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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, 2020

BUSINESS HIGHLIGHTS

- Successfully completed our SEED/HMM0301, one of our two pivotal Phase III registration trials in China: dorzagliatin monotherapy in drug naïve patients, demonstrating sustained efficacy and safety over the 52-week treatment period
- Achieved the primacy efficacy endpoint in our 24-week double-blinded placebo-controlled Phase III registration trial, DAWN/HMM0302. The trial was a dorzagliatin in combination with metformin trial, conducted in metformin tolerant Type 2 diabetes (“T2D”) patients in China
- Completed HMM0110, which demonstrated desirable pharmacokinetics profile in patients with end stage chronic kidney disease, indicating the potential use of dorzagliatin among T2D patients with renal impairment in mild, moderate, severe and end stage before dialysis
- Completed HMM0111, which successfully demonstrated the possibility of administering dorzagliatin in combination with sitagliptin, the global top-selling DPP-4 inhibitor, as well as potential synergies from the combination
- Completed HMM0112, which successfully demonstrated the possibility of administering dorzagliatin in combination with empagliflozin, a top-selling SGLT-2 inhibitor, as well as potential synergies from the combination
- Presented additional data from our SEED 24-week period study, demonstrating improvements in β -cell function in patients treated with dorzagliatin at the 2020 American Diabetes Association’s 80th Scientific Sessions

FINANCIAL HIGHLIGHTS

- Cash position was approximately RMB949.6 million as of June 30, 2020.
- Total expenditures incurred by the Company for the six months ended June 30, 2020 was approximately RMB180.5 million, of which approximately RMB112.3 million was attributable to research and development expenses.
- Research and development expenses decreased by approximately RMB54.3 million or approximately 32.6% to approximately RMB112.3 million for the six months ended June 30, 2020, compared with the six months ended June 30, 2019.
- Loss before tax decreased by approximately RMB62.0 million or approximately 26.3% to approximately RMB173.5 million for the six months ended June 30, 2020, compared with the six months ended June 30, 2019.
- Loss and total comprehensive expense for the period decreased by approximately RMB61.8 million or approximately 26.3% to approximately RMB173.7 million for the six months ended June 30, 2020, compared with the six months ended June 30, 2019.

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 Type 2 diabetes (“T2D”). We filed an Investigational New Drug (“IND”) application with the National Medical Products Administration of the People’s Republic of China (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. Since then, we have completed six Phase I trials in China, four Phase I trials in the United States, one Phase II trial and one Phase III registration trial, SEED/HMM0301 in China. Our Phase III registration trials began in July 2017 in China, with dorzagliatin both as a monotherapy (SEED/HMM0301) and in combination with metformin (DAWN/HMM0302).

During the six months ended June 30, 2020 (the “Reporting Period”), we released positive results of our Phase I trials HMM0110, HMM0111, and HMM0112, and the positive 52-week topline results from one of our pivotal Phase III registration trial in China (SEED/HMM0301). On July 1, 2020, we released the positive 24-week topline results of Phase III metformin combination trial of dorzagliatin (DAWN/HMM0302). We also presented data demonstrating improvements in β -cell function at the American Diabetes Association’s 80th Scientific Sessions (the “2020 ADA”), which builds upon the positive results from our topline results. The results demonstrate dorzagliatin’s potential to restore glucose homeostasis in T2D patients, and continue to support our efforts to launch dorzagliatin as a cornerstone therapy for the treatment of T2D. We continue to progress with our Phase III registration trial DAWN/HMM0302, with the expectation to complete the 52-week trial by the third quarter of 2020, and announce topline results by year-end 2020. We also currently have one ongoing Phase I trial in China, HMM0109, which studies the pharmacokinetics profile of dorzagliatin in hepatic impaired patients.

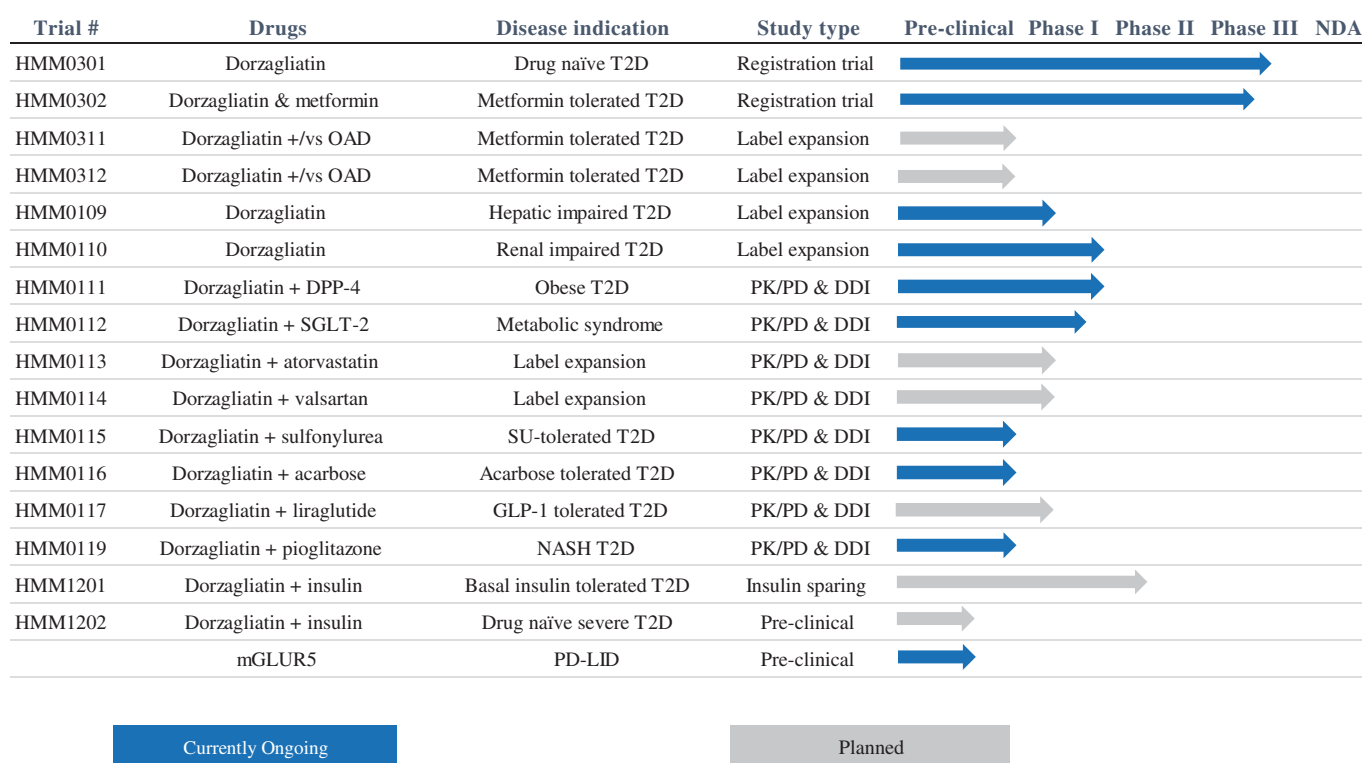
We have initiated multiple studies on dorzagliatin plus existing anti-diabetes therapies at preclinical development and clinical settings. Six patents were filed, which cover the fixed-dose combination of dorzagliatin with six classes of oral anti-diabetic drugs. Some of these classes have already demonstrated complementary or synergistic effects to expand the clinical application across a full range of T2D patients, and those with metabolic syndrome or other diabetes complications.

In preparation for our NDA submission for dorzagliatin with the NMPA, we have fully validated cGMP commercial manufacturing processes for API and drug product to support our launch in China.

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:



Clinical trials completed during the reporting period:

SEED/HMM0301 is a dorzagliatin monotherapy Phase III trial in drug-naïve T2D patients in China. We completed enrollment with 463 patients as of February 28, 2019, and we announced positive 24-week topline results on November 12, 2019. The trial achieved its primary efficacy endpoint at 24-week by demonstrating a statistically significant reduction in HbA1c levels over placebo. During this 24-week period, dorzagliatin was well tolerated and had a good safety profile. For the 52-week treatment period, the efficacy and safety profiles were sustained based on the topline data analysis. During the 28-week open-label period, patients initially receiving a placebo (i.e., the placebo group) were administered dorzagliatin for the first time. The chart and table below illustrate the efficacy (as measured by HbA1c reduction) for the two-cohort groups for the entire 52-week period.

Chart: HbA1c Reduction over 52 weeks

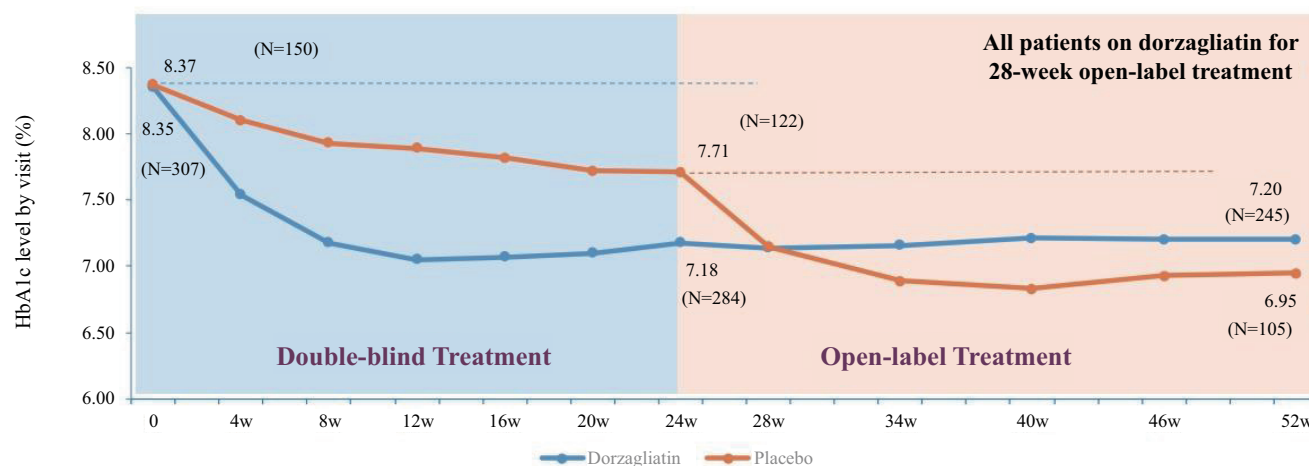


Table: HbA1c Reduction

	24 weeks	52 weeks	p-value*
Treatment Group (simple mean calculation)	-1.15	-1.11	<0.001
Placebo Group (simple mean calculation)	-0.58	-1.27	<0.001

Note: * $p < 0.001$ compared with baseline at 52 week

In the initial 24-week treatment period, dorzagliatin exhibited a safe and well tolerated clinical profile. Fewer than 1 percent of patients experienced clinically significant hypoglycaemia (blood glucose < 3 mmol/L) was reported, based on the ADA's guidelines. During the 28-week open-label treatment period, dorzagliatin continued to exhibit a safe and well-tolerated clinical profile. A safety analysis based on study safety population demonstrated that dorzagliatin was well tolerated and had a good safety profile. The incidence of adverse events was similar between the dorzagliatin-treated and placebo groups. There was less than 1% hypoglycemia with blood glucose < 3 mmol/L during the 52-week treatment period. During the 28-week open-label treatment, patients also saw a continued reduction of insulin resistance (insulin resistance is the hallmark of Type 2 diabetes).

HMM0110 demonstrated desirable pharmacokinetics profile in patients with end stage chronic kidney disease, indicating the potential use of dorzagliatin among T2D patients with renal impairment in mild, moderate, severe and end stage before dialysis.

HMM0111, dorzagliatin demonstrated the possibility of administration in combination with sitagliptin, the global top-selling DPP-4 inhibitor, with superior blood glucose reduction over sitagliptin or dorzagliatin monotherapy.

HMM0112, which successfully demonstrated the possibility of administering dorzagliatin in combination with empagliflozin, a top-selling SGLT-2 inhibitor, also achieved significantly enhanced glucose lowering effect over empagliflozin or dorzagliatin monotherapy.

Ongoing/planned trials:

As part of our strategy to establish dorzagliatin as a cornerstone therapy for the treatment of T2D globally, the positive results of the trials of HMM0110, HMM0111, HMM0112 and HMM0301 allow us to advance its mission. 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 each patients' personal needs. We are also exploring the use of dorzagliatin in T2D patients with hepatic and renal impairment, as many other oral antidiabetic medicines are not readily suitable for these patient populations.

In addition to DAWN/HMM0302, we currently have one additional trial being conducted in China to expand dorzagliatin's indications. HMM0109 is a Phase I trial studying the impact on pharmacokinetics for patients with hepatic impairment in China.

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.

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, 2020, we expect 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.

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.

Business outlook

We plan to announce top-line 52-week Phase III trial results for our combination with metformin trial (DAWN/HMM0302) by year end 2020. We plan to file for NDA approval with the NMPA after the completion of both 52-week trials. Our plan is to partner with either China-based or international pharmaceutical companies to make dorzagliatin available to patients, in both China and regions outside of China. In order to continue expansion of dorzagliatin's indications for the treatment of T2D, we plan to initiate trials with several other available medicines to expand our dorzagliatin-driven portfolio. As part of the strategy to establish dorzagliatin as a cornerstone therapy for the treatment of T2D globally, we would expect to collaborate with global experts in T2D to further understand the potential of dorzagliatin.

Key events after the reporting period

On July 1, 2020, we announced positive results for DAWN/HMM0302. DAWN/HMM0302 is a dorzagliatin add-on to metformin Phase III registration trial in metformin tolerant T2D patients in China. We completed patient enrollment with 766 patients as of August 30, 2019, and we announced positive 24-week topline results on July 1, 2020. The trial met the primary efficacy and safety endpoints in the double-blinded placebo-controlled and randomized 24-week trial period. Dorzagliatin again demonstrated fast onset, potent and sustained HbA1c reduction of 1.02% from baseline at 24 weeks, as compared to a reduction of 0.36% (least squares mean) from baseline for the placebo group (p-value < 0.0001), in T2D patients whose blood glucose cannot be controlled with the maximum tolerated dose of metformin (Glucophage®, 1500mg/day). The American Diabetes Association (ADA) treatment target of HbA1c below 7.0% was achieved by 44.4% of subjects on dorzagliatin and metformin, compared to 10.7% of subjects who received metformin only. Patients treated with dorzagliatin demonstrated statistically significant improvement of HOMA2- β , HOMA2-IR, 2hPPG and FPG over those in the placebo group. In the 24-week period, dorzagliatin continued to exhibit a safe and well-tolerated clinical profile. There was less than 1% hypoglycemia with blood glucose < 3 mmol/L during the 24-week treatment period. There was no drug-related SAE, nor severe hypoglycemia reported. We expect to complete and announce data from the full 52-week trial (plus one-week follow-up) by year end 2020.

As of the date of this announcement, business operations in China have been impacted by the outbreak of the novel coronavirus (COVID-19) since the latter half of January 2020. Due to the extenuating circumstances of the COVID-19 outbreak, many businesses in China halted operations as a result of the quarantine measures imposed by the government. Following guidelines issued by the Chinese government, our Company requested all employees work remotely beginning February 3, 2020. On March 2, 2020, our employees started returning to our offices in China in accordance with government guidelines, and as of the date of this announcement, our employees, as well as those of our partners (e.g., CROs, SMOs and CMOs), have resumed normal operations. Despite these challenging circumstances, we have been able to achieve our major clinical trial milestones during this period without any delay. We announced positive 52-week topline results for SEED/HMM0301 on June 18, 2020, and positive 24-week topline results for DAWN/HMM0302 on July 1, 2020. Throughout this period, we have operated in strict adherence with national guidelines in conducting clinical trials, and also enforced additional trial management guidelines in pharmacovigilance and quality control to ensure our clinical trials remain on track and conducted in high quality. However, we do expect potential delays in the release of top-line results and also potential delays with some NDA-enabling work due to the COVID-19 outbreak, which could lead to a delay in the filing of the NDA with the NMPA.

Financial review

Other income

Our other income consisted primarily of bank interest income and government grants. Our other income was RMB3.6 million in the six months ended June 30, 2020 as compared to RMB3.4 million in the six months ended June 30, 2019, which was mainly attributable to RMB0.3 million of government grants and subsidies.

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. dollars and between Renminbi and HK dollars. Our other gains and losses increased by RMB1.5 million were mainly attributable to foreign exchange gains in connection with bank balances and cash denominated in U.S. dollars and HK dollars and larger appreciation of the U.S. dollars and HK dollars against the Renminbi for the six months ended June 30, 2020.

Our business mainly operates in the PRC, and 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 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 decreased by RMB8.2 million to RMB66.0 million in the six months ended June 30, 2020 from RMB74.2 million in the six months ended June 30, 2019, which was mainly attributable to i) decrease in labor costs which was attributable to the decrease of RMB9.7 million in share-based payment under the accelerated amortization method, adjusted for an increase of RMB2.4 million in cash compensation with headcount increase, ii) decrease in consulting fee of RMB3.6 million associated with commercialization strategy and market research expense incurred in the first half year of 2019 and no such cost in the first half year of 2020, iii) decrease of RMB2.5 million in travelling costs due to the impact of COVID-19 and decrease of RMB2.0 million in recruitment cost based on the recruitment plan, and iv) adjusted for the rental increase of RMB7.5 million with entering into the tenancy agreement for leasing office building in December, 2019 to establish the Global Operation Headquarters and Research and Development Center in China.

Finance cost

Our finance cost consisted primarily of interest on lease liabilities. Our finance cost was RMB2.2 million in the six months ended June 30, 2020 as compared to RMB0.1 million in the six months ended June 30, 2019, which was mainly attributable to the lease of headquarters building at the end of year 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,			
	2020	%	2019	%
	RMB' 000		RMB' 000	
Dorzagliatin Clinical Trials	46,565	41%	85,342	51%
Dorzagliatin Non-clinical Studies	225	0%	308	0%
Chemical, Manufacturing and Control	4,652	4%	17,966	11%
Labor Cost	55,261	50%	54,297	33%
Dorzagliatin Licensing and Patent Fee	1,272	1%	2,018	1%
Others	4,278	4%	6,572	4%
Total	<u>112,253</u>	<u>100.0%</u>	<u>166,503</u>	<u>100.0%</u>

Research and development expenses decreased by RMB54.3 million to RMB112.3 million for the six months ended June 30, 2020 from RMB166.5 million for the six months ended June 30, 2019. The decrease in research and development expenses mainly included:

- a decrease of RMB38.8 million for dorzagliatin clinical trials, which was primarily attributable to decreased costs associated with the successful conclusion of the 52-week study period of SEED/HMM0301 in March 2020 and the increasing number of patients completing DAWN/HMM0302 beginning December 2018;
- a decrease of RMB13.3 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 the first half year of 2019;
- an increase of RMB1.0 million for increased labor costs, which was primarily attributable to an increase of RMB3.1 million in cash compensation with headcount increase, adjusted for a decrease of RMB2.1 million in share-based payment;
- a decrease of RMB2.3 million for others, which was primarily attributable to decreased travelling, consulting and meeting costs due to the impact of COVID-19.

Income tax expense

We recognized no income tax expenses in the six months ended June 30, 2020 and the six months ended June 30, 2019.

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 RMB167.4 million for the six months ended June 30, 2020. As of June 30, 2020, we had cash and cash equivalents of RMB949.6 million.

As of June 30, 2020, 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:

	Six months ended June 30,	
	2020	2019
	RMB' 000	RMB' 000
R&D costs	91,247	145,572
Administrative costs		
– Workforce employment	27,386	20,126
– Others	48,772	32,456
	<u>76,158</u>	<u>52,582</u>
	<u>167,405</u>	<u>198,154</u>

Cash Flows

The following table provides information regarding our cash flows for the six months ended June 30, 2019 and 2020:

	Six months ended June 30,	
	2020	2019
	RMB' 000	RMB' 000
Net cash used in operating activities	(167,405)	(198,154)
Net cash from (used in) investing activities	2,871	(1,666)
Net cash (used in) from financing activities	(3,832)	409
Effect of exchange rate changes	12,350	2,490
	<u>(156,016)</u>	<u>(196,921)</u>

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, 2020, our operating activities used RMB167.4 million of cash, which resulted principally from our loss before tax of RMB173.5 million, adjusted for non-cash charges and non-operating cash charges of RMB29.2 million, and by cash used in our operating assets and liabilities of RMB23.1 million. Our net non-cash charges during the six months ended June 30, 2020 primarily consisted of share-based payments expenses, depreciation of equipment, right of use assets and amortization for intangible assets.

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 equipment and amortization for intangible assets.

Net Cash from (used in) Investing Activities

Net cash provided by investing activities was RMB2.9 million for the six months ended June 30, 2020, which resulted primarily from the interest received from bank for short-term deposit, adjusted for purchase of equipment and intangible assets. 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 equipment, adjusted for interest received from bank for short-term deposit.

Net Cash (used in) from Financing Activities

Net cash used in financing activities was RMB3.8 million for the six months ended June 30, 2020, which resulted from repayments of lease liabilities, adjusted for proceeds from exercise of share options. 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.

Financial position

Our net current assets decreased from RMB1,011.70 million as of December 31, 2019 to RMB868.5 million as of June 30, 2020. Current assets decreased from RMB1,120.5 million as of December 31, 2019 to RMB961.6 million as of June 30, 2020, primarily due to decrease in bank balances and cash from RMB1,105.6 million as of December 31, 2019 to RMB949.6 million as of June 30, 2020, which was due primarily to net cash expenditure during the six months ended June 30, 2020.

Significant change in accounting policy

In the current interim period, we have applied the Amendments to References to the Conceptual Framework in IFRS Standards and the following amendments to IFRSs issued by the International Accounting Standard Board (the ‘IASB’). We also have applied the Amendment to IFRS 16 “Covid-19-Related Rent Concessions.”

Indebtedness

As of June 30, 2020, our lease liabilities amounted to RMB87.5 million. The following table sets forth our lease liabilities as of the dates indicated:

	As of June 30, 2020 RMB’000	As of December 31, 2019 RMB’000
Current portion	14,822	12,019
Non-current portion	72,652	77,959
Total	87,474	89,978

Our lease liabilities as of June 30, 2020 were from leased properties and vehicle lease contracts with lease terms of two to six years. As of June 30, 2020, 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, 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.

	As of June 30, 2020 RMB'000	As of December 31, 2019 RMB'000
Impact on profit or loss		
US\$	(29,140)	(42,433)
HK\$	(2,330)	(2,634)

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, 2020, and December 31, 2019, we recorded net current assets of RMB868.5 million and RMB1,011.7 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.

CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

		Six months ended June 30,	
	NOTES	2020 RMB' 000 (unaudited)	2019 RMB' 000 (unaudited)
Other income	3	3,554	3,379
Other gains and losses		3,463	1,995
Administrative expenses		(65,972)	(74,242)
Finance cost		(2,247)	(129)
Research and development expenses		<u>(112,253)</u>	<u>(166,503)</u>
Loss before tax	4	(173,455)	(235,500)
Income tax expense	5	<u>—</u>	<u>—</u>
Net loss		<u>(173,455)</u>	<u>(235,500)</u>
Other comprehensive loss			
<i>Items that may be reclassified subsequently to profit or loss:</i>			
– Exchange differences on translation of foreign operations		<u>(202)</u>	<u>—</u>
Loss and total comprehensive expense for the period		<u><u>(173,657)</u></u>	<u><u>(235,500)</u></u>
Loss and total comprehensive expense for the period attributable to:			
– Owners of the Company		<u>(173,657)</u>	<u>(235,500)</u>
		<u><u>(173,657)</u></u>	<u><u>(235,500)</u></u>
LOSS PER SHARE	7	RMB	RMB
Basic and diluted		<u><u>(0.18)</u></u>	<u><u>(0.25)</u></u>

CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	NOTES	As of June 30, 2020 RMB' 000 (unaudited)	As of December 31, 2019 RMB' 000 (audited)
Non-current assets			
Equipment	8	10,209	10,988
Right-of-use assets	8	81,224	90,486
Intangible assets		2,535	1,980
Prepayments and other receivables	9	35,113	30,707
		<u>129,081</u>	<u>134,161</u>
Current assets			
Prepayments and other receivables	9	11,977	14,852
Bank balances and cash	10	949,584	1,105,600
		<u>961,561</u>	<u>1,120,452</u>
Current liabilities			
Trade and other payables	11	69,743	88,317
Deferred income		8,450	8,450
Lease liabilities		14,822	12,019
		<u>93,015</u>	<u>108,786</u>
Net Current Assets		<u>868,546</u>	<u>1,011,666</u>
Total Assets Less Current Liabilities		<u>997,627</u>	<u>1,145,827</u>
Non-current liabilities			
Deferred income		7,248	7,248
Lease liabilities		72,652	77,959
		<u>79,900</u>	<u>85,207</u>
Net Assets		<u><u>917,727</u></u>	<u><u>1,060,620</u></u>
Capital and reserves			
Share capital		7,209	7,209
Treasury shares held in trust		(720)	(729)
Reserves		911,238	1,054,140
Total Equity		<u><u>917,727</u></u>	<u><u>1,060,620</u></u>

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

For the six months ended June 30, 2020

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 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,	
	2020	2019
	RMB' 000	RMB' 000
	(unaudited)	(unaudited)
Bank interest income	3,167	3,337
Government grants and subsidies related to income (note)	327	42
Rental concession	60	—
	<u>3,554</u>	<u>3,379</u>

Note:

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. Loss before tax

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

	Six months ended June 30,	
	2020	2019
	RMB' 000	RMB' 000
	(unaudited)	(unaudited)
Depreciation of equipment	2,277	1,504
Depreciation of right-of-use assets	10,106	2,135
Amortization of intangible assets	137	85
Staff cost (including directors' emoluments) (Note):		
– Salaries and other benefits	60,624	56,124
– Retirement benefit scheme contributions	1,657	2,687
– Share-based payment	30,216	42,046
	<u>92,497</u>	<u>100,857</u>
Auditors' remuneration	680	680
Expenses relating to short-term leases and lease of low-value assets	<u>785</u>	<u>1,620</u>

Note:

The government assistance have been implemented for the relief of the social insurance in respect of Covid-19. According to the notice issued by the Ministry of Social Affairs (2020) No .11, in order to minimize the impact of the COVID-19 on social and economic development, the government has reduced the social security fees for medium-sized enterprises from February to June 2020.

5. 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.

6. 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 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.

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 million 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.

7. 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,	
	2020	2019
	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	(173,455)	(235,500)

Number of shares:

	Six months ended June 30,	
	2020	2019
	(unaudited)	(unaudited)
Weighted average number of ordinary shares for the purpose of basic and diluted loss per share	948,878,897	939,507,659

The computation of basic and diluted loss per share for the six months ended June 30, 2020 and 2019 respectively excluded the unvested restricted stock units of the Company.

The computation of diluted loss per share for the six months ended June 30, 2020 and 2019 respectively did not assume the exercise of share options since their assumed exercise would result in a decrease in loss per share.

8. Equipment and right-of-use assets

During the six months ended June 30, 2020, the Group acquired RMB1,498,000 (unaudited) (six months ended June 30, 2019: RMB4,359,000 (unaudited)) of equipment. The net book value of equipment at June 30, 2020 is RMB10,209,000 (unaudited) (December 31, 2019: RMB10,988,000 (audited)).

During the six months ended June 30, 2020, the Group entered into several renewed lease agreements for the use of buildings and office equipment for two to three years, and recognized RMB844,000 (unaudited) of right-of-use asset and RMB844,000 (unaudited) lease liabilities (six months ended June 30, 2019: 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, 2020 is RMB81,224,000 (unaudited) and RMB87,474,000 (unaudited), respectively. The rent concessions occurred as a direct consequence of Covid-19 pandemic and met all of the conditions in IFRS 16.46B, and the Group applied the practical expedient to treat rent concessions as the variable rental payment. During the current interim period, the effects on changes in lease payments due to forgiveness or waiver by the lessors for the relevant leases of RMB 60,000 were recognized as negative variable lease payments. The rent concessions were related to the Wuhan Office and granted by the lessor in the form of direct rent reduction. The rest of the terms of the Wuhan Office were consistent with the original lease and have not been changed.

9. Prepayments and other receivables

	As of June 30, 2020 RMB' 000 (unaudited)	As of December 31, 2019 RMB' 000 (audited)
Prepayments for research and development services	1,986	2,838
Utility and rental deposits		
– current	1,832	1,462
– non-current	3,504	4,117
Value add tax recoverable – non-current	31,270	26,248
Others		
– current	8,159	10,552
– non-current	339	342
	<u>47,090</u>	<u>45,559</u>
Analyzed as		
– current	11,977	14,852
– non-current	<u>35,113</u>	<u>30,707</u>
	<u>47,090</u>	<u>45,559</u>

10. 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 0.001% to 1.2% per annum as of June 30, 2020 (December 31, 2019: from 0.05% to 2.80% per annum).

11. Trade and other payables

	As of June 30, 2020 RMB' 000 (unaudited)	As of December 31, 2019 RMB' 000 (audited)
Trade payables	46,685	47,941
Payroll and bonus payables	16,004	28,577
Other payables	4,132	3,660
Accrued expense	1,857	6,662
Other tax payables	<u>1,065</u>	<u>1,477</u>
	<u>69,743</u>	<u>88,317</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 invoice date at the end of each reporting period is as follows:

	As of June 30, 2020 RMB' 000 (unaudited)	As of December 31, 2019 RMB' 000 (audited)
Uninvoiced or within 30 days	46,685	47,491
	<u>46,685</u>	<u>47,491</u>

12. Interim 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.

13. Events after the reporting period

The Group had no material events for disclosure subsequent to June 30, 2020 and up to the date of issuance of the condensed consolidated financial statements.

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, 2020.

Employees and remuneration policy

As of June 30, 2020, the Group employed a total of 168 employees, as compared to a total of 158 employees as of December 31, 2019. The majority of the employees are employed in mainland China. For the six months ended June 30, 2020, the staff costs (including Directors' emoluments but excluding any contributions to pension scheme) were approximately RMB90.8 million as compared to RMB98.2 million for the six months ended June 30, 2019.

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, 2020.

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 of the Company date August 31, 2018 for further details. To clarify, the 500,000 share options granted by the Company on 20 July 2020 pursuant to the Post-IPO Share Option Scheme were fully cancelled on 28 July 2020.

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, 2020.

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, 2020. 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 has been appointed as a member of the audit committee of the Company as replacement of Dr. Chen Lian Yong on June 25, 2020.

Mr. Tsui Yiu Wa, Alec had resigned as independent non-executive director of DTXS Silk Road Investment Holdings Company Limited 大唐西市絲路投資控股有限公司 (Stock Code: 620) effective on 29 May 2020.

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, 2020 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, 2020, 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 2020 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, 2020 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.

Grant of options under the Post-IPO Share Option Scheme

Reference is made to the section headed “Grant offer letter and notification of grant of options” in the 2019 annual report of the Company published on April 22, 2020.

Set out below are further details of share options granted by the Company under the Post-IPO Share Option Scheme:

	Option type	Note	Number of share options granted	Closing price of the Shares immediately before the date on which the options were granted
Category 1: Directors				
Dr. Li CHEN	Post-IPO Share Option Scheme Accepted: June 25, 2019	1	12,079,000	HK\$8.89
Mr. George Chien Cheng LIN	Post-IPO Share Option Scheme Accepted: May 17, 2019	1	300,000	HK\$8.89
Category 2: Employees				
	Post-IPO Share Option Scheme Accepted: October 29, 2018	2	75,000	HK\$6.81
	Accepted: November 26, 2018	3	500,000	HK\$8.17
	Accepted: December 31, 2018	4	500,000	HK\$8.06
	Accepted: May 15, 2019	1	8,540,300	HK\$8.89
	Accepted: September 19, 2019	5	500,000	HK\$6.80
Category 3: Individual consultants				
	Post-IPO Share Option Scheme Accepted: May 15, 2019	1	200,000	HK\$8.89

- (1) With grant date of March 8, 2019 and vesting commencement date of January 23, 2019 or November 11, 2019 and are exercisable in accordance with the vesting schedule that the Shares subject to the options will be vested on the first anniversary of the vesting commencement date and the remaining 75% of the Shares subject to the options will be vested in 36 monthly installments thereafter, subject to the grantee’s continued employment through the applicable vesting date, at an exercise price of HK\$8.866.
- (2) With grant date of October 29, 2018 and vesting commencement date of October 29, 2018 and are exercisable in accordance with the vesting schedule that the Shares subject to the options will be vested on the first anniversary of the vesting commencement date and the remaining 75% of the Shares subject to the options will be vested in 36 monthly installments thereafter, subject to the grantee’s continued employment through the applicable vesting date, at an exercise price of HK\$7.192.

- (3) With grant date of November 26, 2018 and vesting commencement date of November 26, 2018 and are exercisable in accordance with the vesting schedule that the Shares subject to the options will be vested on the first anniversary of the vesting commencement date and the remaining 75% of the Shares subject to the options will be vested in 36 monthly installments thereafter, subject to the grantee's continued employment through the applicable vesting date, at an exercise price of HK\$7.970.
- (4) With grant date of December 31, 2018 and vesting commencement date of December 31, 2018 and are exercisable in accordance with the vesting schedule that the Shares subject to the options will be vested on the first anniversary of the vesting commencement date and the remaining 75% of the Shares subject to the options will be vested in 36 monthly installments thereafter, subject to the grantee's continued employment through the applicable vesting date, at an exercise price of HK\$8.30.
- (5) With grant date of August 29, 2019 and vesting commencement date of September 19, 2019 and are exercisable in accordance with the vesting schedule that the Shares subject to the options will be vested on the first anniversary of the vesting commencement date and the remaining 75% of the Shares subject to the options will be vested in 36 monthly installments thereafter, subject to the grantee's continued employment through the applicable vesting date, at an exercise price of HK\$6.80.

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
“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)
“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
“Post-IPO Share Option Scheme”	the post-IPO share option scheme approved and adopted by the 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 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 17, 2020

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.