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# 華領醫藥

(Incorporated in the Cayman Islands with limited liability)
(Stock code: 2552)

# INTERIM RESULTS ANNOUNCEMENT FOR THE SIX MONTHS ENDED JUNE 30, 2022

The board (the "Board") of directors (the "Directors") of Hua Medicine (the "Company") is pleased to announce the unaudited consolidated results of the Company and its subsidiaries (together, the "Group", "we" or "us") for the six months ended June 30, 2022, together with the comparative figures for the six months ended June 30, 2021. Unless otherwise defined herein, capitalized terms used in this announcement shall have the same meaning as those defined in the prospectus of the Company dated August 31, 2018 (the "Prospectus").

### **BUSINESS HIGHLIGHTS**

- As we await China approval for dorzagliatin, our team has been working earnestly on launch strategy and commercialization preparation with Bayer, our commercialization partner in China, as well as manufacturing and supply preparations with our various strategic partners.
- In February 2022, we announced a supply agreement with WuXi STA for the commercial manufacturing of dorzagliatin to further enhance our existing collaboration.
- In May 2022, we published two peer-reviewed papers on the Phase III clinical trials results of dorzagliatin in *Nature Medicine*, an international top-medical journal. These two papers described and analyzed the clinical efficacy and safety characteristics of dorzagliatin monotherapy (SEED) in drug-naïve Type 2 diabetes (T2D) patients and the combination therapy of dorzagliatin and metformin (DAWN) in patients who failed in metformin adequacy therapy for the treatment of T2D, respectively.
- In June 2022, three research findings on dorzagliatin were presented at the 2022 82nd American Diabetes Association ("2022 ADA"): i) An oral presentation at the 2022 ADA Scientific Sessions on the results of SENSITIZE, a clinical study demonstrating dorzagliatin improved insulin secretion and glucose sensitivity; ii) A post-hoc analysis of the Phase III trials of dorzagliatin to validate the potential of dorzagliatin in improving early phase insulin secretion and restoring glucose sensitivity in type 2 diabetes (T2D) patients; and iii) The results of the DREAM study from the dorzagliatin monotherapy (SEED) study to explore the potential of dorzagliatin in diabetes remission.
- In addition to our preparations for commercialization of dorzagliatin in China, we continued to advance the development of our second generation GKA, with the potential for once daily administration and a more efficient manufacturing process.

## FINANCIAL HIGHLIGHTS

- Bank balances and cash position was approximately RMB586.3 million as of June 30, 2022.
- Total expenditures incurred by the Company for the six months ended June 30, 2022 was approximately RMB142.6 million, of which approximately RMB72.3 million was attributable to research and development expenses.
- Research and development expenses decreased by approximately RMB25.7 million or approximately 26.2% to approximately RMB72.3 million for the six months ended June 30, 2022, compared with the six months ended June 30, 2021.
- Loss before tax decreased by approximately RMB60.7 million or approximately 36.7% to approximately RMB104.6 million for the six months ended June 30, 2022, compared with the six months ended June 30, 2021.
- Total comprehensive expense for the period decreased by approximately RMB60.8 million or approximately 36.8% to approximately RMB104.5 million for the six months ended June 30, 2022, compared with the six months ended June 30, 2021.

### MANAGEMENT DISCUSSION AND ANALYSIS

### **Business overview**

We are a pre-revenue China-based drug development company currently focusing on the development of dorzagliatin, a first-in-class oral drug for the treatment of T2D. We filed an Investigational New Drug ("IND") application with the NMPA for dorzagliatin under Category 1.1 (New Drug) in 2012 and initiated a Phase Ia clinical study of our novel glucokinase activator dorzagliatin in September 2013. We also filed an IND application with the U.S. Food and Drug Administration ("FDA") for dorzagliatin in March 2015. We have completed eight Phase I trials in China, four Phase I trials in the United States, one Phase II trial in China, and two Phase III trials in China. Our two Phase III trials enrolled 1,230 patients across 110 sites throughout China.

Both Phase III trials (also known as the SEED and DAWN trials) met their primary endpoints, and the safety and tolerability profile of dorzagliatin was good during the trial period. The final 52-week results of both Phase III trials were announced in 2020. In March 2021, we submitted a NDA for dorzagliatin for the treatment of T2D to the NMPA, and we received notification from the NMPA that our NDA was accepted in April 2021. The NDA is currently under active review by the NMPA.

In September 2021 at the 6th China BioMed Innovation and Investment Conference, certain principal investigators from our SEED Phase III trial presented the extensive results from the clinical study called DREAM. The main objective of the DREAM study was to evaluate the ability of T2D patients who participated in our SEED study and achieved glycemic control as defined by investigators, to maintain normal to near-normal HbA1c levels<sup>1</sup> (i.e., remission of T2D), without any glucose-lowering medication after the completion of the SEED study for a minimum follow-up period of 52-weeks. The results showed that the subjects had a 52-week diabetes remission rate of 65.2% at week 52 (95% CI, 53.4%, 77.0%)<sup>2</sup> during the research period.

In May 2022, we published two peer-reviewed papers on the Phase III clinical trials results of dorzagliatin in *Nature Medicine*, an international top-medical journal. These two papers described and analyzed the clinical efficacy and safety characteristics of dorzagliatin monotherapy (SEED) in drug-naïve Type 2 diabetes (T2D) patients and the combination therapy of dorzagliatin and metformin (DAWN) in patients who failed in metformin adequacy therapy for the treatment of T2D, respectively.

- 1 HbA1c levels < 7.0%.
- 2 Calculated using the Kaplan-Meier methodology.

In June 2022, three research findings on dorzagliatin were presented at the 2022 82nd American Diabetes Association ("2022 ADA"):

- 1) An oral presentation at the 2022 ADA Scientific Sessions on the results of SENSITIZE, a clinical study demonstrating dorzagliatin improved insulin secretion and glucose sensitivity. The study was initiated by Professor Juliana Chan, an internationally recognized endocrinologist from the Chinese University of Hong Kong. SENSITIZE explored the effects of dorzagliatin on patients with recent onset T2D and glucokinase-maturity-onset diabetes of the young (GCK-MODY or MODY-2). The study results, using glucose clamp technique, showed that dorzagliatin can significantly improve second phase insulin secretion and glucose sensitivity in GCK-MODY patients and can significantly improve basal insulin secretion rates in patients with recent onset T2D. As the speaker of the oral presentation and one of the researchers of the SENSITIZE study, Professor Elaine Chow from the Chinese University of Hong Kong, won the 2022 Women's Interprofessional Network of the American Diabetes Association abstract award in the category of Clinical Diabetes, Epidemiology, and Diabetes Complications in recognition of her outstanding results and significant contributions in the SENSITIZE study and the whole field of diabetes research.
- 2) A post-hoc analysis of the Phase III trials of dorzagliatin led by the former President of the Chinese Diabetes Society and present Vice President of the Asian Association for Study of Diabetes, Professor Yang Wenying of China-Japan Friendship Hospital to validate the potential of dorzagliatin in improving early phase insulin secretion and restoring glucose sensitivity in type 2 diabetes (T2D) patients (presented via poster presentation at the 2022 ADA Scientific Sessions); and
- The results of the DREAM study conducted by Professor Jianhua Ma, Director of the 3) Department of Endocrinology, Nanjing First Hospital, Standing Member of the Chinese Diabetes Society, and other researchers in the dorzagliatin monotherapy (SEED) study to explore the potential of dorzagliatin in diabetes remission (presented via poster presentation at the 2022 ADA Scientific Sessions). The DREAM study is a non-drug intervention observational clinical study initiated by certain researchers participating in the SEED study. The main purpose of this study is to evaluate the remission of diabetes for 52 weeks after patients who completed the SEED study and whose blood glucose reached control targets, and stopped taking dorzagliatin as well as any other glucose-lowering medication. The results of the study showed that during the observation period when no anti-diabetes drugs were administered, the remission rate was 65.2% at 52 weeks. HbA1c, FPG and 2h-PPG levels were sustained during the 52 weeks after dorzagliatin discontinuation, and β-cell function was maintained during the observation period. The study indicated that dorzagliatin has the potential to be a promising treatment option for achieving remission of diabetes: for newly diagnosed patients, especially those who have a short course of disease, dorzagliatin treatment can promote diabetes remission, indicating that improvements of β-cell function by restoration of glucose stimulated early-phase insulin secretion may be a potential viable mechanism.

As we continue to progress with our development of our lead candidate, dorzagliatin, we are also moving forward with preparations for the drug's life cycle management for expansion of patient population and entering into new indications. We filed applications and secured patents for fixed dose combinations of dorzagliatin with select approved oral anti-diabetes therapies. We have also initiated pre-clinical development and filed patent applications globally for a second generation glucokinase activator, based on our experience and insights gained in working with dorzagliatin.

We also continue to move forward with our collaboration with the leading diabetes partner in China, Bayer, in preparation of the commercial launch of dorzagliatin in China. In September 2021, we entered into a strategic agreement with Sinopharm Group Co., Ltd. (Hong Kong Stock Code: 1099), to cooperate in logistics warehousing, supply chain management and channel data analysis, and to jointly promote the commercialization of dorzagliatin for its expected market launch in China. In February 2022, we announced a supply agreement with WuXi STA for the commercial manufacturing of dorzagliatin to further enhance our existing collaboration.

In addition to our development and commercialization efforts with dorzagliatin, we also continue to develop various other compounds, currently in the pre-clinical stage. One is focused on mGLUR5 for Parkinson's disease levodopa-induced dyskinesia, and the other is a fructose kinase inhibitor for metabolic disease.

Cautionary Statement required under Rule 18A.08(3) of the Listing Rules: We may not be able to ultimately develop and market our dorzagliatin successfully.

# **Product pipeline**

Set out below are the key stages of our product candidates under development:

<b>Product Name</b>	Indication	Development phase	Pre-clinical	IND	Phase I	Phase II	Phase III	NDA
	T2D	NDA Filed (China)						<b></b>
Dorzagliatin HMS5552	DKD	Phase I enabling		$\longrightarrow$				
	T1D	IND-enabling						
HMSFDC 6857 Dorzagliatin + Metformin	T2D	Phase I ready			<b></b>			
HMSFDC 6868	T2D	Phase I ready						
Dorzagliatin + Sitagliptin	Insulin Sparing	IND-enabling		•				
HMSFDC 5868 Dorzagliatin + Empagliflozin	T2D CVR	Phase I ready			<b>-</b>			
HMSFDC 5688 Dorzagliatin + pioglitazone	NASH	IND-enabling						
HMS 5678 Dorzagliatin + GLP-1	Alzheimer Disease	IND-enabling						
HMS 6789	Late Stage T2D	IND-enabling						
Dorzagliatin + Insulin	T1D	IND-enabling						
mGLUR5 NAM	PD-LID	Pre-clinical						
Fructose Kinase Inhibitor	Metabolic Disease	Pre-clinical						
2 <sup>nd</sup> Generation GKA	Metabolic Disease	Pre-clinical						

### **Business outlook**

At present, the NDA for dorzagliatin is under active review by the NMPA, and we are actively working to obtain approval for our NDA as soon as possible. If approved, we plan to commercialize dorzagliatin in China with our partner, Bayer, to seek entry into the National Reimbursement Drug List (the "NRDL"), and to expand its use as a cornerstone treatment for T2D as monotherapy or in combination with other approved antidiabetic drugs. We are also advancing development of our fixed dose combinations with dorzagliatin, as well as our second generation glucokinase activator for potential future international expansion.

# Key events after the reporting period

There are no important events that have occurred since June 30, 2022 and up to the date of this announcement.

### Financial review

### Other income

Our other income consisted primarily of bank interest income and government grants. Our other income was RMB21.4 million for the six months ended June 30, 2022 as compared to RMB3.6 million for the six months ended June 30, 2021, which was mainly attributable to an increase of RMB19.2 million in government grants for the six months ended June 30, 2022, adjusted for a decrease of RMB1.1 million in bank interest income from short-term deposits.

# Other gains and losses

Our other gains and losses consisted primarily of gains due to fluctuations in the exchange rates between the Renminbi and the U.S. dollar and between Renminbi and the HK dollar. Our other gains and losses increased by RMB20.4 million and were mainly attributable to foreign exchange gains in connection with bank balances and cash denominated in U.S. dollar and HK dollar and the appreciation of the U.S. dollar and HK dollar against the Renminbi for the six months ended June 30, 2022.

Our business mainly operates in the PRC, and most of our transactions are settled in Renminbi. Since inception, we have financed our business principally through equity financings, with related proceeds denominated in U.S. dollar, HK dollar and Renminbi. We converted a portion of those U.S. dollar proceeds to Renminbi and HK dollar proceeds to U.S. dollar immediately, with the remaining amounts reserved for additional conversions to Renminbi as needed. Translation for financial statement presentation purposes of our assets and liabilities exposes us to currency-related gains or losses and the actual conversion of our U.S. dollar and HK dollar denominated cash balances will also expose us to currency exchange risk. We have not engaged in any foreign exchange hedging related activity.

# Administrative expenses

Our administrative expenses consisted primarily of employee compensation and related costs. Our administrative expenses increased by RMB5.0 million to RMB68.5 million for the six months ended June 30, 2022 from RMB63.5 million for the six months ended June 30, 2021, which was mainly attributable to i) an increase of RMB6.9 million in consultant fee, which was mainly due to our NDA application related consulting, pricing strategy consulting and economic evaluation consulting of dorzagliatin conducted during the six months ended June 30, 2022 and no such consulting activities conducted during the six months ended June 30, 2021, ii) an adjustment for the decrease of RMB1.2 million in recruitment expense due to our recruitment strategy, and iii) an adjustment for the decrease of RMB0.4 million in meeting fee and RMB0.5 million in travelling expense due to decreased meeting and travelling activities compared to the six months ended June 30, 2021, which was impacted by COVID-19 in the first half of 2022.

## Other expenses

We have no other expenses for the six months ended June 30, 2022 as compared to RMB1.6 million (equivalent to USD250,000) for the six months ended June 30, 2021 to establish the Type 2 Diabetes research fund at the Department of Biochemistry and Biophysics at the Raymond and Ruth Perelman School of Medicine of the University of Pennsylvania.

# Finance cost

Our finance cost consisted primarily of interest on lease liabilities. Our finance cost was RMB1.8 million for the six months ended June 30, 2022 as compared to RMB2.0 million for the six months ended June 30, 2021, which was mainly attributable to the surrender of old offices in the first half of 2021, after moving into our new headquarter at the end of 2020.

### Research and development expenses

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

	Six months ended June 30,			
	2022	2	2021	
	RMB'000	%	RMB'000	%
Dorzagliatin Clinical Trials	2,948	4.1%	18,564	19.0%
Dorzagliatin Non-clinical Studies	789	1.1%	3,236	3.3%
Chemical, Manufacturing and Control	9,015	12.5%	7,450	7.6%
Labor Cost	47,279	65.4%	54,271	55.3%
Dorzagliatin Licensing and Patent Fee	774	1.1%	_	0.0%
Others	11,481	15.8%	14,461	14.8%
Total	72,286	100.0%	97,982	100.0%

Research and development expenses decreased by RMB25.7 million to RMB72.3 million for the six months ended June 30, 2022 from RMB98.0 million for the six months ended June 30, 2021. The decrease in research and development expenses mainly included:

- a decrease of RMB15.6 million for dorzagliatin clinical trials, which was primarily attributable to the data analysis and TMF report preparation of SEED/HMM0301 and DAWN/ HMM0302 conducted in the first half of 2021. In the first half of 2022, we primarily focused on our NDA approval and conducted several additional clinical research to support the review by the NMPA;
- an increase of RMB1.6 million in chemical, manufacturing, and control expenses, which was primarily attributable to the process validation, drug substance and production for clinical trial for the review of our NDA approval conducted in the first half of 2022;
- a decrease of RMB2.4 million for dorzagliatin non-clinical studies, which was primarily attributable to the ISS data and analysis expense for our NDA filing, FDC efficacy study of dorzagliatin with insulin/acarbose and efficacy study of dorzagliatin in animal model of T2D complicating cognitive disorder conducted in the first half of 2021 and no such studies happened in the first half of 2022;
- a decrease of RMB7.0 million in labor cost, which was primarily attributable to decreased bonus for the period and the decrease of share-based payment under the accelerated amortization method; and
- a decrease of RMB3.0 million in other expenses, which was primarily attributable to decreased travelling cost, meeting cost and utility cost due to the impact of COVID-19 in the first half of 2022.

### Income tax expense

We recognized no income tax expenses for the six months ended June 30, 2022 and the six months ended June 30, 2021.

# Liquidity and capital resources

Since our inception, we have incurred net losses and negative cash flows from operations. Our primary use of cash is to fund research and development expenses. Our operating activities utilized RMB116.7 million for the six months ended June 30, 2022. As of June 30, 2022, we had cash and cash equivalents of RMB586.3 million.

As of June 30, 2022, there were no significant investments held by the Company, nor were there any material acquisitions or disposals of subsidiaries, associates and joint ventures during the six months ended June 30, 2022.

# **Cash Operating Cost**

The following table sets out the components of our cash operating cost for the periods indicated:

Six months ended June 30,		
2022	2021	
RMB'000	RMB'000	
70,599	90,873	
38,276	29,377	
33,448	44,040	
71,724	73,417	
142,323	164,290	
	2022 RMB'000 70,599 38,276 33,448 71,724	

### **Cash Flows**

The following table provides information regarding our cash flows for the six months ended June 30, 2022 and 2021:

	Six months ended June 30,		
	2022	2021	
	RMB'000	RMB'000	
Net cash used in operating activities	(116,659)	(164,290)	
Net cash from (used in) investing activities	17,024	(10,124)	
Net cash used in financing activities	(4,293)	(5,788)	
Effect of exchange rate changes	14,997	(4,960)	
Net decrease in cash and cash equivalents	(88,931)	(185,162)	

# Net Cash Used in Operating Activities

The primary use of our cash was to fund our research and development activities, regulatory and other clinical trial costs, and related supporting administration. Our prepayments and other current assets, accounts payable and other payables balances were affected by the timing of vendor invoicing and payments.

During the six months ended June 30, 2022, our operating activities used RMB116.7 million of cash, which resulted principally from our loss before tax of RMB104.6 million, adjusted for non-cash charges and non-operating cash gains of RMB1.6 million, and by cash used in our operating assets and liabilities of RMB10.5 million. Our net non-cash charges during the six months ended June 30, 2022 primarily consisted of share-based payment expense, depreciation of equipment, right-of-use assets and amortization for intangible assets.

During the six months ended June 30, 2021, our operating activities used RMB164.3 million of cash, which resulted principally from our loss before tax of RMB165.3 million, adjusted for non-cash charges and non-operating cash charges of RMB38.8 million, and by cash used in our operating assets and liabilities of RMB37.8 million. Our net non-cash charges during the six months ended June 30, 2021 primarily consisted of share-based payment expense, depreciation of equipment, right-of-use assets and amortization for intangible assets.

## Net Cash from (used in) Investing Activities

Net cash from investing activities was RMB17.0 million for the six months ended June 30, 2022, which resulted primarily from the government grant received to subsidize the Group's leasehold improvement, furniture, fixture and equipment purchased in the prior years and the interest received from bank for short-term deposit, adjusted for the purchase of plant and equipment and intangible assets. Net cash used in investing activities was RMB10.1 million for the six months ended June 30, 2021, which resulted primarily from the purchase of equipment and intangible assets, adjusted for interest received from bank for short-term deposit.

## Net Cash used in Financing Activities

Net cash used in financing activities was RMB4.3 million for the six months ended June 30, 2022, which resulted from repayments of lease liabilities, adjusted for proceeds from exercise of share options. Net cash used in financing activities was RMB5.8 million for the six months ended June 30, 2021, which resulted from repayments of lease liabilities, adjusted for proceeds from exercise of share options.

### **Financial position**

Our net current assets decreased from RMB597.7 million as of December 31, 2021 to RMB541.8 million as of June 30, 2022. Current assets decreased from RMB704.6 million as of December 31, 2021 to RMB622.3 million as of June 30, 2022, primarily due to decrease in bank balances and cash from RMB675.2 million as of December 31, 2021 to RMB586.3 million as of June 30, 2022, which was primarily due to net cash expenditure during the six months ended June 30, 2022.

### **Indebtedness**

As of June 30, 2022, our lease liabilities amounted to RMB73.3 million. The following table sets forth our lease liabilities as of the dates indicated:

	As of June 30, 2022 <i>RMB'000</i>	As of December 31, 2021 RMB'000
Current portion Non-current portion	20,879 52,413	13,296 58,232
Total	73,292	71,528

Our lease liabilities as of June 30, 2022 were from leased properties lease contracts with lease terms of two to four years. As of June 30, 2022, we did not have any other indebtedness.

## Qualitative and Quantitative Disclosures About Market Risk

We are exposed to a variety of market risks, including currency risk, interest rate risk, credit risk, and liquidity risk, details of which are set out below. We manage and monitor these exposures to ensure appropriate measures are implemented in a timely and effective manner. We currently do not hedge or consider it necessary to hedge any of these risks.

# Currency Risk

Our business mainly operates in the PRC with most of our transactions settled in Renminbi, and our financial statements are presented in Renminbi. Renminbi is not a freely convertible currency. The State Administration of Foreign Exchange, under the authority of the People's Bank of China, controls the conversion of Renminbi into foreign currencies. The value of Renminbi is subject to changes in central government policies and to international economic and political developments affecting supply and demand in the China Foreign Exchange Trade System market. We do not believe that we currently have any significant direct foreign exchange risk and have not used any derivative financial instruments to hedge our exposure to such risk.

Since our inception, we have raised funds through various rounds of offshore financings and received proceeds of such financings in U.S. dollars, HK dollars and Renminbi. We converted a portion of those funds to Renminbi immediately and placed the remaining amount in time deposits. We converted additional amounts to Renminbi as needed. The value of the Renminbi against the U.S. dollars and other currencies may fluctuate and is affected by, among other things, changes in China's political and economic conditions. To the extent that we need to convert U.S. dollars or other currencies we have received in previous financings into Renminbi for our operations, or if any of our arrangements with other parties are denominated in U.S. dollars and need to be converted into Renminbi, appreciation of the Renminbi against the U.S. dollars or other currencies would have an adverse effect on the Renminbi amount we receive from the conversion. Conversely, if we decide to convert Renminbi into U.S. dollars or other currencies for business purposes, appreciation of the U.S. or HK dollars against the Renminbi would have a negative effect on the U.S. dollars or other currencies amounts available to us. We have conducted a sensitivity analysis to determine our exposure to changes in foreign currency rate.

The following table details our sensitivity to a 5% increase and decrease in the Renminbi against the U.S. dollar and the HK dollar, the foreign currencies to which we may have material exposure. No sensitivity analysis has been disclosed for the Taiwan dollar denominated assets as the impact on profit is immaterial. 5% represents management's assessment of the reasonably possible changes in foreign exchange rate. The sensitivity analysis uses outstanding foreign currency denominated monetary items as a base and adjusts their translation as of June 30, 2022 for a 5% change in foreign currency rate. A negative number below indicates an increase in loss where Renminbi strengthens 5% against the U.S. dollar and the HK dollar. For a 5% weakening of the Renminbi against the U.S. dollar and the HK dollar there would be an equal and opposite impact on gain for the period.

	As of June 30, 2022 <i>RMB'000</i>	As of December 31, 2021 RMB'000
Impact on profit or loss		
US\$	(10,219)	(18,134)
HK\$	(2,077)	(2,057)

### Interest Rate Risk

The Group is primarily exposed to fair value interest rate risk in relation to fixed-rate short-term bank deposits. The Group currently does not have an interest rate hedging policy to mitigate interest rate risk. Nevertheless, the management monitors interest rate exposure and will consider hedging significant interest rate risk should the need arise.

The Group is also exposed to cash flow interest rate risk in relation to variable-rate bank balances. The Group's cash flow interest rate risk is mainly concentrated on the fluctuation of interest rates on bank balances. The Directors consider that the exposure of cash flow interest rate risk arising from variable-rate bank balances is insignificant, therefore no sensitivity analysis on such risk has been prepared.

## Liquidity Risk

As of June 30, 2022 and December 31, 2021, we recorded net current assets of RMB541.8 million and RMB597.7 million, respectively. In the management of the liquidity risk, we monitor and maintain a level of cash and cash equivalents deemed adequate by our management to finance our operations and mitigate the effects of fluctuations in cash flows.

## **Key Financial Ratios**

The following table sets forth our key financial ratios as of the dates indicated:

	As of June 30, 2022	As of December 31, 2021
Current ratio (1)	7.7	6.6
Quick ratio (2)	7.7	6.6
Gearing ratio (3)	20.0%	15.9%

- (1) Current ratio represents current assets divided by current liabilities as of the same date.
- (2) Quick ratio represents current assets less inventories divided by current liabilities as of the same date.
- (3) Gearing ratio represents liability divided by equity as of the same date. Liability is defined as lease liabilities (excluding trade and other payables, deferred income and contract liability). Equity includes all capital and reserves of the Group.

The current ratio and quick ratio as of June 30, 2022 increased by 1.1 compared with that as of December 31, 2021, which was mainly due to the payment of research activities and daily operation.

# Charge of the Group's assets

As of June 30, 2022, RMB7.8 million of the Group's bank deposits were charged by the bank to secure commencement and completion of the factory construction and launch of production.

### **Capital commitments**

The following table sets forth our capital commitments as of the dates indicated:

	As of June 30, 2022 <i>RMB'000</i>	As of December 31, 2021 RMB'000
Capital expenditure in respect of the acquisition of construction contracted for but not provided in the consolidated financial statements	556	4,381

## Future plans for material investments or capital assets

As of June 30, 2022, we plan to continually invest in the Hua Medicine drug manufacturing company which was established at Shanghai Lingang Special Area for ensuring adequate dorzagliatin commercial supply.

### **Contingent liabilities**

Save as disclosed in this announcement, the Group had no material contingent liabilities as of June 30, 2022.

# CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

		Six months end	,	
		2022	2021	
	NOTES	RMB'000	RMB'000	
		(unaudited)	(unaudited)	
Other income	3	21,352	3,612	
Other gains and losses	4	16,656	(3,788)	
Administrative expenses		(68,536)	(63,518)	
Finance cost	5	(1,805)	(1,999)	
Research and development expenses		(72,286)	(97,982)	
Other expenses			(1,617)	
Loss before tax	6	(104,619)	(165,292)	
Income tax expense	7			
Loss for the period		(104,619)	(165,292)	
Other comprehensive income (expense)  Items that may be reclassified subsequently to profit or loss:  - Exchange differences on translation of foreign operations		72	(2)	
Other comprehensive income (expense)				
for the period, net of income tax		72	(2)	
Total comprehensive expense for the period		(104,547)	(165,294)	
Total comprehensive expense for the period attributable to:				
<ul> <li>Owners of the Company</li> </ul>		(104,547)	(165,294)	
LOSS PER SHARE	10	RMB	RMB	
Basic and diluted		(0.11)	(0.17)	
		( )	( /	

# CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	NOTES	At June 30, 2022 RMB'000 (unaudited)	At December 31, 2021 <i>RMB'000</i> (audited)
Non-current assets Plant and equipment Right-of-use assets Intangible assets	11 11	56,367 94,855 9,106	57,942 98,658 9,026
Pledged bank deposits Prepayments and other receivables	13 12	3,130 6,696	3,130 30,197
Current assets		170,154	198,953
Prepayments and other receivables Pledged bank deposits Bank balances and cash	12 13 13	31,250 4,696 586,307	24,666 4,696 675,238
		622,253	704,600
Current liabilities Trade and other payables Deferred income Lease liabilities	14	49,042 10,559 20,879	79,738 13,850 13,296
		80,480	106,884
Net Current Assets		541,773	597,716
<b>Total Assets Less Current Liabilities</b>		711,927	796,669
Non-current liabilities Deferred income Contract liabilities Lease liabilities		9,268 283,019 52,413	5,087 283,019 58,232
		344,700	346,338
Net Assets		367,227	450,331
Capital and reserves Share capital Treasury shares held in trust Reserves		7,212 (607) 360,622	7,211 (626) 443,746
<b>Total Equity</b>		367,227	450,331

### NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

For the six months ended June 30, 2022

### 1. General information

The Company was established in the Cayman Islands as an exempted company with limited liability on November 10, 2009 and its shares have been listed on The Stock Exchange since September 14, 2018. The address of the registered office is PO Box 309, Ugland House, Grand Cayman, KY1-1104, Cayman Islands. The principal place of business of the Company is 275 Ai Di Sheng Road, Shanghai 201203, PRC.

The Company is an investment holding company. The Company and its subsidiaries (collectively referred to as "Group") are principally engaged in developing a global first-in-class oral drug, dorzagliatin or HMS5552, for the treatment of T2D.

### 2. Basis of preparation

The condensed consolidated financial statements have been prepared in accordance with International Accounting Standard 34 *Interim Financial Reporting* issued by the International Accounting Standards Board as well as with the applicable disclosure requirements of Appendix 16 to the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited.

The condensed consolidated financial statements have been prepared on the historical cost basis at the end of each reporting period.

Historical cost is generally based on the fair value of the consideration given in exchange for goods and services.

The functional currency of the Company is Renminbi ("RMB"), which is the same as the presentation currency of the condensed consolidated financial statements.

#### 3. Other income

	Six months ended June 30,		
	2022	2021	
	RMB'000	RMB'000	
	(unaudited)	(unaudited)	
Bank interest income	1,698	2,786	
Government grants (Note)	19,654	481	
<ul> <li>R&amp;D activities related grants</li> </ul>	16,687	_	
<ul> <li>Assets-related grants</li> </ul>	2,423	_	
- Others	544	481	
Covid-19-related rent concessions		345	
	21,352	3,612	

#### Note:

The amount mainly represents 1) government grant related to income received as compensation for future research and development costs expected to be incurred and require the Group to comply with conditions attached to the grants and the government to acknowledge the compliance of these conditions. These grants related to income were recorded in deferred income when received and recognized in profit or loss when related costs were subsequently incurred and the Group received government acknowledge of compliance; and 2) amortization of subsidies received from the PRC local government authorities to subsidize the purchase of the Group's leasehold improvement, furniture, fixture and equipment.

# 4. Other gains and losses

Other gains and losses mainly represent the foreign exchange gains and losses during the six months ended June 30, 2022 and 2021, respectively.

## 5. Finance cost

	Six months en	Six months ended June 30,	
	2022	2021	
	RMB'000	RMB'000	
	(unaudited)	(unaudited)	
Interest on the lease liabilities	1,805	1,999	
	1,805	1,999	

## 6. Loss before tax

Loss before tax for the period has been arrived at after charging:

	Six months ended June 30,		
	2022 <i>RMB'000</i> (unaudited)	2021 <i>RMB'000</i> (unaudited)	
	(unauunteu)	(unaudited)	
Depreciation of plant and equipment	5,894	6,128	
Depreciation of right-of-use assets	9,871	9,055	
Amortization of intangible assets	224	395	
Total depreciation and amortization	15,989	15,578	
Capitalized in construction in progress	(403)		
	15,586	15,578	
Covid-19-related rent concessions	_	345	
Other expense	_	1,617	
Staff cost (including directors' emoluments):			
<ul> <li>Salaries and other benefits</li> </ul>	63,561	66,009	
<ul> <li>Retirement benefit scheme contributions</li> </ul>	5,725	5,271	
<ul> <li>Share-based payment</li> </ul>	16,810	19,364	
	86,096	90,644	
Auditors' remuneration	647	680	
Expenses relating to short-term leases and leases of low-value assets	355	263	

### 7. Income tax expense

The Company was incorporated in the Cayman Islands and is exempted from income tax.

No Hong Kong profit tax was provided for as there was no estimated assessable profit of the Group's Hong Kong subsidiary that was subject to Hong Kong profit tax during the period presented in the condensed consolidated financial statements.

Under the Law of the PRC of Enterprise Income tax (the "EIT Law") and Implementation Regulation of the EIT Law, the estimated tax rate of the Group's PRC subsidiary is 25% during the period presented in the condensed consolidated financial statements. No PRC Enterprise Income tax was provided for as there was no estimated assessable profit of the Group's PRC subsidiary during the period presented in the condensed consolidated financial statements.

The subsidiary incorporated in the United States are subject to Federal and State Income taxes, the effective combined income tax rate is 21% for the current interim period.

Deferred taxation had not been recognized on the unused tax losses and deductible temporary differences due to the unpredictability of future profit streams.

### 8. License agreement

In December 2011, the Group entered into a research, development and commercialization agreement ("GKA Agreement") with Hoffman-La Roche Inc., and F. Hoffman-La Roche AG (collectively referenced as "Roche") under which Roche granted the Group an exclusive license of patent rights, know-how and regulatory filings with respect to a compound which is a glucokinase activator to research, develop and commercialize products ("Licensed Product") in the field of diabetes in the licensed territory ("Licensed Territory"). Pursuant to the GKA Agreement, the Group made US\$2,000,000 non-refundable upfront payment to Roche in 2012.

In 2017, the Group made US\$1,000,000 milestone payment to Roche upon the commencement of clinical trial Phase III in the PRC (excluding Hong Kong and Macau) for the Licensed Product.

In 2021, the Group made US\$1,000,000 milestone payment to Roche upon NDA filing in the PRC (excluding Hong Kong and Macau) to the National Medical Products Administration.

The Group is further obligated to make US\$3,000,000 milestone payments upon the achievement of development of the Licensed Product through new drag approval in the PRC (excluding Hong Kong and Macau) and US\$33,000,000 in the Licensed Territory other than the PRC (excluding Hong Kong and Macau). Upon commercialization, the Group is contingently obligated to make US\$15,000,000 milestone payments for the first time when the territory-wide calendar year net sales exceed US\$500,000,000 and US\$40,000,000 milestone payments for the first time when the territory-wide calendar year net sales exceed US\$1,000,000,000. The Group is also obligated to make royalty payments at the applicable incremental royalty rate based on sales of the Licensed Product.

### 9. Dividend

No dividends were paid, declared or proposed during the interim period. The directors of the Company have determined that no dividend will be paid in respect of the interim period.

### 10. Loss per share

The calculation of the basic and diluted loss per share attributable to the owners of the Company is based on the following data:

Loss figures are calculated as follows:

	Six months ended June 30,		
	2022	2021	
	RMB'000	RMB'000	
	(unaudited)	(unaudited)	
Loss for the period attributable to the owners of the Company			
for the purpose of basic and diluted loss per share	(104,619)	(165,292)	
Number of chause			
Number of shares:			
	Six months ended June 30,		
	2022	2021	
	(unaudited)	(unaudited)	
Weighted average number of ordinary shares for the purpose			
of basic and diluted loss per share	958,398,351	955,092,759	

The computation of basic loss per share for the six months ended June 30, 2022 and 2021 respectively excluded the unvested restricted stock units of the Company.

The computation of diluted loss per share for the six months ended June 30, 2022 and 2021 respectively did not assume the exercise of share options and vesting of restricted stock units since their assumed exercise would result in a decrease in loss per share.

### 11. Plant and equipment, and right-of-use assets

During the current interim period, the Group acquired RMB4,319,000 (unaudited) (six months ended June 30, 2021: RMB1,885,000 (unaudited)) of plant and equipment. In addition, during the current interim period, there is no disposal of plant and equipment (six months ended June 30, 2021: aggregate carrying amount of RMB149,500 (unaudited) for proceeds of RMB73,500 (unaudited), resulting in a loss on disposal of RMB76,000 (unaudited).). The net book value of plant and equipment at June 30, 2022 is RMB56,367,000 (unaudited) (December 31, 2021: RMB57,942,000 (audited)).

During the current interim period, the Group extended the lease terms of several existing lease agreements for one to three year. The Group is required to make fixed monthly or quarterly payments. On date of lease modification, the Group recognized right-of-use assets of RMB6,068,000 (unaudited) (six months ended June 30, 2021: RMB1,994,000 (unaudited)) and lease liabilities of RMB6,068,000 (unaudited) (six months ended June 30, 2021: RMB1,994,000 (unaudited)). The net book value of right-of-use assets and lease liabilities at June 30, 2022 is RMB94,855,000 (unaudited) (December 31, 2021: RMB98,658,000 (audited)) and RMB73,292,000 (unaudited) (December 31, 2021: RMB71,528,000 (audited)), respectively.

### 12. Prepayments and other receivables

	At June 30, 2022 <i>RMB'000</i>	At December 31, 2021 RMB'000
	(unaudited)	(audited)
Prepayments for services and materials Utility and rental deposits	19,912	14,303
- current	988	662
<ul><li>non-current</li></ul>	4,311	4,609
Value added tax recoverable – non-current	1,918	24,942
Interest receivables	130	52
Other receivables for considerations of options exercised Others	3,176	359
– current	7,044	9,290
– non-current	467	646
	37,946	54,863
Analyzed as		
– current	31,250	24,666
<ul><li>non-current</li></ul>	6,696	30,197
	37,946	54,863

### 13. Bank balances and cash/pledged bank deposits

Bank balances and cash comprise cash held by the Group and short-term bank deposits with an original maturity of six months or less. The short-term bank deposits carry interests at market rates which ranged from 0.001% to 1.95% per annum as of June 30, 2022 (December 31, 2021: from 0.001% to 1.95% per annum).

Pledged bank deposits are for the performance guarantees to the Management Committee of Lingang New Area, Shanghai Pilot Free Trade Zone, China to secure commencement and completion of the factory construction and launch of production.

Deposits amounting to RMB4,696,000 (unaudited) (December 31, 2021: RMB 4,696,000 (audited)) carry fixed interest rate of 1.50% and have been pledged to secure commencement of the factory construction. Deposits amounting to RMB1,565,000 (unaudited) (December 31, 2021: RMB1,565,000 (audited)) carry fixed interest rate of 2.75% and have been pledged to secure completion of the factory construction. These deposits will be released within 10 working days upon the completion of the factory construction if such completion is before May 13, 2024. The remaining deposits amounting to RMB1,565,000 (unaudited) (December 31, 2021: RMB1,565,000 (audited)) carry fixed interest rate of 2.75% and have been pledged to secure production of the factory. These deposits will be released within 10 working days upon the launch of production, if such launch is before November 12, 2024.

# 14. Trade and other payables

	At	At
	June 30,	December 31,
	2022	2021
	RMB'000	RMB'000
	(unaudited)	(audited)
Trade payables	12,535	23,785
Payroll and bonus payables	18,565	32,149
Other payables	1,574	4,071
Accrued leasehold improvement expenditure	1,468	1,604
Construction expenditure	10,379	10,982
Others	4,521	7,147
	49,042	79,738

The average credit period on purchases of goods/services ranges up to 30 days.

The aging analysis of the trade payables presented based on the invoice date at the end of each reporting period is as follows:

	At	At
	June 30,	December 31,
	2022	2021
	RMB'000	RMB'000
	(unaudited)	(audited)
Uninvoiced or within 30 days	12,535	23,785
	12,535	23,785

### OTHER INFORMATION

# Purchase, sale or redemption of the Company's listed securities

Neither the Company nor any of its subsidiaries had purchased, sold or redeemed any of the Company's listed securities during the six months ended June 30, 2022.

## **Employees and remuneration policy**

As of June 30, 2022, the Group employed a total of 147 employees, as compared to a total of 146 employees as of December 31, 2021. The majority of the employees are employed in mainland China. For the six months ended June 30, 2022, the staff costs (including Directors' emoluments but excluding any contributions to pension scheme) were approximately RMB80.4 million as compared to RMB85.4 million for the six months ended June 30, 2021.

The Group will continue to offer competitive remuneration packages, discretionary share options and bonuses to staff. The Group's employee remuneration policy is determined by taking into account factors such as remuneration in respect of the overall remuneration standard in the industry and employee's performance. The management reviews the Group's employee remuneration policy and agreements on a regular basis. Moreover, the social insurance contributions are made by the Group for its PRC employees in accordance with the relevant PRC regulations.

The Group also provides continuous learning and training programs to its employees to enhance their skills and knowledge, so as to maintain their competitiveness and improve their working efficiency. The Group did not experience any major difficulties in recruitment, nor did it experience any material loss in manpower or any material labor dispute during the six months ended June 30, 2022.

The Company has also adopted a Pre-IPO Share Incentive Scheme and a Post-IPO Share Option Scheme. Please refer to the section headed "Statutory and General Information – D. Share Incentive Schemes" in Appendix IV to the Prospectus for further details.

# Use of net proceeds from the Global Offering

The Shares were listed on the Stock Exchange on September 14, 2018. The net proceeds from the Global Offering amounted to RMB747.2 million (including the issue of additional Shares pursuant to the partial exercise of the over-allotment option on October 5, 2018) which have been, and will continue to be, applied according to the intentions set out in the section headed "Future Plans and Use of Proceeds" in the Prospectus. We expect that a portion of the net proceeds will be carried forward and utilized in the 2023 financial year due to a slight adjustment to the timeline for the development of our manufacturing capabilities.

The following table sets forth the status of the Company's use of proceeds raised in the Global Offering as of June 30, 2022:

		% of use of proceeds	Net proceeds from the Global Offering RMB million	Unutilized net proceeds as of January 1, 2022 RMB million	Utilization during the six months ended June 30, 2022 RMB million	Actual usage up to June 30, 2022 RMB million	Unutilized net proceeds as of June 30, 2022 RMB million	Expected time frame for unutilized amount
(a)	Dorzagliatin research and development	39%	291.4	_	-	291.4	_	N/A
(b)	Dorzagliatin lifecycle management and							By the end of
	additional indications	9%	67.2	26.8	6.8	47.2	20.0	year 2022
(c)	Dorzagliatin launch and							By the end of
	commercialization	27%	201.8	148.8	12.7	65.7	136.1	year 2023
(d)	New product and diabetes care							By the end of
	technology development	11%	82.2	60.3	0.1	22.0	60.2	year 2023
(e)	Product licensing and partnership							By the end of
		4%	29.9	23.5	-	6.4	23.5	year 2023
(f)	General working capital	10%	74.7			74.7		N/A
Tot	al	100%	747.2	259.4	19.6	507.4	239.8	By the end of year 2023

### Interim dividend

The Board has resolved not to declare any interim dividend for the six months ended June 30, 2022 (June 30, 2021: Nil).

# **Securities transactions by the Directors**

The Company has adopted the Model Code as the guidelines for the Directors' dealings in the securities of the Company since the Listing Date. Specific enquiry has been made of each Director and all Directors have confirmed that they have complied with the applicable standards set out in the Model Code for the six months ended June 30, 2022.

## **Corporate governance**

The Company is committed to maintaining a high standard of corporate governance to safeguard the interests of the Shareholders, enhance corporate value, formulate its business strategies and policies, and enhance its transparency and accountability.

The Company has adopted the code provisions of the CG Code as its own code of corporate governance. The CG Code has been applicable to the Company with effect from the Listing Date.

The Board is of the view that the Company has complied with all applicable code provisions of the CG Code throughout the six months ended June 30, 2022. In light of the amendments to the CG Code which came into effect on January 1, 2022 and impose additional requirements applicable to corporate governance reports for the financial year commencing on or after January 1, 2022, the Company will continue to regularly review and monitor its corporate governance structure and practices to ensure compliance with the latest version of the CG Code, and maintain a high standard of corporate governance. The Company will report on the compliance with the latest version of the CG Code in the corporate governance report of the Company for the year ending December 31, 2022.

# Changes to information in respect of the Directors

Mr. Robert Taylor Nelsen had resigned as director of Denali Therapeutics, Inc., a company listed on NASDAQ (stock code: DNLI), with effect from June 4, 2022.

Mr. William Robert Keller had resigned as director of Artisan Acquisition Corp., a company listed on NASDAQ (stock code: ARTA), with effect from May 17, 2022.

Save as disclosed above, there were no other changes to the information required to be disclosed by the Directors pursuant to Rule 13.51B of the Listing Rules.

### Review of interim results

The unaudited condensed consolidated financial results of the Group for the six months ended June 30, 2022 have been reviewed by the Company's auditor, Deloitte Touche Tohmatsu, in accordance with Hong Kong Standard on Review Engagements 2410 "Review of Interim Financial Information Performed by the Independent Auditor of the Entity" ("HKSRE 2410") issued by the Hong Kong Institute of Certified Public Accountants.

The audit committee of the Company has reviewed and discussed with the management of the Company the unaudited interim results of the Group for the six months ended June 30, 2022, and confirms that the applicable accounting principles, standard and requirements have been complied with, and that adequate disclosures have been made.

# Publication of the interim results and 2022 interim report on the websites of the Stock Exchange and the Company

This interim results announcement is published on the respective websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.huamedicine.com). The Company's interim report for the six months ended June 30, 2022 containing all the information required under the Listing Rules will be published on the respective websites of the Stock Exchange and the Company and will be dispatched to the Shareholders of the Company in due course.

### **DEFINITIONS**

In this interim results announcement, the following expressions have the meanings set out below unless the context requires otherwise.

"Board" the board of Directors

"CG Code" the Corporate Governance Code as set out in Appendix 14 to the

Listing Rules

"Company" Hua Medicine (華領醫藥), an exempt limited liability company

incorporated under the laws of the Cayman Islands on November 10,

2009 and whose Shares are listed on the Stock Exchange

"Director(s)" the director(s) of the Company

"FDC" fixed dose combination

"Group", "our", "we", the Company and its subsidiaries

or "us"

"HK\$" or "HK dollars" Hong Kong dollars, the lawful currency of Hong Kong

"Hong Kong" the Hong Kong Special Administrative Region of the People's

Republic of China

"Listing" listing of our Shares on the Stock Exchange

"Listing Date" September 14, 2018, being the date on which the Shares were listed

on the Main Board of the Stock Exchange

"Listing Rules" the Rules Governing the Listing of Securities on The Stock

Exchange of Hong Kong Limited

"Model Code" the Model Code for Securities Transactions by Directors of Listed

Issuers contained in Appendix 10 to the Listing Rules

"NMPA" National Medical Products Administration (國家藥品監督管理局),

and its predecessor, the China Food and Drug Administration (國家

食品藥品監督管理總局)

"NDA" new drug application

"PRC" the People's Republic of China, excluding, for the purposes of

this announcement, Hong Kong, the Macau Special Administrative

Region of the People's Republic of China and Taiwan

"Post-IPO Share the post-IPO share option scheme approved and adopted by the Option Scheme" Company on August 26, 2018 for the benefit of any director,

Company on August 26, 2018 for the benefit of any director, employee, adviser or consultant of the Company or any of its

subsidiaries

"Pre-IPO Share the share incentive scheme approved and adopted by the Company

Incentive Scheme" on March 25, 2013 as amended from time to time, for the benefit of

any director, employee, adviser or consultant of the Company or any

of its subsidiaries

"Prospectus" the prospectus of the company dated August 31, 2018

"RMB" or "Renminbi" Renminbi, the lawful currency of the PRC

"Shareholder(s)" holder of the Shares

"Share(s)" ordinary share(s) with nominal value of US\$0.001 each in the share

capital of the Company

"Stock Exchange" The Stock Exchange of Hong Kong Limited

"T2D" Type 2 Diabetes

"US\$" or "U.S. dollars" United States dollars, the lawful currency of the United States

"U.S." or "United States" the United States of America

By order of the Board
Dr. Li Chen
Chief Executive Officer
and
Executive Director

Hong Kong, August 25, 2022

As at the date of this announcement, the Board comprises Dr. Li Chen and Mr. George Chien Cheng Lin as executive directors of the Company; Mr. Robert Taylor Nelsen and Ms. Wei Zhao as non-executive directors of the Company; and Mr. Walter Teh-ming Kwauk, Mr. William Robert Keller, Mr. Junling Liu and Mr. Yiu Wa Alec Tsui as independent non-executive directors of the Company.