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**HUA MEDICINE**

**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, 2019**

**BUSINESS HIGHLIGHTS**

- Our strategic goal is to become a global diabetes care company
  - We will continue to advance the development of dorzagliatin as a global first-in-class medicine, launched first in China
  - We plan to expand our market access globally through the strength of our drug development platform
  - Our scientific platform focuses on the remodeling of glucose homeostasis by employing dorzagliatin as a cornerstone therapy for diabetes – either as monotherapy or in combination with other currently approved antidiabetic medicines, as well as other popular medicines commonly taken by diabetes patients
- We advanced our two Phase III trials for dorzagliatin in China, with total randomized enrollment of 1,181 patients as of July 31, 2019
  - Our monotherapy Phase III trial (HMM0301) completed enrollment on February 28, 2019
  - As of July 31, 2019, enrollment for our combination with metformin Phase III trial (HMM0302) was 718 patients
- In order to implement the Company’s strategy, we announced our updated pipeline in June 2019, which significantly expands our dorzagliatin-driven portfolio in the diabetes care market

- To support the expansion of dorzagliatin into additional diabetes indications, we have initiated two combination studies with dorzagliatin in clinical trials in the United States
  - Our DPP-4 combination trial (HMM0111) is a pharmacokinetic (PK) and pharmacodynamic (PD) study of dorzagliatin in combination with sitagliptin to investigate the PK/PD of each drug alone or in combination. We dosed our first patient in January 2019
  - Our SGLT-2 combination trial (HMM0112) is a PK/PD study of dorzagliatin in combination with empagliflozin to investigate the PK/PD of each drug alone or in combination. We dosed our first patient in April 2019
- In addition, we continue to advance our development of fixed-dose combination drug candidates with dorzagliatin, with six programs in development, and for which we filed a series of patents in May 2019
- In January 2019, the China National Intellectual Property Administration (CNIPA) issued to our Company a patent on a controlled release formulation of dorzagliatin. This new patent would extend the exclusivity of dorzagliatin to 2037 in China
- In February 2019, we announced the appointment of Dr. Ralph DeFronzo as our Global Consultant – Distinguished Scientific Consultant. Dr. DeFronzo is currently a Professor and Division Chief of Diabetes Division at the University of Texas Health Science Center and the Deputy Director of the Texas Diabetes Institute. He has contributed to several significant milestones in diabetes medicine, including leading the U.S. development of metformin, and its FDA approval in 1995. Since then, he has discovered a new approach to diabetes treatment that targets glucose reabsorption in the kidneys, which led to the development and approval of the SGLT-2 class of drugs.
- Cash position was approximately RMB1,246.4 million as of June 30, 2019.
- Total expenditures incurred by the Company for the six months ended June 30, 2019 was approximately RMB240.9 million, of which approximately RMB166.5 million was attributable to research and development expenses.

## FINANCIAL HIGHLIGHTS

- Research and development expenses increased by approximately RMB70.8 million or approximately 74% to approximately RMB166.5 million for the six months ended June 30, 2019.
- Loss before tax decreased by approximately RMB1,271.4 million or approximately 84.4% to approximately RMB235.5 million for the six months ended June 30, 2019.
- Loss and total comprehensive expense for the period decreased by approximately RMB1,271.4 million or approximately 84.4% to approximately RMB235.5 million for the six months ended June 30, 2019.
- Adjusted loss\* increased by approximately RMB78.2 million or approximately 67.9% to approximately RMB193.5 million for the six months ended June 30, 2019.

\* Adjusted loss is not a financial measure defined under International Financial Reporting Standards (“IFRS”). It is calculated by taking loss before tax for the period and adding back (a) share-based payment; and (b) loss on changes in fair value of financial liabilities at FVTPL.

## MANAGEMENT DISCUSSION AND ANALYSIS

### Business overview

We are a pre-revenue drug development company currently focused on developing dorzagliatin, a first-in-class oral drug for the treatment of Type 2 diabetes (T2D). In the first half of 2019, we defined our strategic goal to become a global diabetes care company. We intend to establish dorzagliatin as a cornerstone therapy for diabetes, either as a monotherapy or in combination with other currently approved medicines.

We filed an Investigational New Drug (IND) application with the National Medical Products Administration (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. Since then, we have completed five Phase I trials in China, two Phase I trials in the United States, and one Phase II trial in China. We are currently conducting two Phase III trials in China and two Phase I trials in the United States. Our Phase III registration trials began in July 2017, with dorzagliatin both as a monotherapy (HMM0301) and in combination with metformin (HMM0302).

To expand our market globally, we recently announced an updated pipeline to investigate the combination of dorzagliatin with several other medicines. Two Phase I trials began in the first half of 2019 in the United States, and are studying the pharmacokinetic (PK) and pharmacodynamic (PD) characteristics of dorzagliatin in combination with sitagliptin (DPP-4 inhibitor) and empagliflozin (SGLT-2 inhibitor), respectively. We plan to initiate trials with several other available medicines to expand our dorzagliatin-driven portfolio.

In preparation for our eventual new drug application (NDA) submission for dorzagliatin with the NMPA, we completed the required active pharmaceutical ingredient commercial manufacturing process validation. We established the leadership team for our China Commercialization Strategy and Marketing (CSM) team for dorzagliatin in 2018, and have continued to grow our CSM team in 2019.

We are also developing mGLUR5, a potential novel drug candidate for the treatment of neurodegenerative diseases, including Parkinson's disease levodopa-induced dyskinesia, or PD-LID.

## Product pipeline

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

Trial #	Drugs	Disease indication	Study type	Pre-clinical	Phase I	Phase II	Phase III	NDA
HMM0301	Dorzagliatin	Drug naïve T2D	Registration trial					
HMM0302	Dorzagliatin & metformin	Metformin tolerated T2D	Registration trial					
HMM0311	Dorzagliatin vs. DPP-4	T2D	Head to head					
HMM0312	Dorzagliatin vs. acarbose	T2D	Head to head					
HMM0109	Dorzagliatin	Hepatic impaired T2D	Label expansion					
HMM0110	Dorzagliatin	Renal impaired T2D	Label expansion					
HMM0111	Dorzagliatin + DPP-4	Obese T2D	PK/PD & DDI					
HMM0112	Dorzagliatin + SGLT-2	Metabolic syndrome	PK/PD & DDI					
HMM0113	Dorzagliatin + atorvastatin	Label expansion	PK/PD & DDI					
HMM0114	Dorzagliatin + valsartan	Label expansion	PK/PD & DDI					
HMM0115	Dorzagliatin + sulfonylurea	SU-tolerated T2D	PK/PD & DDI					
HMM0116	Dorzagliatin + acarbose	Acarbose tolerated T2D	PK/PD & DDI					
HMM0117	Dorzagliatin + liraglutide	GLP-1 tolerated T2D	PK/PD & DDI					
HMM0119	Dorzagliatin + pioglitazone	NASH T2D	PK/PD & DDI					
HMM1201	Dorzagliatin + insulin	Basal insulin tolerated T2D	Insulin sparing					
HMM1202	Dorzagliatin + insulin	Drug naïve severe T2D	Pre-clinical					
	mGLUR5	PD-L1/5	Pre-clinical					

HMM0301 is a dorzagliatin monotherapy Phase III trial in drug-naïve T2D patients in China. We completed enrollment with over 450 patients as of February 28, 2019, and we expect to announce top-line 24-week results by the fourth quarter of 2019.

HMM0302 is a dorzagliatin combination with metformin Phase III trial in metformin tolerant T2D patients in China. We expect to complete patient enrollment in the third quarter of 2019, and we expect to announce top-line 24-week result by the second quarter of 2020.

As part of our strategy to establish dorzagliatin as a cornerstone therapy for the treatment of T2D globally, we are also investigating the combination of dorzagliatin with various approved classes of orally available anti-diabetic medicines as well as other popular medicines commonly taken by diabetes patients to address patients' personal needs.

HMM0111 is a dorzagliatin combination with sitagliptin (DPP-4 inhibitor) Phase I trial in T2D patients in the United States. We announced that the first patient was dosed in January 2019 and expect to complete and announce results by year end 2019.

HMM0112 is a dorzagliatin combination with empagliflozin (SGLT-2 inhibitor) Phase I trial in T2D patients in the United States. We announced the first patient was dosed in April 2019 and expect to complete and announce results by first half 2020.

We expect to initiate a head to head comparison trial (HMM0311) with a DPP-4 inhibitor (sitagliptin, aka Januvia®) in the second half of 2019. As Januvia® and Janumet® combined generated over US\$5.9 billion in global sales in 2018, this trial has the potential to expand and accelerate the Company's commercialization plans for dorzagliatin. Shanghai Municipal Science & Technology Commission has provided a government grant subsidy in support of this important trial. For similar reasons, the Company is also beginning preparatory work for initiation of its head to head comparison trial (HMM0312) between dorzagliatin and  $\alpha$ -glucosidase inhibitor, the leading China oral anti-diabetic drug class with RMB8.7 billion annual sales in 2017 in China (according to Frost & Sullivan). We are also planning to conduct additional dorzagliatin combination trials with several other T2D drugs on the market as well.

The Company believes T2D drug-naïve population in China provides a huge market opportunity due to the relatively low rate of diagnosis in China (estimated at only 47.7% in 2017 by Frost & Sullivan), and coupled with the government's explicit announcement to invest in areas outside of Tier 3 cities to increase that rate. The Company has observed, though, that many such Chinese T2D drug-naïve patients have already advanced to a rather late stage of T2D (as measured by their diagnosed HbA1c levels) when finally diagnosed. It is this specific population that the Company believes its combination with insulin could provide a very strong therapy regimen as first-line therapy.

We continue to conduct pre-clinical studies on our mGLUR5 program for neurodegenerative disorders. Based on the results of these studies, we plan to make a decision on whether or not to proceed with such drug developments later in 2020.

We continue to work closely with and supervise our contract research organizations (CROs), clinical site management organizations (SMOs) and contract manufacturing organizations (CMOs), who provide us with a range of services at a consistently high level of quality. In addition, we continue to expand our network of key opinion leaders and experts globally. In February 2019, we appointed Dr. Ralph DeFronzo as our Global Consultant – Distinguished Scientific Consultant. Dr. DeFronzo is currently a Professor and Division Chief of Diabetes Division at the University of Texas Health Science Center and the Deputy Director of the Texas Diabetes Institute. He has contributed to several significant milestones in diabetes medicine, including leading the U.S. development of metformin, and its FDA approval in 1995. Since then, he has discovered a new approach to diabetes treatment that targets glucose reabsorption in the kidneys, which led to the development and approval of the SGLT-2 class of drugs.

We continue to ensure our patent portfolio is up to date. In January 2019, the China National Intellectual Property Administration (CNIPA) issued to our Company a patent on a controlled release formulation of dorzagliatin. This new patent would extend the exclusivity of dorzagliatin to 2037 in China. In May 2019, we filed a series of patents for fixed-dose combinations with dorzagliatin, and have six programs in development.

To date, we have not yet generated any revenue from the sale of goods or from the rendering of services, recognizing only limited income in the form of government grants and investment income. As of June 30, 2019, we expect to continue to incur significant losses for the foreseeable future with no product revenues prior to obtaining marketing approval for dorzagliatin from the NMPA and commercializing dorzagliatin.

Our future success depends substantially on the success in China of our only clinical drug candidate, dorzagliatin. Our current plan is to make our initial NDA submission after completion of both Phase III trials. Our ongoing Phase III clinical trials for dorzagliatin in China may not succeed, we may fail to successfully commercialize dorzagliatin in China or experience significant delays in doing so, or we may not meet our goal of establishing dorzagliatin as a first-line standard of care in China, any of which could materially harm our business.

## **Business outlook**

Within the next 12 months, we expect to announce top-line 24-week data for both of our Phase III trials in China, and also the results of our two Phase I combination drug-drug interaction trials in the United States. Upon receipt of positive Phase III data, we plan to partner with international pharmaceutical companies to make dorzagliatin available to patients outside of China. This will include partnerships for conducting clinical trials and navigating the drug approval process, as well as for the marketing and commercialization of dorzagliatin outside of China. We plan to expand our CSM team in anticipation of China launch of dorzagliatin by the end of 2020 or early 2021. We also plan to incur additional and significant expenses relating to establishing our manufacturing facilities in China. As part of our strategy to establish dorzagliatin as a cornerstone therapy for the treatment of diabetes globally, we would expect to expand and grow our collaborations with global experts in diabetes to further understand the potential of dorzagliatin.

## **Financial review**

### ***Other income***

Our other income consisted primarily of bank interest income and government grants and subsidies. Our other income decreased by RMB3.4 million to RMB3.4 million for the six months ended June 30, 2019 from RMB6.8 million for the six months ended June 30, 2018, which was mainly attributable to the decrease of RMB6.4 million in government grants resulting from no government grants recognized as income since no acknowledgement reports occurred during the period and the increase of bank interest income by RMB2.9 million for the six months ended June 30, 2019.

### ***Other gains***

Our other gains consisted primarily of gains due to fluctuations in the exchange rates between the Renminbi and the U.S. dollars and between Renminbi and HK dollars. Our other gains and losses decreased by RMB27.6 million to a gain of RMB2.0 million for the six months ended June 30, 2019 from a gain of RMB29.6 million for the six months ended June 30, 2018. In particular, the gains in both 2018 and 2019 were mainly attributable to foreign exchange gains in connection with bank balances and cash denominated in U.S. dollars and HK dollars and appreciation of the U.S. dollars and HK dollars against the Renminbi.

Our business mainly operates in the PRC, and with the exception of our listing expenses incurred in connection with our HK IPO, most of our transactions settled in Renminbi. Since inception, we have financed our business solely through equity financings, with related proceeds denominated in U.S. dollars, HK dollars and Renminbi. We converted a portion of those U.S. dollars proceeds to Renminbi and HK dollars proceeds to U.S. dollars 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. dollars and HK dollars denominated cash balances (including the HK dollars proceeds received from the HK IPO into Renminbi) 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 RMB41.8 million to RMB74.2 million in the six months ended June 30, 2019 from RMB32.4 million in the six months ended June 30, 2018, which was mainly attributable to i) increase in labor costs which was attributable to the increase of RMB12.3 million in share-based payment including share options and restricted share units that were granted, and increase of RMB9.9 million in cash compensation due to increased headcount of 11 new employees in the six months ended June 30, 2019 for the establishment of our commercial strategy and marketing team, ii) consulting fee of RMB14.5 million mainly associated with ongoing public expense, headhunting cost and commercialization strategy expense in 2019, and iii) overhead costs associated with the headcount increases.

### ***Finance cost***

Our finance cost consisted of expenses associated with the issue of redeemable convertible preferred shares and interest on lease liabilities. Our finance cost was RMB0.1 million in the six months ended June 30, 2019 as compared to RMB4.4 million in the six months ended June 30, 2018, which was attributable to the Series D and Series E preferred shares financings completed in March 2018.

### ***Listing expenses***

Our listing expenses mainly include sponsor fee, underwriting fees and commissions, and professional fees paid to legal advisers and the reporting accountants for their services rendered in relation to the HK IPO. We incurred listing expenses of approximately RMB34.8 million for the six months ended June 30, 2018, which were recognized as expenses. No such expense incurred for the six months ended June 30, 2019.

### ***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,			
	2019	%	2018	%
	RMB' 000		RMB' 000	
Dorzagliatin Clinical Trials	85,342	51%	55,143	57%
Dorzagliatin Non-clinical Studies	308	0%	807	1%
Chemical, Manufacturing and Control	17,966	11%	6,250	7%
Labor Cost	54,297	33%	29,777	31%
Dorzagliatin Licensing and Patent Fee	2,018	1%	238	0%
Others	6,572	4%	3,475	4%
Total	<u>166,503</u>	<u>100.0%</u>	<u>95,690</u>	<u>100.0%</u>



Research and development expenses increased by RMB70.8 million to RMB166.5 million for the six months ended June 30, 2019 from RMB95.7 million for the six months ended June 30, 2018. The increase in research and development expenses mainly included:

- an increase of RMB30.2 million for dorzagliatin clinical trials, which was primarily attributable to increased costs associated with the progress of our Phase III clinical trials and additional Phase I clinical trials conducted in 2019;
- an increase of RMB11.7 million in chemical, manufacturing, and control expenses, which was primarily attributable to process validation for spray dried powder (SDP) manufacturing and scaling-up development and method validation of SDP completed in 2019;
- an increase of RMB24.5 million for increased labor costs, which was primarily attributable to an increase of RMB10.4 million in cash compensation with headcount increasing from 63 as of June 30, 2018 to 92 as of June 30, 2019 and an increase of RMB14.1 million in share-based payment;
- an increase of RMB1.8 million for increased dorzagliatin licensing and patent fee, which was primarily attributable to a Patent Cooperation Treaty (PCT) application for dorzagliatin; and
- an increase of RMB3.1 million for others, which was primarily attributable to increased travelling, consulting and meeting costs, and increased rental cost.

#### ***Loss on changes in fair value of financial liabilities at FVTPL***

Our loss on changes in fair value of convertible redeemable preferred shares consisted primarily of the increase in fair value per share.

In connection with the HK IPO, all our outstanding convertible redeemable preferred shares were converted into ordinary shares on September 14, 2018, after which, we would no longer recognize any loss on changes in fair value of convertible redeemable preferred shares. Thus, no loss incurred for the six months ended June 30, 2019.

#### ***Income tax expense***

We recognized no income tax expenses in the six months ended June 30, 2019 and the six months ended June 30, 2018.

#### ***Adjusted net loss***

Adjusted net loss was calculated by taking loss before tax for the period and adding back (a) share-based payment; and (b) loss on changes in fair value of financial liabilities at FVTPL.

	<b>Six months ended June 30,</b>	
	<b>2019</b>	<b>2018</b>
	<b>RMB' 000</b>	<b>RMB' 000</b>
Loss before tax for the period	(235,500)	(1,506,939)
Adjust for:		
Loss on changes in fair value of financial liabilities at FVTPL	–	1,376,057
Share-based payment	42,046	15,646
	<u>          </u>	<u>          </u>
Adjusted net loss	<u><u>(193,454)</u></u>	<u><u>(115,236)</u></u>

### **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 R&D expenses. Our operating activities utilized RMB198.2 million for the six months ended June 30, 2019. As of June 30, 2019, we had cash and cash equivalents of RMB1,246.4 million.

As of June 30, 2019, 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 reporting period.

### **Cash Operating Cost**

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

	<b>Six months ended June 30,</b>	
	<b>2019</b>	<b>2018</b>
	<b>RMB' 000</b>	<b>RMB' 000</b>
R&D costs	145,572	77,474
Administrative costs		
– Workforce employment	20,126	25,174
– Others	32,456	18,225
	<u>          </u>	<u>          </u>
	52,582	43,399
	<u><u>198,154</u></u>	<u><u>120,873</u></u>

## Cash Flows

The following table provides information regarding our cash flows for the six months ended June 30, 2018 and 2019:

	Six months ended June 30,	
	2019	2018
	RMB' 000	RMB' 000
Net cash used in operating activities	(198,154)	(120,873)
Net cash (used in) from investing activities	(1,666)	16,045
Net cash from financing activities	409	722,361
Effect of exchange rate changes	2,490	29,324
	<u>          </u>	<u>          </u>
Net (decrease) increase in cash and cash equivalents	<u>(196,921)</u>	<u>646,857</u>

### *Net Cash Used in Operating Activities*

The primary use of our cash was to fund the development of 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, 2019, our operating activities used RMB198.2 million of cash, which resulted principally from our loss before tax of RMB235.5 million, adjusted for non-cash charges and non-operating cash charges of RMB40.0 million, and by cash used in our operating assets and liabilities of RMB2.7 million. Our net non-cash charges during the six months ended June 30, 2019 primarily consisted of share-based payments expenses, depreciation of plant and equipment and amortization for intangible assets.

During the six months ended June 30, 2018, our operating activities used RMB120.9 million of cash, which resulted principally from our loss before tax of RMB1,506.9 million, adjusted for non-cash charges and non-operating cash charges of RMB1,360.4 million, and by cash provided by our operating assets and liabilities of RMB25.6 million. Our net non-cash charges during the six months ended June 30, 2018 primarily consisted of loss on changes in fair value of financial liabilities at FVTPL, depreciation of plant and equipment, amortization for intangible assets, share-based payments expenses, and net foreign exchange gain.

### *Net Cash (used in) from Investing Activities*

Net cash used in investing activities was RMB1.7 million for the six months ended June 30, 2019, which resulted primarily from the purchase of plant and equipment, adjusted for interest received from bank for short-term deposit. Net cash provided by investing activities was RMB16.0 million for the six months ended June 30, 2018, which resulted primarily from the disposals of other financial assets.

## ***Net Cash from Financing Activities***

Net cash from financing activities was RMB0.4 million for the six months ended June 30, 2019, which resulted from proceeds from exercise of share options, adjusted for repayments of lease liabilities. Net cash from financing activities was RMB722.4 million for the six months ended June 30, 2018, which resulted primarily from proceeds from the issue of our Series D and E preferred shares.

## **Financial position**

Our net current assets decreased from RMB1,396.9 million as of December 31, 2018 to RMB1,194.8 million as of June 30, 2019. Current assets decreased from RMB1,474.5 million as of December 31, 2018 to RMB1,264.1 million as of June 30, 2019, primarily due to decrease in bank balances and cash from RMB1,443.3 million as of December 31, 2018 to RMB1,246.4 million as of June 30, 2019, which was due primarily to net cash expenditure during the six months ended June 30, 2019.

## **Significant change in accounting policy**

We have applied IFRS 16 for the first time since January 1, 2019 and IFRS 16 superseded IAS 17 Leases (“IAS 17”), and the related interpretations. The lease contractual obligations were reflected into the account of lease liabilities in our condensed consolidated statement of financial position as of June 30, 2019.

## **Indebtedness**

As of June 30, 2019, we did not have any indebtedness, including but not limited to mortgages, charges, debentures, other issued and outstanding debt capital, bank overdrafts, borrowings, liabilities under acceptance or acceptance credits, hire purchase commitments, unutilized banking facilities or other similar indebtedness, any guarantees or other material contingent liabilities. Accordingly, the gearing ratio is not applicable.

## **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, as 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 is 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 Trading 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 convert a portion of those funds to Renminbi immediately and place the remaining amount in time deposits. We convert 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 Renminbi against U.S. dollars and HK dollars, the foreign currencies with which we may have material exposure. No sensitivity analysis has been disclosed for the Taiwan dollars denominated assets as the impact on profit is immaterial. 5% represents management's assessment of the reasonably possible change in foreign exchange rate. The sensitivity analysis uses outstanding foreign currency denominated monetary items as a base and adjusts their translation at the end of the reporting period for a 5% change in foreign currency rate. A negative number below indicates an increase in loss where Renminbi strengthens 5% against U.S. dollars and HK dollars. For a 5% weakening of Renminbi against U.S. dollars and HK dollars there would be an equal and opposite impact on gain for the period.

	<b>As of June 30, 2019 RMB' 000</b>	<b>As of December 31, 2018 RMB' 000</b>
<b>Impact on profit or loss</b>		
US\$	(31,051)	(50,411)
HK\$	(20,421)	(20,438)

### ***Interest Rate Risk***

The Company and its subsidiaries (collectively referred to as 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 of the Company 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, 2019, and December 31, 2018, we recorded net current assets of RMB1,194.8 million and RMB1,396.9 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.

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

		Six months ended June 30,	
	NOTES	2019 RMB' 000 (unaudited)	2018 RMB' 000 (unaudited)
Other income	3	3,379	6,827
Other gains	4	1,995	29,554
Administrative expenses		(74,242)	(32,369)
Finance cost	5	(129)	(4,380)
Listing expenses		–	(34,824)
Research and development expenses		(166,503)	(95,690)
Loss on changes in fair value of financial liabilities at fair value through profit or loss (“FVTPL”)		–	(1,376,057)
		<u>–</u>	<u>(1,376,057)</u>
Loss before tax	6	(235,500)	(1,506,939)
Income tax expense	7	–	–
		<u>–</u>	<u>–</u>
Loss and total comprehensive expense for the period		<u>(235,500)</u>	<u>(1,506,939)</u>
Loss and total comprehensive expense for the period attributable to:			
– Owners of the Company		(235,500)	(1,505,667)
– Non-controlling interests		–	(1,272)
		<u>–</u>	<u>(1,272)</u>
		<u>(235,500)</u>	<u>(1,506,939)</u>
<b>LOSS PER SHARE</b>	9	<b>RMB</b>	<b>RMB</b>
Basic and diluted		<u>(0.25)</u>	<u>(13.58)</u>



## CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	NOTES	As of June 30, 2019 RMB' 000 (unaudited)	As of December 31, 2018 RMB' 000 (audited)
<b>Non-current assets</b>			
Equipment	10	8,183	5,328
Right-of-use assets	10	4,965	–
Intangible assets		1,228	859
Prepayments and other receivables	11	20,655	9,552
		35,031	15,739
<b>Current assets</b>			
Prepayments and other receivables	11	14,236	24,337
Prepayments to related parties		3,437	6,863
Bank balances and cash	12	1,246,389	1,443,310
		1,264,062	1,474,510
<b>Current liabilities</b>			
Trade and other payables	13	63,962	76,033
Deferred income		1,600	1,600
Lease liabilities		3,700	–
		69,262	77,633
<b>Net Current Assets</b>		1,194,800	1,396,877
<b>Total Assets Less Current Liabilities</b>		1,229,831	1,412,616
<b>Non-current liabilities</b>			
Deferred income		16,178	9,128
Lease liabilities		1,295	–
		17,473	9,128
<b>Net Assets</b>		1,212,358	1,403,488

	As of June 30, 2019 RMB' 000 (unaudited)	As of December 31, 2018 RMB' 000 (audited)
<b>Capital and reserves</b>		
Share capital	7,209	7,209
Treasury shares held in trust	(777)	(797)
Reserves	<u>1,205,926</u>	<u>1,397,076</u>
<b>Total Equity</b>	<u><u>1,212,358</u></u>	<u><u>1,403,488</u></u>

## NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

For the six months ended June 30, 2019

### 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, Uglan 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 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 of the condensed consolidated financial statements

The condensed consolidated financial statements have been prepared in accordance with International Accounting Standard 34 (IAS 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 “Listing Rules”)

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

### 3. Other income

	Six months ended June 30,	
	2019	2018
	RMB' 000	RMB' 000
	(unaudited)	(unaudited)
Bank interest income	3,337	389
Government grants and subsidies related to income (note)	42	6,438
	<u>3,379</u>	<u>6,827</u>

Note:

The government grants and subsidies related to income have been received to compensate for the expenses of the Group's research and development. Some of the grants related to income have future related 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 incomes were recognized in profit or loss when related costs are subsequently incurred and the Group received government acknowledgement of compliance.

Other government grants related to income that are received as compensation for expenses or losses already incurred or for the purpose of giving immediate financial support to the Group with no future related costs are recognized in profit or loss when received by the Group.

#### 4. Other gains

	Six months ended June 30,	
	2019	2018
	RMB' 000	RMB' 000
	(unaudited)	(unaudited)
Loss on disposal of plant and equipment	–	(7)
Net foreign exchange gain	1,995	29,302
Gain from changes in fair value of other financial assets – realized	–	259
	<u>1,995</u>	<u>29,554</u>

#### 5. Finance cost

	Six months ended June 30,	
	2019	2018
	RMB' 000	RMB' 000
	(unaudited)	(unaudited)
Interest expense on the lease liabilities	129	–
Transaction cost for the issue of the Company's convertible redeemable preferred shares, subsidiary's ordinary shares and written put option over subsidiary	–	(4,380)
	<u>129</u>	<u>(4,380)</u>

#### 6. Loss before tax

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

	Six months ended June 30,	
	2019	2018
	RMB' 000	RMB' 000
	(unaudited)	(unaudited)
Depreciation of plant and equipment	1,504	508
Depreciation of right-of-use assets	2,135	–
Amortization of intangible assets	85	–
Staff cost (including directors' emoluments):		
– Salaries and other benefits	56,124	26,887
– Retirement benefit scheme contributions	2,687	2,680
– Share-based payment	42,046	15,646
	<u>100,857</u>	<u>45,213</u>
Auditors' remuneration	680	1,000
Expenses relating to short-term leases and lease of low-value assets	<u>1,620</u>	<u>–</u>

## **7. Income tax expense**

The Company was incorporated in the Cayman Islands and is exempted from Cayman Islands 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 periods 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 periods presented in the condensed consolidated financial statements.

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 Company 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 Company 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 Company made a US\$2.0 million non-refundable upfront payment to Roche which was recorded as research and development expenses in 2012.

In 2017, the Company made a US\$1.0 million milestone payment to Roche upon the commencement of Phase III clinical trials in the PRC (excluding Hong Kong and Macau) for the Licensed Product which was recorded as research and development expenses as incurred.

The Company is obligated to make a US\$4.0 million milestone payment upon the approval of the Licensed Product in the PRC (excluding Hong Kong and Macau) and an aggregate of US\$33.0 million of milestone payments upon approval in the Licensed Territory other than the PRC (excluding Hong Kong and Macau). Upon commercialization, the Company is contingently obligated to make a US\$15.0 million milestone payment for the first time when the territory-wide calendar year net sales exceed US\$500.0 million and US\$40.0 milestone payment for the first time when the territory-wide calendar year net sales exceed US\$1.0 billion. The Company is also obligated to make royalty payments at the applicable incremental royalty rate based on sales of the Licensed Product.

## 9. 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:

	<b>Six months ended June 30,</b>	
	<b>2019</b>	<b>2018</b>
	<b>RMB' 000</b>	<b>RMB' 000</b>
	<b>(unaudited)</b>	<b>(unaudited)</b>
Loss for the period attributable to the owners of the Company for the purpose of basic and diluted loss per share	<u>(235,500)</u>	<u>(1,505,667)</u>

Number of shares:

	<b>Six months ended June 30,</b>	
	<b>2019</b>	<b>2018</b>
	<b>(unaudited)</b>	<b>(unaudited)</b>
Weighted average number of ordinary shares for the purpose of basic and diluted loss per share	<u>939,507,659</u>	<u>110,876,161</u>

The computation of basic and diluted loss per share for the six months ended June 30, 2019 and 2018 respectively excluded the unvested restricted stock units of the Company.

The computation of diluted loss per share for the six months ended June 30, 2019 and 2018 respectively did not assume the exercise of share options since their assumed exercise would result in a decrease in loss per share.

## 10. EQUIPMENT AND RIGHT-OF-USE ASSETS

During the six months ended June 30, 2019, the Group acquired RMB4,359,000 (unaudited) (six months ended June 30, 2018: RMB706,000 (unaudited)) of equipment. The net book value of equipment at June 30, 2019 is RMB8,183,000 (unaudited) (December 31, 2018: RMB5,328,000 (audited)).

During the six months ended June 30, 2019, the Group entered into several new lease agreements for the use of buildings and office equipment for two to three years, and recognized RMB2,389,000 (unaudited) of right-of-use asset and RMB2,389,000 (unaudited) lease liabilities. The Group is required to make fixed monthly or quarterly payments. The net book value of right-of-use asset and lease liabilities at June 30, 2019 is RMB4,965,000 (unaudited) and RMB4,995,000 (unaudited), respectively.

## 11. Prepayments and other receivables

	As of June 30, 2019 RMB' 000 (unaudited)	As of December 31, 2018 RMB' 000 (audited)
Prepayments for research and development services	11,160	21,157
Utility and rental deposits	1,955	1,530
Value add tax recoverable – non-current	19,070	9,552
Others	2,706	1,650
	<u>34,891</u>	<u>33,889</u>
Analyzed as		
– non-current	20,655	9,552
– current	14,236	24,337
	<u>34,891</u>	<u>33,889</u>

## 12. Bank balances and cash

Bank balances and cash comprise cash held by the Group and short-term bank deposits with an original maturity of three months or less. The short term bank deposits carry interests at market rates which ranged from 0.05% to 2.60% per annum as of June 30, 2019 (December 31, 2018: from 0.01% to 0.30% per annum).

## 13. Trade and other payables

	As of June 30, 2019 RMB' 000 (unaudited)	As of December 31, 2018 RMB' 000 (audited)
Trade payables	45,830	55,676
Payroll and bonus payables	12,906	14,867
Accrued expense	3,989	4,652
Others	1,237	838
	<u>63,962</u>	<u>76,033</u>

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 goods/services receipt date at the end of each reporting period is as follows:

	As of June 30, 2019 RMB' 000 (unaudited)	As of December 31, 2018 RMB' 000 (audited)
Within 30 days	45,830	35,118
31 to 60 days	–	6,411
61 to 180 days	–	14,147
	<u>45,830</u>	<u>55,676</u>



## **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 for the six months ended June 30, 2019.

### **Employees and remuneration policy**

As of June 30, 2019, the Group employed a total of 138 employees, as compared to a total of 115 employees as of December 31, 2018. The majority of the employees are employed in mainland China. For the six months ended June 30, 2019, the staff costs (including Directors' emoluments but excluding any contributions to pension scheme) were approximately RMB98.2 million as compared to RMB42.5 million for the six months ended June 30, 2018.

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, 2019.

### **Share incentive plan**

The Company conditionally adopted a share option scheme (the "Share Option Scheme") on August 26, 2018, which became effective on the Listing Date. The total number of Shares which may be issued upon exercise of all options to be granted under the Share Option Scheme cannot exceed 105,191,330 Shares. As of June, 30, 2019, the Company granted 22,344,300 options to subscribe for Shares and 1,080,000 options were forfeited due to resignation under the Share Option Scheme.

The Company has also adopted the Pre-IPO Share Incentive Scheme and established an employee trust to administer the scheme. A total of 117,000,000 Shares, representing all the Shares underlying the options and awards granted under the Pre-IPO Share Incentive Scheme, were issued to HLYY Limited, the nominee under the trust, to hold the Shares to satisfy the options and awards granted upon exercise/vesting. No further Shares will be allotted and issued to the HLYY Limited or the trustee for the purpose of the Pre-IPO Share Incentive Scheme (other than pursuant to capitalization issue, rights issue, sub-division or consolidation of shares in accordance with the Pre-IPO Share Incentive Scheme), and no further option or award will be granted under the Pre-IPO Share Incentive Scheme. As the Pre-IPO Share Incentive Scheme does not involve the grant of options to subscribe for any new Shares of the Company, it is not required to be subject to the provisions under Chapter 17 of the Listing Rules.

## **Interim dividend**

The Board has resolved not to declare any interim dividend for the six months ended June 30, 2019 (June 30, 2018: 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 to 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, 2019.

## **Corporate governance**

The Company is committed to maintaining 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 set out in Appendix 14 to the Listing Rules 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, 2019. The Board will review the corporate governance structure and practices from time to time and shall make necessary arrangements when the Board considers appropriate.

## **Changes to information in respect of the Directors**

Mr Tsui Yiu Wa, Alec had resigned as Independent Non-Executive Director of Kangda International Environment Company Limited 康達國際環保有限公司 (Stock Code: 6136) effective on April 4, 2019.

Since the announcement date, there was no other changes to the information required to be disclosed by the Directors pursuant to Rule 13.51B of the Listing Rules where applicable.

## **Review of interim results**

The unaudited condensed consolidated financial results of the Group for the six months ended June 30, 2019 have been reviewed by the 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, 2019, 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 2019 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](http://www.hkexnews.hk)) and the Company ([www.huamedicine.com](http://www.huamedicine.com)). The Company's interim report for the six months ended June 30, 2019 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 result announcement, the following expressions have the meanings set out below unless the context requires otherwise.

“Board”	the board of Directors of the Company
“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
“Group”	the Company and its subsidiaries
“HK\$” or “HK dollars”	Hong Kong dollars, the lawful currency of Hong Kong
“HK IPO”	the global offering of the Shares, comprising the Hong Kong public offering of 10,476,000 Shares, and the international offering of 94,280,000 Shares and 2,980,500 Shares pursuant to the partial exercise of the over-allotment option granted by the Company
“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 the Securities Transactions by Directors of Listed Issue's 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)

“PCT”	Patent Cooperation Treaty
“PRC”	the People’s Republic of China, excluding, for the purposes of this announcement, the Hong Kong Special Administrative Region of the People’s Republic of China, the Macau Special Administrative Region of the People’s Republic of China and Taiwan
“Pre-IPO Share Incentive Scheme”	the share incentive scheme approved and adopted by the Company 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
“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
“US\$” or “U.S. dollars”	United States dollars, the lawful currency of the United States of America
“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 15, 2019

*As of the date of this announcement, the board of directors of the Company comprises Dr. Li Chen and Mr. George Chien Cheng Lin as executive directors of the Company; Mr. Robert Taylor Nelsen and Dr. Lian Yong Chen 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.*