,790)	(2,616)
Finance income, net	12	33,964	600
Share of loss of investments accounted for using the equity method	18	(11,643)	(1,251)
Loss before income tax		(348,374)	(522,723)
Income tax expense	13	–	–
Loss for the period		(348,374)	(522,723)
Loss attributable to:			
Owners of the Company		(344,286)	(511,954)
Non-controlling interests		(4,088)	(10,769)
		(348,374)	(522,723)
Loss per share for loss attributable to owners of the Company for the period (expressed in RMB per share)			
– Basic	14	(0.21)	(0.34)
– Diluted	14	(0.21)	(0.34)
Other comprehensive income			
<i>Items that may be subsequently reclassified to profit or loss</i>			
Currency translation differences		132	7
Total comprehensive loss		(348,242)	(522,716)
Total comprehensive loss attributable to:			
Owners of the Company		(344,154)	(511,947)
Non-controlling interests		(4,088)	(10,769)
		(348,242)	(522,716)

The above condensed consolidated statement of comprehensive loss should be read in conjunction with the accompanying notes.

INTERIM CONDENSED CONSOLIDATED BALANCE SHEET

		As at June 30	As at December 31
	Note	2022 RMB'000 (Unaudited)	2021 RMB'000 (Audited)
Assets			
Non-current assets			
Property, plant and equipment	15	881,512	836,713
Right-of-use assets	16	128,244	141,724
Intangible assets	17	460,473	475,090
Investments accounted for using the equity method	18	126,328	137,971
Other receivables, prepayments and deposits		103,968	176,431
Total non-current assets		1,700,525	1,767,929
Current assets			
Inventories	19	27,549	24,184
Other receivables, prepayments and deposits		100,401	84,780
Cash and cash equivalents		814,488	155,168
Term deposits with initial terms of over three months		–	50,000
Total current assets		942,438	314,132
Total assets		2,642,963	2,082,061
Equity			
Equity attributable to owners of the Company			
Share capital	20	1,659,445	1,531,670
Reserves		1,533,242	947,482
Accumulated losses		(1,986,724)	(1,642,438)
		1,205,963	836,714
Non-controlling interests	27	6,288	10,369
Total equity		1,212,251	847,083

INTERIM CONDENSED CONSOLIDATED BALANCE SHEET

		As at June 30	As at December 31
	Note	2022 RMB'000 (Unaudited)	2021 RMB'000 (Audited)
Liabilities			
Non-current liabilities			
Borrowings	22	255,263	232,469
Lease liabilities		9,718	19,478
Deferred government grants		12,000	12,000
Deferred tax liabilities	23	37,687	37,687
Financial liabilities at fair value through profit or loss	24	442,684	384,287
Total non-current liabilities		757,352	685,921
Current liabilities			
Borrowings	22	167,170	60,409
Trade payables	25	188,868	158,818
Other payables and accruals		295,129	311,043
Lease liabilities		22,193	18,787
Total current liabilities		673,360	549,057
Total liabilities		1,430,712	1,234,978
Total equity and liabilities		2,642,963	2,082,061

The above condensed consolidated balance sheet should be read in conjunction with the accompanying notes.

INTERIM CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

	Note	Attributable to owners of the Company			Non-controlling interests	Total
		Share capital	Reserves	Accumulated losses		
		RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
At 1 January 2021		1,492,693	612,260	(631,442)	28,211	1,501,722
Comprehensive loss						
Loss for the period		-	-	(511,954)	(10,769)	(522,723)
Other comprehensive income		-	7	-	-	7
Transaction with owners						
Issuance of shares to series C investors	20	38,977	221,720	-	-	260,697
Share-based payments	21	-	76,062	-	13	76,075
At 30 June 2021 (Unaudited)		1,531,670	910,049	(1,143,396)	17,455	1,315,778
At 1 January 2022		1,531,670	947,482	(1,642,438)	10,369	847,083
Comprehensive loss						
Loss for the period		-	-	(344,286)	(4,088)	(348,374)
Other comprehensive income		-	132	-	-	132
Transaction with owners						
Issuance of ordinary shares upon global offering	20	127,775	578,165	-	-	705,940
Share-based payments	21	-	7,463	-	7	7,470
At 30 June 2022		1,659,445	1,533,242	(1,986,724)	6,288	1,212,251

The above condensed consolidated statement of changes in equity should be read in conjunction with the accompanying notes.

INTERIM CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS

	Six months ended 30 June	
	2022 RMB'000 (Unaudited)	2021 RMB'000 (Unaudited)
Cash flows from operating activities		
Cash used in operations	(194,418)	(357,588)
Interest received	1,636	3,291
Net cash used in operating activities	(192,782)	(354,297)
Cash flows from investing activities		
Investments in associates	–	(1)
Purchases of property, plant and equipment	(61,598)	(103,509)
Purchases of financial assets at fair value through profit or loss	(37,000)	(850,000)
Proceeds from disposal of financial assets at fair value through profit or loss	37,158	1,034,057
Placement of term deposits with initial terms of over three months	–	(50,000)
Withdrawal of term deposits with initial terms of over three months	50,613	20,000
Net cash (used in)/generated from investing activities	(10,827)	50,547
Cash flows from financing activities		
Capital contributions from shareholders	–	261,120
Proceeds from issuance of ordinary shares upon global offering	739,227	–
Payments for listing expenses	(30,971)	(1,752)
Proceeds from bank borrowings	139,555	–
Repayments of bank borrowings	(10,000)	–
Payments of lease liabilities		
– Principal	(2,153)	(11,872)
– Interest	(664)	(1,084)
Bank loan interest and other finance costs paid	(7,173)	(3,126)
Net cash generated from financing activities	827,821	243,286
Net increase/(decrease) in cash and cash equivalents	624,212	(60,464)
Cash and cash equivalents at the beginning of period	155,168	402,867
Effects of exchange rate changes on cash and cash equivalents	35,108	(1,175)
Cash and cash equivalents at end of period	814,488	341,228

The above condensed consolidated statement of cash flows should be read in conjunction with the accompanying notes.

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

1 GENERAL INFORMATION

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

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

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

This interim condensed consolidated financial information for the six months ended 30 June 2022 has been reviewed, not audited.

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

2 SIGNIFICANT EVENT

- (a) On 23 February 2022, the Company has completed a global offering of 126,876,000 H Shares of par value of RMB1.00 each at the price of HK\$7.13 per H Share (the “**Offering Price**”), and its shares were listed on the Main Board of The Stock Exchange of Hong Kong Limited. The gross proceeds arisen from the listing amounted to approximately HK\$905 million (equivalent of RMB734 million). On 22 March 2022, the Company issued additional 899,000 new H Shares upon the exercises of over-allotment of the global offering at the Offering Price, and gross proceeds arisen amounted to approximately HK\$6 million (equivalent of RMB5 million). Details please refer to Note 20.
- (b) In view of the outbreak of the Omicron variant and the control measures in different cities (such as Shanghai) in 2022, the Company believes that Coronavirus Disease 2019 (“**COVID-19**”) would not result in a material disruption to the Group’s business operations or cause a material impact on the financial position or financial performance of the Group. As the Group’s clinical trial sites are geographically dispersed, the control measures in certain cities had not significantly affected the progress of clinical trials in and outside Mainland China. The Group will continue to closely monitor the development of the COVID-19 outbreak and take appropriate counter-measures if any adverse impact is arising.

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

3 BASIS OF PREPARATION

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

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

4 SIGNIFICANT ACCOUNTING POLICIES

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

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

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

The Group has not early adopted the new standards and amendments to IFRSs that have been issued and not yet effective for the year ended 31 December 2021 in the interim condensed consolidated financial information.

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

5 ESTIMATES

The preparation of interim condensed consolidated financial information requires management to make judgements, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets and liabilities, income and expense. Actual results may differ from these estimates.

In preparing this interim condensed consolidated financial information, the significant judgments made by management in applying the Group's accounting policies and the key sources of estimation uncertainty were the same as those that applied to the 2021 Annual Financial Statements.

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

6 FINANCIAL RISK MANAGEMENT

6.1 Financial risk factors

The Group's activities expose it to a variety of financial risks: market risk, credit risk and liquidity risk.

The interim condensed consolidated financial information does not include all financial risk management information and disclosures required in the annual financial statements, and should be read in conjunction with the 2021 Annual Financial Statements.

There have been no significant changes in the risk management policies since 31 December 2021.

6.2 Liquidity risk

There was no material change in the contractual undiscounted cash out flows for financial liabilities.

The Group is not subject to any significant liquidity risk in view of the sufficiency of its working capital.

6.3 Fair value estimation

Financial assets at fair value through profit or loss of the Group represents the structured deposits from banks with expected but not guaranteed rates of return.

Financial liabilities at fair value through profit or loss represents the variable consideration payable arisen from acquisition of 40% equity interests of certain subsidiary from non-controlling interest.

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

6 FINANCIAL RISK MANAGEMENT (CONTINUED)

6.3 Fair value estimation (continued)

The following table presents the Group's liabilities that were measured at fair value as at 30 June 2022 and 31 December 2021.

	Level 1 RMB'000	Level 2 RMB'000	Level 3 RMB'000	Total RMB'000
At 30 June 2022				
Financial liabilities				
Financial liabilities at fair value through profit or loss (Note 24)	–	–	446,242	446,242
At 31 December 2021				
Financial liabilities				
Financial liabilities at fair value through profit or loss (Note 24)	–	–	385,466	385,466

- (a) The following table presents the changes in Level 3 of financial assets at fair value through profit or loss for the six months ended 30 June 2022 and 2021:

	Six months ended 30 June	
	2022 RMB'000	2021 RMB'000
Opening balance	–	330,657
Additions	37,000	850,000
Settlements	(37,158)	(1,034,057)
Gains recognised in profit or loss	158	3,758
Closing balance	–	150,358
Net unrealized gains for the period	–	358

- (b) The changes of financial liabilities at fair value through profit or loss for the six months ended 30 June 2022 and 2021 are presented in Note 24.

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

7 SEGMENT INFORMATION

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

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

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

8 OTHER INCOME

	Six months ended 30 June	
	2022 RMB'000	2021 RMB'000
Government grants	4,478	135
Investment income on financial assets at fair value through profit or loss	158	3,400
Rental and related income	–	550
Others	526	28
	5,162	4,113

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

9 EXPENSES BY NATURE

	Six months ended 30 June	
	2022 RMB'000	2021 RMB'000
Clinical trial expenses	87,034	187,876
Employee benefit expenses	85,580	136,839
Depreciation and amortisation	45,315	47,507
Pre-clinical study costs	37,568	51,479
Raw material and consumables used	9,797	28,691
Professional services fees	1,808	872
Utilities	2,177	2,531
Office expenses	1,452	1,342
Traveling and transportation expenses	1,102	2,465
Auditors' remuneration	800	–
Listing expenses	33,466	22,309
Others	9,536	9,041
Total administrative expenses, research and development expenses and other expenses	315,635	490,952

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

	Six months ended 30 June	
	2022 RMB'000	2021 RMB'000
Fair value losses on financial liabilities at fair value through profit or loss (Note 24)	(60,776)	(34,637)
Fair value gains on financial assets at fair value through profit or loss	–	358
	(60,776)	(34,279)

11 OTHER GAINS/(LOSSES), NET

	Six months ended 30 June	
	2022 RMB'000	2021 RMB'000
Net gains on disposal of right-of use assets (Note 16)	608	–
Expected credit (losses)/gains	(54)	90
Others	–	(1,044)
	554	(954)

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

12 FINANCE INCOME AND COSTS

	Six months ended 30 June	
	2022 RMB'000	2021 RMB'000
Bank interest income	1,778	3,216
Net exchange gain	34,976	–
Finance income	36,754	3,216
Interest on bank borrowings	(7,248)	(3,107)
Interest on lease liabilities	(709)	(1,182)
Bank charges	(488)	(252)
Net exchange loss	–	(1,182)
	(8,445)	(5,723)
Less: Amount capitalised (a)	5,655	3,107
Finance costs	(2,790)	(2,616)
Finance income, net	33,964	600

- (a) The capitalisation rates used to determine the amount of borrowing costs to be capitalised are the weighted average interest rates applicable to the Group's borrowings, which are 4.18% and 4.20% for the six months ended 30 June 2022 and 2021 respectively.

13 INCOME TAX EXPENSE

	Six months ended 30 June	
	2022 RMB'000	2021 RMB'000
Current income tax expense	–	–
Deferred income tax expense	–	–
Income tax expense	–	–

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

Shanghai Miracogen Inc. ("Miracogen Shanghai") is qualified as a High and New Technology Enterprise ("HNTE") under the relevant PRC laws and regulations on 18 November 2020. Accordingly, it was entitled to a preferential corporate income tax rate of 15% on its estimated assessable profits for the years ended 31 December 2020 to 2022.

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

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

13 INCOME TAX EXPENSE (CONTINUED)

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

According to the relevant laws and regulations promulgated by the State Administration of Taxation of the PRC that has been effective from 2018 onwards, enterprise engaging in research and development activities are entitled to claim 175% of their research and development expenses incurred as tax deductible expenses when determining their assessable profits for that year. Pursuant to the relevant tax regulations, effective from 2021 onwards, manufacturing enterprises are entitled to claim 200% of their research and development expenses incurred as tax deductible expenses.

14 LOSS PER SHARE

(a) Basic loss per share

Basic loss per share is calculated by dividing:

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

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

(b) Diluted loss per share

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

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

15 PROPERTY, PLANT AND EQUIPMENT

	Equipment and instruments RMB'000	Office equipment and furniture RMB'000	Motor vehicles RMB'000	Leasehold improvements and Antibody purification resin RMB'000	Construction-in-progress RMB'000	Total RMB'000
At 31 December 2021						
Cost	173,566	20,543	951	102,415	633,350	930,825
Accumulated depreciation	(33,663)	(7,952)	(466)	(52,031)	–	(94,112)
Net book amount	139,903	12,591	485	50,384	633,350	836,713
Six months ended 30 June 2022						
Opening net book amount	139,903	12,591	485	50,384	633,350	836,713
Additions	1,438	179	–	–	67,260	68,877
Transfer upon completion	5,610	–	–	–	(5,610)	–
Depreciation charge	(8,712)	(2,490)	(68)	(12,808)	–	(24,078)
Closing net book amount	138,239	10,280	417	37,576	695,000	881,512
At 30 June 2022						
Cost	180,614	20,722	951	102,415	695,000	999,702
Accumulated depreciation	(42,375)	(10,442)	(534)	(64,839)	–	(118,190)
Net book amount	138,239	10,280	417	37,576	695,000	881,512

16 RIGHT-OF-USE ASSETS

	Land use rights RMB'000	Leased equipment RMB'000	Leased properties RMB'000	Total RMB'000
At 31 December 2021				
Cost	128,817	4,402	75,671	208,890
Accumulated depreciation	(16,958)	(4,402)	(45,806)	(67,166)
Net book amount	111,859	–	29,865	141,724
Six months ended 30 June 2022				
Opening net book amount	111,859	–	29,865	141,724
Additions	–	–	–	–
Disposal	–	–	(3,638)	(3,638)
Depreciation charge	(3,221)	–	(6,621)	(9,842)
Closing net book amount	108,638	–	19,606	128,244
At 30 June 2022				
Cost	128,817	–	57,787	186,604
Accumulated depreciation	(20,179)	–	(38,181)	(58,360)
Net book amount	108,638	–	19,606	128,244

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

17 INTANGIBLE ASSETS

	Goodwill RMB'000	Intellectual properties RMB'000	Total RMB'000
At 31 December 2021			
Cost	52,636	515,908	568,544
Accumulated amortisation	–	(93,454)	(93,454)
Net book amount	52,636	422,454	475,090
Six months ended 30 June 2022			
Opening net book amount	52,636	422,454	475,090
Additions	–	–	–
Amortisation charge	–	(14,617)	(14,617)
Closing net book amount	52,636	407,837	460,473
At 30 June 2022			
Cost	52,636	515,908	568,544
Accumulated amortisation	–	(108,071)	(108,071)
Net book amount	52,636	407,837	460,473

Note: Management has assessed and concluded that no provision for impairment of goodwill has to be recognised as of 30 June 2022 (31 December 2021: Nil).

18 INVESTMENTS ACCOUNTED FOR USING THE EQUITY METHOD

The amounts recognised in the interim condensed consolidated balance sheet are as follows:

	As at 30 June 2022 RMB'000	As at 31 December 2021 RMB'000
Associates	126,328	137,971

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

18 INVESTMENTS ACCOUNTED FOR USING THE EQUITY METHOD (CONTINUED)

The amounts recognised in the interim condensed consolidated statement of comprehensive loss are as follows:

	Six months ended 30 June	
	2022 RMB'000	2021 RMB'000
Associates	(11,643)	(1,251)

Note: Movements in the Group's interest in the associates are as follows:

	Six months ended 30 June	
	2022 RMB'000	2021 RMB'000
At beginning of the period	137,971	160,294
Additions	–	1
Share of loss of investments	(11,643)	(8,545)
Dilution of the ownership interest (i)	–	7,294
At end of the period	126,328	159,044

(i) During the six months ended 30 June 2021, Hangzhou HealSun Biotechnology Co., Ltd. ("Hangzhou HealSun") has completed new financing activity by issuing share capital to certain investors, the percentage of share of interests held by the Company in Hangzhou HealSun was diluted from 30.00% to 26.37%. The dilution of the ownership interest in associates resulted in recognition of gain in condensed consolidated statements of comprehensive loss.

19 INVENTORIES

	As at 30 June 2022 RMB'000	As at 31 December 2021 RMB'000
	Raw materials	27,549

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

20 SHARE CAPITAL

	Number of shares	Nominal value of shares RMB'000
Authorised and issued and fully paid		
At 1 January 2022	1,531,669,838	1,531,670
Issuance of ordinary shares upon global offering (a)	126,876,000	126,876
Exercise of over-allotment option (b)	899,000	899
At 30 June 2022	1,659,444,838	1,659,445
At 1 January 2021	1,492,692,648	1,492,693
Issue of ordinary shares to series C investors (c)	38,977,190	38,977
At 30 June 2021 (Unaudited)	1,531,669,838	1,531,670

(a) On 23 February 2022, the Company has completed a global offering of 126,876,000 H Shares of par value of RMB1.00 each at the price of HK\$7.13 per H Share.

(b) On 22 March 2022, the Company issued additional 899,000 new H Shares upon the exercises of over-allotment of the global offering at the price of HK\$7.13 per H Share.

Share issuance costs related to the global offering mainly include share underwriting commissions, lawyers' fees, reporting accountant's fee and other costs. Incremental costs that are directly attributable to the issue of the new shares amounting to approximately RMB33,287,000 was treated as a deduction against the share premium arising from the issuance.

(c) On 8 April 2021, the Company entered into investment agreement with Vivo Capital Fund IX, L.P. ("**Vivo Capital**") and Shanghai Biomedical Industrial Equity Investment Fund Partnership (Limited Partnership) ("**Shanghai Biomedical**"), pursuant to which Vivo Capital and Shanghai Biomedical subscribed 24,360,744 and 14,616,446 shares of the Company respectively, with consideration of RMB163,200,000 and RMB97,920,000, respectively. The issuance cost to be paid is approximately RMB423,000. The par value of the shares under subscription is approximately RMB38,977,000, and the difference with the total consideration after deducting insurance cost of approximately RMB221,720,000 is charged to share premium. The issuance of shares was completed on 17 April 2021.

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

21 SHARE-BASED PAYMENTS

Huarui Zongheng (Beijing) Technology Co., Ltd. (華瑞縱橫(北京)科技有限公司), Shanghai Zupai Technology Partnership (Limited Partnership) (上海築湃科技合夥企業(有限合夥)), Shanghai Zulin Technology Partnership (Limited Partnership) (上海築麟科技合夥企業(有限合夥)), Shanghai Renhong Technology Partnership (Limited Partnership) (上海韜宏科技合夥企業(有限合夥)) and Shanghai Progeun Technology Co., Ltd. (上海苕槿科技有限責任公司) (collectively referred to as the “**Vehicles**”) were all incorporated in the PRC under the Company Law of the PRC as a vehicle to hold the ordinary shares for the Company’s employees under the Employee Share Ownership Plan (the “**ESOP**”) of 2020.

As the Company did not have power to govern the relevant activities of the Vehicles nor repurchase or settlement obligations but only derive benefits from the contributions of the eligible employees who are awarded with the shares under the ESOP, the directors of the Company consider not to consolidate the Vehicles. No statutory financial statements had been prepared by the Vehicles during the six months ended 30 June 2022.

(a) ESOP

On 7 December 2020, 151 eligible employees (the “**Grantees**”) were granted 45,149,702 shares of the Company at a consideration of RMB1.00 per share which are vested when Grantees complete a contractual term of service with the authorization from the Board of Directors of the Company to acquire their long-term service in future.

Such plan grants under the plan vest over a period of four years of continuous service, with one-fourth (1/4) vesting upon the first anniversary of the stated vesting commencement date and the remaining vesting rateably over the following 36 months.

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

21 SHARE-BASED PAYMENTS (CONTINUED)

(a) ESOP (continued)

Set out below are the movement in the number of awarded restricted shares under the ESOP:

	Number of awarded restricted shares
At 1 January 2022	24,731,556
Forfeited	(3,151,270)
At 30 June 2022	21,580,286
At 1 January 2021	45,149,702
Vested	(11,262,500)
Forfeited	(271,064)
At 30 June 2021 (Unaudited)	33,616,138

(b) Modification of the ESOP

In April 2021, as a reward for certain senior managements' service, the Group has entered into supplemental agreements with those senior managements to modify key terms under the original ESOP. As a result, the restriction of service conditions of 11,262,500 shares granted to those senior managements on 7 December 2020 were cancelled, and period of continuous service of 3,000,000 shares granted to a certain senior management has been shortened. Expenses related to vesting of restricted share and true up of shortened service condition restriction aforementioned amounted to approximately RMB45,202,000 were recognised immediately upon modification.

22 BORROWINGS

	As at 30 June 2022 RMB'000	As at 31 December 2021 RMB'000
<i>Current</i>		
Bank borrowings, non-secured	142,170	40,409
Bank borrowings, secured (a)	25,000	20,000
<i>Non-current</i>		
Bank borrowings, secured (a)	255,263	232,469
	422,433	292,878

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

22 BORROWINGS (CONTINUED)

As at 30 June 2022 and 31 December 2021, the Group's borrowings were repayable as follows:

	As at 30 June 2022 RMB'000	As at 31 December 2021 RMB'000
Within 1 year	167,170	60,409
Between 1 and 2 years	35,000	30,000
Between 2 and 5 years	220,000	180,000
Over 5 years	263	22,469
	422,433	292,878

- (a) As at 30 June 2022, the Group has pledged its land use rights and construction-in-progress with carrying amounts of approximately RMB59,702,000 and RMB622,574,000 respectively (31 December 2021: RMB61,559,000 and RMB562,232,000 respectively) to bank as the security for the bank borrowings of RMB280,263,000 (31 December 2021: RMB252,469,000). The borrowings bear interests at float rate range from 4.05% to 4.60% (31 December 2021: 4.15% to 4.60%) per annum. Interest is payable quarterly. The principals for the borrowings are payable in batches from 20 December 2022 to 20 June 2027.

Dr. Pu Zhongjie, the Controlling Shareholder, has been the guarantor of the Group's aforementioned secured bank borrowings with irrevocable joint guarantee liabilities. The guarantee period is 2 years from 1 September 2027 to 1 September 2029. Such guarantee was released on 20 April 2021.

The fair value of borrowings approximated their carrying amounts as at 30 June 2022 and 31 December 2021 as the borrowings carried interests which were benchmarked against rates announced by the People's Bank of China from time to time.

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

23 DEFERRED INCOME TAX

The deferred income tax assets and liabilities are mainly due from the acquisition of subsidiaries, and the amount of offsetting deferred income tax assets and liabilities as at 30 June 2022 is RMB23,689,000 (31 December 2021: RMB25,046,000).

(a) Deferred tax assets

	Six months ended 30 June	
	2022 RMB'000	2021 RMB'000
At beginning of the period	25,046	27,760
Charged to profit or loss	(1,357)	(1,357)
At end of the period	23,689	26,403

(b) Deferred tax liabilities

	Six months ended 30 June	
	2022 RMB'000	2021 RMB'000
At beginning of the period	(62,733)	(65,447)
Credited to profit or loss	1,357	1,357
At end of the period	(61,376)	(64,090)

24 FINANCIAL LIABILITIES AT FAIR VALUE THROUGH PROFIT OR LOSS

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

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

24 FINANCIAL LIABILITIES AT FAIR VALUE THROUGH PROFIT OR LOSS (CONTINUED)

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

	Six months ended 30 June	
	2022 RMB'000	2021 RMB'000
Opening balance	385,466	309,181
Change in fair value (Note 10)	60,776	34,637
Closing balance	446,242	343,818

25 TRADE PAYABLES

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

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

26 COMMITMENTS

(a) Capital commitments

Capital expenditure contracted for at the balance sheet dates but not yet incurred is as follows:

	As at 30 June 2022 RMB'000	As at 31 December 2021 RMB'000
Property, plant and equipment	524,011	164,689

The Group entered into licensing agreements with certain collaboration parties. As at 30 June 2022, the possible contractual milestone obligation payments is approximately RMB504,308,000 (31 December 2021: RMB481,984,000), such possible obligation will be confirmed only by the occurrence of specific uncertain future events during the Group's long-term collaboration with such collaboration parties.

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

26 COMMITMENTS (CONTINUED)

(b) Operating lease commitments

At end of the reporting period, the Group's commitments for future minimum lease payments under non-cancellable short-term leases as follows:

	As at 30 June 2022 RMB'000	As at 31 December 2021 RMB'000
No later than 1 year	4,929	710

27 NON-CONTROLLING INTERESTS ("NCI")

Set out below is summarised financial information for each subsidiary that has non-controlling interests that are material to the Group. The amounts disclosed for each subsidiary are before inter-company eliminations.

Summarised balance sheet

	Taizhou Hanzhong Biotechnology Co., Ltd. ("Taizhou Hanzhong")		Taizhou Houde Aoke Technology Co., Ltd. ("Taizhou Aoke")	
	As at 30 June 2022 RMB'000	As at 31 December 2021 RMB'000	As at 30 June 2022 RMB'000	As at 31 December 2021 RMB'000
Current assets	24,421	24,842	97,235	106,029
Current liabilities	(380,359)	(349,879)	(77,493)	(73,772)
Net current (liabilities)/assets	(355,938)	(325,037)	19,742	32,257
Non-current assets	119,740	122,383	13	2,308
Non-current liabilities	–	–	–	–
Net non-current assets	119,740	122,383	13	2,308
Net (liabilities)/assets	(236,198)	(202,654)	19,755	34,565
Accumulated NCI	–	–	5,926	10,369

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

27 NON-CONTROLLING INTERESTS (“NCI”) (CONTINUED)

Summarised statements of comprehensive loss

	Taizhou Hanzhong		Taizhou Aoke	
	Six months ended 30 June		Six months ended 30 June	
	2022	2021	2022	2021
	RMB'000	RMB'000	RMB'000	RMB'000
Other income	1	1	131	701
Loss for the year	(33,553)	(89,279)	(14,809)	(21,291)
Other comprehensive loss	–	–	–	–
Total comprehensive loss	(33,553)	(89,279)	(14,809)	(21,291)
Loss allocated to NCI	(1)	(1)	(4,443)	(6,387)

28 RELATED PARTY TRANSACTIONS

Parties are considered to be related if one party has the ability, directly or indirectly, to control the other party or exercise significant influence over the other party in making financial and operating decisions. Parties are also considered to be related because they are subject to common control, common significant influence or joint control in the controlling shareholder’s families. Members of key management and their close family member of the Group are also considered as related parties.

The directors are of the view that the following parties are other related parties exclude subsidiaries and associates that had transactions or balances with the Group:

Name	Relationship with the Group
Beijing Zhongjie Tiangong Medical Technology Co., Ltd. (北京中傑天工醫療科技有限公司)	Subsidiary of an entity which the director is a close family member of Dr. Pu Zhongjie
Beijing Pufeng Medical Management Co., Ltd. (北京普峰醫療管理有限公司)	Subsidiary of an entity which the director is a close family member of Dr. Pu Zhongjie
Beijing Volt Technology Co., Ltd. (北京伏爾特技術有限公司)	Subsidiary of an entity which the director is a close family member of Dr. Pu Zhongjie
Beijing Highthink Pharmaceutical Technology Service Co., Ltd. (北京海金格醫藥科技股份有限公司)	Entity which the director is Dr. Pu Zhongjie
Shanghai Shape Memory Alloy Material Co., Ltd. (上海形狀記憶合金材料有限公司)	Controlled by controlling shareholder
Beijing Lepu Hushengtang Network Technology Co., Ltd. (北京樂普護生堂網絡科技有限公司)	Controlled by controlling shareholder
Beijing Lejian Dongwai Clinic Co., Ltd. (北京樂健東外門診部有限公司)	Controlled by controlling shareholder
CG Oncology, Inc.	Entity which the director is Ms. Pu Jue, who is the director of the Company

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

28 RELATED PARTY TRANSACTIONS (CONTINUED)

The following significant transactions were carried out between the Group and its related parties during the reporting period. In the opinion of the directors of the Company, the related party transactions were carried out in the normal course of business and at terms negotiated between the Group and the respective related parties.

28.1 Transactions with other related parties

	Six months ended 30 June	
	2022 RMB'000	2021 RMB'000
Sale of raw material to related parties	272	–
Leasing from related parties	1,601	9,517
Purchase of technical development services from related parties	9,642	55,939
Purchase of professional services from related parties	106	659
Purchase of raw material from related parties	16	212
Rental services provided to associates	–	550

28.2 Balances with related parties

	As at 30 June 2022 RMB'000	As at 31 December 2021 RMB'000
	Balances due from related parties	
Prepayment to related parties	1,390	1,390
Balances due to related parties		
Trade payables to related parties	33,766	33,551
Other payables and accruals to related parties	2,313	3,889
	36,079	37,440

As at 30 June 2022 and 31 December 2021, there was no any non-trade nature balance with related parties, all balances with related parties were non-interest bearing and trade in nature, and their fair values approximated their carrying amounts due to their short maturities.

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

28 RELATED PARTY TRANSACTIONS (CONTINUED)

28.3 Key management compensation

Key management includes executive directors, supervisors and senior managements. The compensation paid or payable to key management personnel other than directors and supervisors is shown as below:

	Six months ended 30 June	
	2022 RMB'000	2021 RMB'000
Salaries, bonus and other allowances	6,057	6,237
Pension costs – defined contribution plans	59	54
Other social security costs, housing benefits, and other employee benefits	71	68
Share-based payment expenses	1,857	61,693
	8,044	68,052

29 DIVIDEND

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

30 EVENTS OCCURRING AFTER THE REPORTING PERIOD

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

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

“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
“AE”	adverse event, which may be mild, moderate, or severe, any untoward medical occurrences in a patient administered a drug or other pharmaceutical product during clinical trials and which do not necessarily have a causal relationship with the treatment
“Articles”	the articles of association of the Company, as amended, modified or supplemented from time to time
“associate(s)”	has the meaning ascribed to it 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
“Beijing Houde Yimin”	Beijing Houde Yimin Investment Management Co., Ltd. (北京厚德義民投資管理有限公司), a limited liability company incorporated in the PRC on August 17, 2009
“Board of Directors” or “Board”	the board of Directors of the Company
“CD20”	a B-lymphocyte antigen that is expressed on the surface of B cells, starting at the per-B cell atage and also on mature B cells in the bone marrow and in the periphery
“CDE”	Center for Drug Evaluation (藥品審評中心) of the NMPA
“CDMO”	contract development and manufacturing organization, a pharmaceutical company that develops and manufactures drugs for other pharmaceutical companies on a contractual basis

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

“CG Oncology”	CG Oncology, Inc. (previously known as Cold Genesys, Inc.), a clinical-stage immuno-oncology company headquartered in the U.S., 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
“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
“Companies Ordinance”	the Companies Ordinance (Chapter 622 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“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” or “PRC 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’s 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
“Compliance Advisor”	has the meaning ascribed to it under the Listing Rules
“connected person(s)”	has the meaning ascribed to it under the Listing Rules
“Controlling Shareholder”	has the meaning ascribed under the Listing Rules and unless the context otherwise requires, refers to Dr. Pu Zhongjie
“Core Product(s)”	has the meaning ascribed to it in Chapter 18A of the Listing Rules; for purposes of this report, our core products include MRG003, MRG002, HX008 and LP002
“Corporate Governance Code”	the Corporate Governance Code contained in Appendix 14 to the Listing Rules

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

“CR”	complete response, the disappearance of all signs of cancer in response to treatment
“CRO”	contract research organization, a pharmaceutical company that conducts research for other pharmaceutical companies on a contractual basis
“DCR”	disease control rate, the total proportion of patients who demonstrate a response to treatment, equal to the sum of complete responses (CR), partial responses (PR) and stable disease (SD)
“Director(s)”	the director(s) of the Company
“Domestic Share(s)”	ordinary share(s) in the share capital of the Company, with a nominal value of RMB1.00 each, which are subscribed for and paid up in RMB and are unlisted Shares which are currently not listed or traded on any stock exchange
“Dr. Pu” or “Dr. Pu Zhongjie”	Dr. Pu Zhongjie (蒲忠傑), the Controlling Shareholder of our Company
“EGFR”	epidermal growth factor receptor
“Employee Share Ownership Plan” or “ESOP”	the employee share ownership plan established by the Company in December 2020
“ES-SCLC”	extensive stage small-cell lung cancer
“FDA”	Food and Drug Administration of the United States
“first-line” or “1L”	with respect to any disease, the first line therapy, which is the treatment regimen or regimens that are generally accepted by the medical establishment for initial treatment. It is also called primary treatment or therapy
“FISH”	fluorescence in situ hybridization, a test that maps the genetic material in human cells, including specific genes or portions of genes
“GC”	gastric cancer
“GEJ”	gastroesophageal junction
“Global Offering”	the offer of the H Shares for subscription as described in the Prospectus

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

“GMP”	a system for ensuring that products are consistently produced and controlled according to quality standards, which is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. It is also the practice required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of pharmaceutical products
“Group”, “we”, “us” or “our”	the Company and its subsidiaries
“H Share(s)”	overseas listed foreign invested ordinary share(s) in the ordinary share capital of the Company, with a nominal value of RMB1.00 each, listed on the Main Board of the Stock Exchange
“H Share Registrar”	Computershare Hong Kong Investor Services Limited
“Hangzhou HealSun”	Hangzhou HealSun Biopharma Co., Ltd. (杭州皓陽生物技術有限公司), a limited liability company incorporated in the PRC on November 19, 2015
“HanX”	Hangzhou HanX Biomedical Co., Ltd. (杭州翰思生物醫藥有限公司), a limited liability company incorporated in the PRC on August 3, 2016, which is a biopharmaceutical company principally engaged in biological products, biotechnology, medical technology development and consulting, and held by Mr. Zhang Faming, the director of Miracogen Shanghai as to 53.75% and four Independent Third Parties as to 46.25% in aggregate with each Independent Third Party holding no more than 20% of the equity interest of HanX
“HCC”	hepatocellular carcinoma, a common form of liver cancer
“HER2”	human epidermal growth factor receptor 2
“HER2-expressing”	HER2 status of tumor cells identified with a test score of IHC 1+ or above
“HER2 low-expressing”	HER2 status of tumor cells identified with a test score of IHC 1+ or IHC 2+ plus FISH (or ISH)-
“HER2-positive” or “HER2 over-expressing”	HER2 status of tumor cells identified with a test score of either IHC 3+ or IHC 2+/FISH (or ISH) + (IHC 2+ plus FISH (or ISH)+)
“HK\$” or “Hong Kong dollars”	Hong Kong dollars, the lawful currency of Hong Kong
“HNSCC”	head and neck squamous cell carcinoma

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

“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 U.S.
“Independent Third Party(ies)”	person(s) or company(ies) and their respective ultimate beneficial owner(s), who/which, to the best of the Directors’ knowledge, information and belief, having made all reasonable enquiries, is/are not a connected person of the Company within the meaning ascribed thereto under the Listing Rules
“ITT”	intention to treat
“Kington Capital”	Kington Capital No. 1 Equity Investment Partnership (Limited Partnership) (蘇州翼樸一號股權投資合夥企業(有限合夥))
“KYM”	KYM Biosciences Inc., a Delaware corporation and a joint venture formed in the US by Keymed and our Group
“Latest Practicable Date”	September 23, 2022, being the latest practicable date prior to the printing of this report for the purpose of ascertaining certain information contained in this report
“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
“Listing”	the listing of the H Shares of the Company on the Main Board of the Stock Exchange
“Listing Date”	February 23, 2022

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

“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
“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
“Miracogen HK”	Miracogen Limited, a limited liability company established under the laws of Hong Kong and a special purpose investment vehicle wholly-owned by Miracogen Inc., which in turn is a company wholly-owned by Dr. Hu Chaohong, our executive Director and co-chief executive officer of our Company
“Miracogen Shanghai”	Shanghai Miracogen Inc. (上海美雅珂生物技術有限責任公司), a limited liability company incorporated in the PRC on January 27, 2014, and a wholly owned subsidiary of the Company
“MMAE”	monomethyl auristatin E, a potent tubulin binder with a half maximal inhibitory concentration (IC50) in the subnanomolar range
“Model Code”	the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix 10 to the Listing Rules
“MSI-H/dMMR”	high levels of microsatellite instability/deficient mismatch repair
“NDA”	new drug application
“NHL”	non-Hodgkin’s lymphoma
“Ningbo Houde Yimin”	Ningbo Houde Yimin Information Technology Co., Ltd. (寧波厚德義民信息科技有限責任公司), a limited liability company incorporated in the PRC on March 29, 2017, and the promoter of the Company
“NK Cell”	natural killer cell, a kind of cells that play important roles in immunity against viruses and in the immune surveillance of tumors
“NMPA”	the National Medical Products Administration of the PRC (國家藥品監督管理局)

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

“Nomination Committee”	the nomination committee of the Board
“NPC”	nasopharyngeal cancer
“NSCLC”	non-small cell lung cancer
“ORR”	objective response rate, which is equal to the sum of CR and PR
“PD-1”	programmed cell death protein 1, an immune checkpoint receptor expressed on T cells, B cells and macrophages
“PD-L1”	PD-1 ligand 1, which is a protein on the surface of a normal cell or a cancer cell that binds to its receptor, PD-1, on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell
“PFS”	progression-free survival, the length of time during and after the treatment of a disease, such as cancer, that a patient lives with the disease but it does not get worse
“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

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

“PRC”	the People’s Republic of China, excluding, for the purpose of this interim report, Hong Kong, Macau and Taiwan
“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
“Prospectus”	the prospectus issued by the Company dated February 10, 2022
“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
“registrational trial”	a clinical trial or study intended to provide evidence for a drug marketing approval
“Reporting Period”	the six months ended June 30, 2022
“RMB”	Renminbi, the lawful currency of the PRC
“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
“SFO”	the Securities and Futures Ordinance, Chapter 571 of the Laws of Hong Kong, as amended, supplemented or otherwise modified from time to time
“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

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

“SHC”	Shanghai Healthcare Capital Partnership (Limited Partnership) (上海生物醫藥產業股權投資基金合夥企業(有限合夥))
“SMO”	site management organization, an organization that provides clinical trial related services to medical device companies having adequate infrastructure and staff to meet the requirements of the clinical trial protocol
“solid tumors”	an abnormal mass of tissue that usually does not contain cysts or liquid areas. Solid tumors may be benign (not cancer), or malignant (cancer). Different types of solid tumors are named for the type of cells that form them
“standard of care”	treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals
“Stock Exchange”	the Stock Exchange of Hong Kong Limited
“subsidiaries”	has the meaning ascribed to it in section 15 of the Companies Ordinance
“Supervisor(s)”	supervisor(s) of the Company
“Supervisory Committee”	the supervisory committee of the Company
“Suzhou Suzi”	Suzhou Suzi Investment Limited Partnership (蘇州蘇梓投資合夥企業(有限合夥))
“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
“Taizhou Aoke”	Taizhou Houde Aoke Technology Co., Ltd. (泰州厚德奧科科技有限公司), a limited liability company incorporated in the PRC on March 23, 2018, and a non-wholly owned subsidiary of the Company
“TGFBR11”	TGF- β receptor II
“tissue factor” or “TF”	a protein encoded by the F3 gene, present in subendothelial tissue and leukocytes. Many cancer cells express high level of TF
“TNBC”	triple-negative breast cancer

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

“UC”	unrothelial cancer
“Unlisted Foreign Shares”	ordinary shares issued by the Company with a nominal value of RMB1.00 each and are held by foreign investors and are not listed on any stock exchange
“US” or “United States” or “the U.S.”	the United States of America, its territories and possessions, any State of the United States, and the District of Columbia
“vc linker”	valine-citrulline linker, which is adequately stable in blood circulation and cleaved effectively by the lysosomal cathepsin enzyme after the ADC is internalized and enters lysosome
“Yipu LP”	Suzhou Yipu No. 2 Venture Investment Limited Partnership* 蘇州翼樸二號創業投資合夥企業(有限合夥), a shareholder of Hangzhou Healsun

* For identification purposes only