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HUA MEDICINE

華領醫藥

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2552)

ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED DECEMBER 31, 2020

The board (the “**Board**”) of directors (the “**Directors**”) of Hua Medicine (the “**Company**”) is pleased to announce the audited consolidated results of the Company and its subsidiaries (together, the “**Group**”, “**we**” or “**us**”) for the year ended December 31, 2020, together with comparative figures for the year ended December 31, 2019. Unless otherwise defined herein, capitalized terms used in this announcement shall have the same meaning as those defined in the prospectus of the Company dated August 31, 2018 (the “**Prospectus**”).

BUSINESS HIGHLIGHTS

Clinical trials:

- Completed SEED (HMM0301), the first Phase III registration trial in China to investigate the efficacy and safety of dorzagliatin monotherapy in drug naïve Type 2 diabetes (T2D) patients, and announced the 52-week positive topline results with sustained efficacy, and good safety and tolerability profiles
- Completed DAWN (HMM0302), the second Phase III registration trial in China to investigate the efficacy and safety of dorzagliatin in T2D patients inadequately glycaemic-controlled with metformin, and announced both the 24-week and 52-week positive topline results with sustained efficacy, and good safety and tolerability profiles
- Presented data from SEED 24-week monotherapy clinical trial at the 80th American Diabetes Association (ADA) Annual Scientific Sessions, which demonstrated significant improvements in β -cell function and 2h-PPG reduction. Presented additional data from DAWN at the Chinese Diabetes Society’s 2020 Scientific Meeting, demonstrating improvements in β -cell function and reduction of insulin resistance

Clinical trials: (continued)

- Completed HMM0110, which demonstrated desirable pharmacokinetics profile in patients with end stage chronic kidney disease, indicating the potential use of dorzagliatin with no dose adjustment among T2D patients with moderate, severe and end stage chronic kidney disease (i.e. stages 3-5 of CKD)
- Completed HMM0111, investigating the pharmacokinetic (PK) and pharmacodynamic (PD) parameters of dorzagliatin either alone or in combination with sitagliptin (a DPP-4 inhibitor), and demonstrated a clear synergistic effect in efficacy of blood glucose reduction and improvement of β -cell function in T2D patients through regulation of GLP-1 secretion under combination therapy of dorzagliatin with sitagliptin
- Completed HMM0112, investigating the PK and PD characteristics of dorzagliatin and empagliflozin (a SGLT-2 inhibitor) as either monotherapy or combination therapy, and demonstrated a clear synergistic effect in efficacy of blood glucose reduction under combination therapy of dorzagliatin with empagliflozin with improvement of β -cell function

CHINA COMMERCIALIZATION AND OTHERS:

- Entered into a commercialization agreement and strategic partnership with Bayer Healthcare Company Limited for mainland China
- Entered into a commercial supply agreement with Zhejiang Raybow Pharmaceutical as an additional supplier to existing manufacturing partners
- Granted the Drug Manufacturing Permit for dorzagliatin in China by the Shanghai Municipal Drug Administrative Bureau
- Announced global operation headquarters and research and development centre in Shanghai's ZhangJiang Science City officially established

FINANCIAL HIGHLIGHTS

- Cash position was approximately RMB1,032.1 million as of December 31, 2020
- Total expenditures incurred by the Company for the year ended December 31, 2020 was approximately RMB367.2 million, of which approximately RMB221.0 million was research and development expenses
- For the year ended December 31, 2020, research and development expenses decreased by approximately RMB100.9 million or approximately 31% to approximately RMB221.0 million
- For the year ended December 31, 2020, loss before tax decreased by approximately RMB32.1 million or approximately 8% to approximately RMB393.1 million
- For the year ended December 31, 2020, loss and total comprehensive expense for the year decreased by approximately RMB31.7 million or approximately 7% to approximately RMB393.6 million

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 eight Phase I trials in China, four Phase I trials in the United States, one Phase II in China, and two Phase III trials in China. Our two Phase III trials enrolled 1,230 patients across 110 sites throughout China. Both Phase III trials met their primary endpoints, and the safety and tolerability profile of dorzagliatin was good during the trial period. The final 53-week results of both Phase III trials were announced and published in 2020.

As we continue to progress with our development of our lead candidate, dorzagliatin, we are also moving forward with preparations for the drug’s life cycle management. We filed method of use patents for use of dorzagliatin in diabetic kidney disease (DKD) patients. We have initiated multiple studies on dorzagliatin plus existing anti-diabetes therapies at preclinical development and clinical settings.

During the year ended December 31, 2020 (the “**Reporting Period**”), despite the spread of the COVID-19 pandemic globally, we have continued to move forward with our clinical development and NDA preparations, as summarized below.

Successful completion of both pivotal Phase III registration trials in China (SEED/HMM0301 and DAWN/HMM0302). Amidst the COVID-19 pandemic, we ensured the uninterrupted delivery of dorzagliatin to patients and clinical centers, even during the height of the pandemic in China, and associated national lock-down, in February 2020. Both SEED and DAWN were completed on time and in high quality in 2020.

Expansion of dorzagliatin indications. We completed three Phase I trials to set the grounds for expansion of dorzagliatin’s future indications. Two of the Phase I trials, HMM0112 and HMM0111 investigated the pharmacokinetic and pharmacodynamics characteristics of dorzagliatin with empagliflozin (a SGLT-2 inhibitor), and dorzagliatin with sitagliptin (a DPP-4 inhibitor), both indicating a synergistic effect in efficacy under combination therapy. The third Phase I trial was conducted in patients with end stage chronic kidney disease, demonstrating a desirable pharmacokinetic profile in patients, and indicating the potential use of dorzagliatin among T2D patients with moderate, severe and end stage chronic kidney disease.

Collaboration with the leading diabetes partner in China, Bayer. As we approach the commercial launch of dorzagliatin in China, we have entered into a commercialization agreement and strategic partnership with Bayer Healthcare Company Limited. Under the terms of the agreement, we received an upfront payment of RMB300 million in 2020, and additional payments could reach up to RMB4.18 billion if certain milestones are met. We will pay Bayer tiered service fees based on net sales in China, initially sharing equally in sales, with adjusting sales percentages based on agreed China net sales thresholds. We will continue to be the market authorization holder of dorzagliatin, and responsible for clinical development, registration, product supply and distribution, while Bayer, as the promotion service provider, will be responsible for the marketing, promotion, and medical education activities in China.

Rapid progress for dorzagliatin’s manufacturing scale up in China. In October 2020, we obtained the drug manufacturing permit for dorzagliatin, indicating that Hua Medicine has established the required systems and capabilities to satisfy national drug quality and pharmacovigilance management standards. We and our CMOs have completed the requisite manufacturing process validation work related to commercialization of the drug. The drug manufacturing permit is a requisite for submitting the NDA, and we are among the first group of biotechnology companies that have obtained the permit since the implementation of the new Drug Administration Law on December 1, 2019. In November 2020, we entered into a commercial supply agreement with Zhejiang Raybow Pharmaceutical as an additional supplier to existing partners, to ensure the API supply of dorzagliatin.

Further validation of the glucokinase activator concept. Our senior scientific consultant, Dr. Franz Matschinsky, Professor of Biochemistry and Biophysics at the Institute for Diabetes, Obesity and Metabolism Perelman School of Medicine, University of Pennsylvania, was awarded the Rolf Luft Award 2020 by the Karolinska Institutet. He was recognized for “the discovery that glucokinase (“GK”) is the sensor controlling glucose-stimulated insulin secretion in the pancreatic β -cell”. Specifically, his studies led to the experimentation of GK in correcting metabolic defects in human pancreatic islet cells and other tissues involved in Type 2 diabetes, resulting ultimately in the discovery of novel allosteric GK activators, such as our dorzagliatin (HMS5552) which has completed two Phase III trials in China. Dr. Matchinsky’s comprehensive work has uniquely advanced the understanding of beta-cell biology and insulin secretion in health and in diabetes. Due to the COVID-19 pandemic in 2020, his presentation to the Nobel Forum at the Karolinska Institutet has been postponed to 2021.

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

We continue to work closely with and supervise our contract research organizations (CROs), clinical site management operators (SMOs), and contract manufacturing organizations (CMOs), who provide us with a range of services at a consistently high level of quality.

Product pipeline

Product Name	Indication	Development phase	Pre-clinical	IND	Phase I	Phase II	Phase III	NDA
Dorzagliatin HMS5552	T2D	NDA Filing (China)						
	DKD	Phase I enabling						
	T1D	IND-enabling						
HMSFDC 6857 Dorzagliatin + Metformin	T2D	Phase I ready						
HMSFDC 6868 Dorzagliatin +Sitagliptin	T2D	Phase I ready						
	Insulin Sparing	IND-enabling						
HMSFDC 5868 Dorzagliatin +Empagliflozin	T2D CVR	Phase I ready						
HMSFDC 5688 Dorzagliatin +pioglitazone	NASH	IND-enabling						
HMS 5678 Dorzagliatin + GLP -1	Alzheimer Disease	IND-enabling						
HMS 6789 Dorzagliatin + Insulin	Late Stage T2D Insulin sparing	IND-enabling						
	T1D	IND-enabling						
mGLUR5 NAM	PD-LID	Pre-clinical						
Fructose Kinase Inhibitor	Metabolic Disease	Pre-clinical						

Clinical trials completed during the Reporting Period:

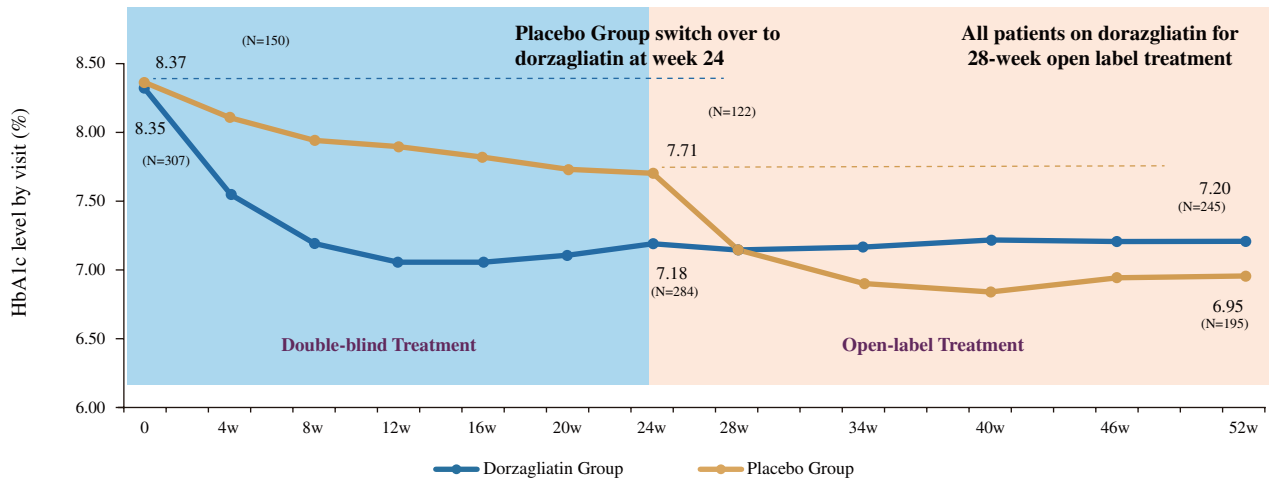
Phase III registration trials:

SEED/HMM0301

SEED is a randomized, double-blind, placebo-controlled Phase III study in 463 drug naïve T2D patients. Patients were treated with twice-daily doses of dorzagliatin (75 mg) or placebo, randomized 2:1. The clinical study evaluated the efficacy and safety of dorzagliatin during 24 weeks of double-blinded treatment, followed by a subsequent 28-week open-label treatment period, for a total of 52 weeks plus one-week follow-up. During the 28-week open-label period, both patient groups were treated with twice-daily doses of dorzagliatin (75 mg). The trial was conducted at 40 clinical sites across China led by Professor Dalong Zhu, President of the Chinese Diabetes Society. (NCT03173391).

In November 2019, Hua Medicine announced the trial had achieved its primary efficacy and safety endpoints over the initial 24-week double blinded period. 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. Figure 1 below illustrates the efficacy (as measured by HbA1c reduction) for the two-cohort groups for the entire 52-week period.

Figure 1: Change of HbA1c during the 52-week treatment period



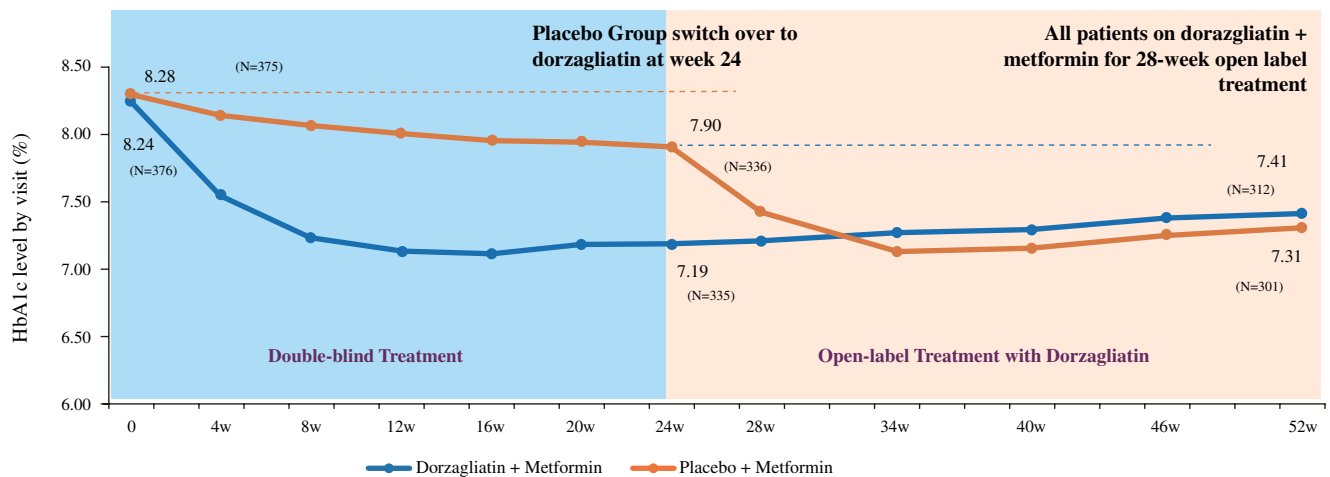
In addition, data from the 24-week double-blinded treatment period demonstrates that there was significant β -cell function improvement (as measured by HOMA2- β 1) in the treatment group versus the placebo group – an increase of 2.56% vs. a decline of 0.72% in β -cell function improvement. The data also indicates significant 2-hour post-prandial glucose reduction (-2.83mmol/L vs -0.50mmol/L, $p < 0.001$).

DAWN/HMM0302

DAWN is a randomized, double-blind, placebo-controlled Phase III study in 767 Type 2 diabetes patients whose blood glucose cannot be controlled with the maximum tolerated dose of equal or greater than 1500 mg/day of metformin. Subjects were treated with metformin (Glucophage®) at 1500mg/day as basic therapy throughout the whole 52-week treatment period. Patients were given twice-daily doses of dorzagliatin (75mg) or placebo, randomized on a 1:1 ratio. The clinical study evaluated the efficacy and safety of dorzagliatin during 24 weeks of double-blinded treatment, followed by a subsequent 28-week open-label treatment period receiving dorzagliatin 75mg twice daily. The primary efficacy endpoint was evaluated at the conclusion of the first 24 weeks. The trial was conducted in 73 clinical sites across China led by Professor Wenying Yang at China-Japan Friendship Hospital. (NCT03141073).

In July 2020, Hua Medicine announced the DAWN Trial had achieved its primary efficacy and safety endpoints over the initial 24-week double blinded period. 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 placebo + metformin (i.e., the placebo group) switched to receive dorzagliatin + metformin. Figure 2 below illustrates the fast onset and sustained efficacy (as measured by HbA1c levels) for the two-cohort groups for the entire 52-week period.

Figure 2: Change of HbA1c during the 52-week treatment period



Similar to observations made in the SEED Trial, conducted with drug-naïve T2D patients with average disease history of one year, a significant increase in HOMA2-β and reduction in HOMA2-IR over placebo were observed in the DAWN Trial, suggesting a consistent improvement of β-cell function and reduction in insulin resistance in diabetes patients with average disease history of almost six years and who had failed glycemic control on maximum daily dose of metformin (1,500mg/day).

Other clinical trials:

HMM0110 demonstrated desirable pharmacokinetics profile in patients with end stage chronic kidney disease, indicating the potential use of dorzagliatin without dose adjustment among T2D patients with renal impairment in mild, moderate, severe and end stage before dialysis. These results supports dorzagliatin as a promising solution and potential supplementary option for T2D patients with diabetic kidney disease, as most current oral anti-diabetic drugs are not readily suitable for patients with renal impairment.

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. The trial also demonstrated that dorzagliatin add-on to sitagliptin increases endogenous GLP-1 secretion.

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. The positive results of HMM0112 indicate enhanced blood sugar control for T2D patients using the dorzagliatin add-on to SGLT-2 inhibitors, which provides an improved solution to T2D patients who benefit from the cardiovascular benefits and weight loss of SGLT-2 inhibitors.

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 oral and injectable anti-diabetic medicines as well as other popular medicines commonly taken by diabetes patients to address patients' personal needs.

To date, except for the RMB300 million upfront payment we received from Bayer in exchange for certain commercialization rights in mainland China as contract liabilities, 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 interest income. As of December 31, 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 submit our NDA for dorzagliatin to the NMPA in China in the first half of 2021. In the second half of 2021, we plan to initiate additional studies for dorzagliatin in DKD and for dorzagliatin combinations, including with GLP-1 and insulin for T2D patients, and insulin for T1D patients. We are also advancing our fixed-dose combination pipeline for dorzagliatin.

Key events after the Reporting Period

Save as disclosed above, there are no important events that have occurred up to the date of this announcement.

Financial review

Other income

Our other income consisted primarily of bank interest income, rent concession and government grants. Our other income decreased by RMB13.7 million to RMB15.9 million for the year ended December 31, 2020 from RMB29.6 million for the year ended December 31, 2019, which was mainly attributable to a decrease of RMB13.6 million in government grants for the year ended December 31, 2020, a decrease of RMB2.9 million in bank interest income from short-term time deposits, adjusted for an increase of RMB2.8 million in rent concession. We received RMB17.3 million government grants from the local governments for research and development and operating activities and rent concession for the year ended December 31, 2020, among which we recorded RMB11.5 million in other income and RMB5.8 million in deferred income.

Other gains and losses

Our other gains and losses consisted primarily of gains or losses due to fluctuations in the exchange rates between the Renminbi and the U.S. dollar and between the Renminbi and the HK dollar. Our other gains and losses decreased by RMB58.1 million to a loss of RMB41.8 million in the year ended December 31, 2020 from a gain of RMB16.3 million in the year ended December 31, 2019, which was mainly attributable to foreign exchange losses in connection with bank balances and cash denominated in U.S. dollars and HK dollars and the large depreciation of the U.S. dollar and HK dollar against the Renminbi in the year ended December 31, 2020, compared to the small appreciation of the U.S. dollar and HK dollar against the Renminbi in the year ended December 31, 2019.

Our business mainly operates in the PRC, and most of our transactions are settled in Renminbi. Since inception, we have financed our business principally through equity financings, with related proceeds denominated in U.S. dollars, HK dollars and Renminbi. We converted a portion of those U.S. dollar proceeds to Renminbi, with the remaining amounts reserved for additional conversions to Renminbi as needed. Translation for financial statement presentation purposes of our assets and liabilities exposes us to currency-related gains or losses and the actual conversion of our U.S. dollar and HK dollar denominated cash balances (including the HK dollar proceeds received from the Global Offering (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) 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 decreased by RMB6.5 million to RMB140.1 million in the year ended December 31, 2020 from RMB146.6 million in the year ended December 31, 2019, which was mainly attributable to i) decrease in labour costs which was attributable to the decrease of RMB10.6 million in share-based payment under the accelerated amortization method, adjusted for an increase of RMB1.2 million in cash compensation with headcount increase, ii) decrease of RMB4.2 million in travelling costs and decrease of RMB2.4 million in recruitment cost based on the recruitment plan, iii) increase in consulting fee of RMB3.4 million associated with the qualified collaboration with Bayer, adjusted for a decrease in consulting fee of RMB2.5 million associated with commercialization strategy and market research expense incurred in the year of 2019 and no such cost in the year of 2020, and iv) adjusted for the rental increase of RMB7.4 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 and low-value IT consumable expenditure of RMB1.2 million for the office building incurred in the year of 2020.

Other expenses

Our other expenses consist of expense associated with a donation of RMB1.7 million (equivalent to USD250,000) for each of the years ended December 31, 2019 and 2020 to establish the Type 2 Diabetes research fund at the Department of Biochemistry and Biophysics at the Raymond and Ruth Perelman School of Medicine of the University of Pennsylvania.

Finance cost

Our finance cost consisted of expenses associated with the interest on lease liabilities. Our finance cost was RMB4.4 million for the year ended December 31, 2020 as compared to RMB0.9 million for the year ended December 31, 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 year indicated.

	For the year ended December 31,			
	2020		2019	
	<i>RMB'000</i>	<i>%</i>	<i>RMB'000</i>	<i>%</i>
Dorzagliatin Clinical Trials	79,964	36.2%	158,900	49.4%
Dorzagliatin Non-clinical Studies	3,996	1.8%	3,124	1.0%
Chemical, Manufacturing and Control	9,780	4.4%	33,061	10.3%
Labor Cost	110,133	49.9%	109,458	34.0%
Dorzagliatin Licensing and Patent Fee	5,189	2.3%	2,018	0.6%
Others	11,900	5.4%	15,343	4.7%
Total	<u>220,962</u>	<u>100.0%</u>	<u>321,904</u>	<u>100.0%</u>

Research and development expenses decreased by RMB100.9 million to RMB221.0 million for the year ended December 31, 2020 from RMB321.9 million for the year ended December 31, 2019. The decrease in research and development expenses included:

- a decrease of RMB78.9 million for dorzagliatin clinical trials, which was primarily attributable to decreased costs associated with the last patient out of the 52-week study period of SEED/HMM0301 in March 2020 and DAWN/HMM0302 in September 2020;
- a decrease of RMB23.3 million in chemical, manufacturing, and control (CMC) expenses, which was primarily attributable to scaling-up development, method validation and process validation for spray dried powder (SDP) manufacturing and drug product manufacturing completed in 2019;
- an increase of RMB0.6 million for increased labor costs, which was primarily attributable to an increase of RMB5.4 million in cash compensation mainly associated with headcount increase, adjusted for a decrease of RMB4.8 million in share-based payment;
- an increase of RMB3.1 million for increased dorzagliatin licensing and patent fee, which was primarily attributable to a Patent Cooperation Treaty (PCT) application for the fixed-dosed combination associated with dorzagliatin;
- a decrease of RMB3.4 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 for the year ended December 31, 2020 and the year ended December 31, 2019.

Liquidity and capital resources

Since our inception, we have been in a net loss position with and net cash outflows from operations. Our primary use of cash is to fund our research and development activities. Our operating activities used RMB20.9 million for the year ended December 31, 2020. As of December 31, 2020, we had cash and cash equivalents of RMB1,032.1 million.

As of December 31, 2020, there were no significant investments held by the Company (including any investment in an investee company with a value of 5 per cent. or more of the Company's total assets as at 31 December 2020), 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 years indicated:

	For the year ended	
	December 31, 2020	2019
	RMB'000	RMB'000
Research and development costs	161,388	238,337
Administrative costs		
– Workforce employment	48,094	46,267
– Others	111,424	57,463
	<u>159,518</u>	<u>103,730</u>
	<u>320,906</u>	<u>342,067</u>

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2019 and 2020:

	For the year ended	
	December 31, 2020	2019
	RMB'000	RMB'000
Net cash used in operating activities	(20,906)	(342,067)
Net cash used in investing activities	(14,086)	(9,515)
Net cash used in financing activities	(7,262)	(1,236)
Effect of exchange rate changes	(31,256)	15,108
	<u>(73,510)</u>	<u>(337,710)</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 year ended December 31, 2020, our operating activities used RMB20.9 million of cash, which resulted principally from our loss before tax of RMB393.1 million, adjusted for non-cash charges and non-operating cash charges of RMB99.9 million, and by cash used in our operating assets and liabilities of RMB272.3 million. Our net non-cash charges during the year ended December 31, 2020 primarily consisted of RMB4.9 million of depreciation of equipment, RMB13.2 million of depreciation for right-of-use assets, RMB0.3 million of intangible assets amortization, RMB4.4 million of interest on lease liabilities; RMB58.9 million share option expenses, RMB4.4 million of bank interest income, RMB5.8 million of income from government grants; RMB2.6 million of rent concession and RMB30.8 million net foreign exchange losses.

During the year ended December 31, 2019, our operating activities used RMB342.1 million of cash, which resulted principally from our loss before tax of RMB425.3 million, adjusted for non-cash charges and non-operating cash charges of RMB61.7 million, and by cash used in our operating assets and liabilities of RMB21.5 million. Our net non-cash charges during the year ended December 31, 2019 primarily consisted of RMB3.4 million of depreciation of equipment, RMB6.9 million of amortization for right-of-use assets, RMB74.4 million share option expenses, RMB7.3 million of bank interest income, RMB1.6 million of income from government grants and RMB15.1 million net foreign exchange gains.

Net Cash used in Investing Activities

Net cash used in investing activities was RMB14.1 million for the year ended December 31, 2020, which resulted primarily from the purchase of equipment, partially offset by the interest received from bank. Net cash used in investing activities was RMB9.5 million for the year ended December 31, 2019, which resulted primarily from payments for rental deposits and the purchase of equipment, partially offset by the interest received from bank.

Net Cash used in Financing Activities

Net cash used in financing activities was RMB7.3 million for the year ended December 31, 2020, which resulted from payments relating to lease liabilities, offset by proceeds from exercise of share options. Net cash used in financing activities was RMB1.2 million for the year ended December 31, 2019, which resulted from payments relating to lease liabilities, offset by proceeds from exercise of share options.

Financial position

Our net current assets decreased from RMB1,011.7 million as of December 31, 2019 to RMB938.7 million as of December 31, 2020. Current assets decreased from RMB1,120.5 million as of December 31, 2019 to RMB1,045.3 million as of December 31, 2020, primarily due to a decrease in bank balances and cash from RMB1,105.6 million as of December 31, 2019 to RMB1,032.1 million as of December 31, 2020, which was due primarily to the payments for our research and development activities and daily operation.

Significant change in accounting policy

We have applied the Amendment to IFRS 16 “Covid-19-Related Rent Concessions” issued by the International Accounting Standard Board (the “IASB”).

Indebtedness

As of December 31, 2020 and 2019, our lease liabilities amounted to RMB80.7 million and RMB90.0 million, respectively. The following table sets forth our lease liabilities as of the dates indicated:

	As of December 31,	
	2020	2019
	<i>RMB'000</i>	<i>RMB'000</i>
Current portion	11,503	12,019
Non-current portion	69,212	77,959
Total	<u>80,715</u>	<u>89,978</u>

Our lease liabilities as of December 31, 2020 were from leased properties lease contracts with lease terms of two to six years. As of December 31, 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 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. dollar 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. dollar 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. dollar 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. dollar or other currencies for business purposes, appreciation of the U.S. or HK dollar against the Renminbi would have a negative effect on the U.S. dollar 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/positive number below indicates an increase/decrease 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 or loss for the year.

	As of December 31,	
	2020	2019
	<i>RMB'000</i>	<i>RMB'000</i>
Impact on profit or loss		
US\$	(22,228)	(42,433)
HK\$	(2,210)	(2,634)

Interest Rate Risk

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

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

Liquidity Risk

As of December 31, 2020 and 2019, we recorded net current assets of RMB938.7 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.

Key Financial Ratios

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

	As of December 31,	
	2020	2019
Current ratio ⁽¹⁾	9.8	10.3
Quick ratio ⁽²⁾	9.8	10.3

(1) Current ratio represents current assets divided by current liabilities as of the same date.

(2) Quick ratio represents current assets less inventories divided by current liabilities as of the same date.

The current ratio and quick ratio as of December 31, 2020 decreased by 0.5 compared with that as of December 31, 2019, which was mainly due to the cost of research activities and daily operation.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

	NOTES	For the year ended December 31,	
		2020 RMB'000 (audited)	2019 RMB'000 (audited)
Other income	3	15,859	29,574
Other gains and losses	4	(41,827)	16,275
Administrative expenses		(140,084)	(146,584)
Finance cost	5	(4,396)	(907)
Other expenses		(1,724)	(1,724)
Research and development expenses		(220,962)	(321,904)
Loss before tax	6	(393,134)	(425,270)
Income tax expense	7	—	—
Net loss		(393,134)	(425,270)
Other comprehensive loss			
Items that may be reclassified subsequently to profit or loss:			
– Exchange differences on translation of foreign operations		(453)	—
Loss and total comprehensive expense for the year		(393,587)	(425,270)
Loss and total comprehensive expense for the year attributable to:			
– Owners of the Company		(393,587)	(425,270)
– Non-controlling interests		—	—
LOSS PER SHARE	9	RMB	RMB
Basic and diluted		0.41	0.45

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	<i>NOTES</i>	As of December 31, 2020 <i>RMB'000</i> (audited)	As of December 31, 2019 <i>RMB'000</i> (audited)
Non-current assets			
Equipment		49,341	10,988
Right-of-use assets	10	74,177	90,486
Intangible assets		3,387	1,980
Prepayments and other receivables	11	26,339	30,707
		<u>153,244</u>	<u>134,161</u>
Current assets			
Prepayments and other receivables	11	13,187	14,852
Bank balances and cash	12	1,032,090	1,105,600
		<u>1,045,277</u>	<u>1,120,452</u>
Current liabilities			
Trade and other payables	13	80,794	88,317
Lease liabilities		11,503	12,019
Deferred income		14,250	8,450
		<u>106,547</u>	<u>108,786</u>
Net Current Assets		<u>938,730</u>	<u>1,011,666</u>
Total Assets Less Current Liabilities		<u>1,091,974</u>	<u>1,145,827</u>
Non-current liabilities			
Lease liabilities		69,212	77,959
Contract liabilities	14	283,019	–
Deferred income		7,248	7,248
		<u>359,479</u>	<u>85,207</u>
Net Assets		<u><u>732,495</u></u>	<u><u>1,060,620</u></u>

	As of December 31, 2020	As of December 31, 2019
<i>NOTES</i>	<i>RMB'000</i>	<i>RMB'000</i>
	(audited)	(audited)
Capital and reserves		
Share capital	7,209	7,209
Treasury shares held in trust	(690)	(729)
Reserves	<u>725,976</u>	<u>1,054,140</u>
Equity attributable to owners of the Company	<u>732,495</u>	<u>1,060,620</u>
Total Equity	<u><u>732,495</u></u>	<u><u>1,060,620</u></u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

For the year ended December 31, 2020

1. General information

The Company was established in the Cayman Islands as an exempted company with limited liability on November 10, 2009. 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 Company and its subsidiaries (collectively referred to as “Group”) are principally engaged in developing a global first-in-class oral drug, dorzagliatin or HMS5552, for the treatment of Type 2 diabetes.

2. Basis of preparation of the consolidated financial statements

The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards issued by the International Accounting Standards Board. In addition, the consolidated financial statements include applicable disclosures required by the Rules Governing the Listing of Securities on the Stock Exchange and complied with the Hong Kong Companies Ordinance.

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

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

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

3. Other income

	For the year ended December 31,	
	2020	2019
	RMB' 000	RMB' 000
	(audited)	(audited)
Bank interest income	4,370	7,317
Government grants and subsidies (Note)	8,664	22,257
Rental concessions	2,825	—
	<u>15,859</u>	<u>29,574</u>

Note:

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

Other government grants related to income that are receivable 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 in the period in which they become collectable.

4. Other gains and losses

Other gains and losses mainly represent the foreign exchange losses and gains during the years ended December 31, 2020 and 2019.

5. Finance cost

	For the year ended December 31,	
	2020	2019
	<i>RMB'000</i>	<i>RMB'000</i>
	(audited)	(audited)
Interest on lease liabilities	4,396	907

6. Loss before tax

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

	For the year ended December 31,	
	2020	2019
	<i>RMB'000</i>	<i>RMB'000</i>
	(audited)	(audited)
Depreciation for equipment	4,949	3,361
Depreciation of right-of-use assets	20,132	6,920
Amortization for intangible assets	322	151
	25,403	10,432
Capitalized in construction in progress	(6,955)	–
	18,448	10,432
Other expenses	1,724	1,724
Staff cost (including directors' emoluments):		
– Salaries and other benefits	124,339	116,846
– Retirement benefit scheme contributions	4,071	9,066
– Share option expenses	58,942	74,384
	187,352	200,296
Covid-19-related rent concessions	(2,825)	–
Auditors' remuneration		
– Audit services	1,720	1,800
– Non-audit services	1,280	680
	3,000	2,480
Expenses relating to short-term leases	1,686	2,560

7. Income tax expense

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

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

The subsidiary incorporated in the United States are subject to Federal and State Income taxes, the effective combined income tax rate is 21% for the year ended December 31, 2020.

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 US\$2.0 million non-refundable upfront payment and US\$1.0 million milestone payment upon the commencement of clinical trial Phase III in the mainland China for the Licensed Product to Roche in 2012 and 2017, respectively.

The Company is obligated to make a US\$4.0 million milestone payment upon the approval of the Licensed Product in the mainland China and an aggregate of US\$33.0 million of milestone payments upon approval in the Licensed Territory other than mainland China. 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 an additional US\$40.0 million of 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 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:

	For the year ended	
	December 31,	
	2020	2019
	RMB'000	RMB'000
	(audited)	(audited)
Loss for the period attributable to the owners of the Company for the purpose of basic and diluted loss per share	<u>(393,134)</u>	<u>(425,270)</u>

Number of shares:

	For the year ended December 31,	
	2020	2019
	(audited)	(audited)
Weighted average number of ordinary shares for the purpose of basic and diluted loss per share	<u>950,508,749</u>	<u>942,060,515</u>

The computation of basic and diluted loss per share for the years ended December 31, 2020 and 2019 respectively excluded the unvested restricted shares and unvested restricted stock units of the Company.

The computation of diluted loss per share for the year ended December 31, 2020 and 2019 did not assume the exercise of share options since their assumed exercise would result in a decrease in loss per share.

10. Right-of-use assets

The Group entered into several new lease or lease modifications agreements for the use of leased properties and vehicles for two to six years, and the net book value of right-of-use assets as of December 31, 2020 and 2019 is RMB74,177,000 and RMB90,486,000.

11. Prepayments and other receivables

	As of December 31, 2020 RMB' 000 (audited)	As of December 31, 2019 RMB' 000 (audited)
Prepayments for research and development services	2,146	2,838
Utility and rental deposits – current	1,814	1,462
Utility and rental deposits – non-current	4,194	4,117
Value add tax recoverable – non-current	21,910	26,248
Interest receivables	704	2,779
Other receivables for considerations of options exercised	287	1,398
Others – current	8,236	6,375
Others – non-current	235	342
	<u>39,526</u>	<u>45,559</u>
Analysis as		
– current	13,187	14,852
– non-current	26,339	30,707
	<u>39,526</u>	<u>45,559</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 0.001% to 2.30% per annum as of December 31, 2020 (December 31, 2019: from 0.05% to 2.8% per annum).

13. Trade and other payables

	As of December 31, 2020 <i>RMB'000</i> (audited)	As of December 31, 2019 <i>RMB'000</i> (audited)
Trade payables	25,821	47,941
Other payables	4,179	3,660
Payroll and bonus payables	32,285	28,577
Accrued leasehold improvement expenditure	12,383	–
Others	6,126	8,139
	<u>80,794</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 goods/services relevant invoice or billing date at the end of each reporting period is as follows:

	As of December 31, 2020 <i>RMB'000</i> (audited)	As of December 31, 2019 <i>RMB'000</i> (audited)
Uninvoiced or within 30 days	<u>25,821</u>	<u>47,941</u>
	<u>25,821</u>	<u>47,941</u>

14. CONTRACT LIABILITIES

	As of December 31, 2020 <i>RMB'000</i> (audited)	As of December 31, 2019 <i>RMB'000</i> (audited)
Advance from a customer for exclusive distribution rights	<u>283,019</u>	<u>–</u>

In December 2020, the Group received an advance payment from a customer to grant it the exclusive distribution rights on the licensed products after the Group obtain the new drug approval in China from the local authorities.

Other information

Purchase, sale or redemption of the company's listed securities

Neither the Company nor any of its subsidiaries had purchased, sold or redeemed any of the Company's listed securities during the year ended December 31, 2020.

Employees and remuneration policy

As of December 31, 2020, the Group employed a total of 162 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 year ended December 31, 2020, staff costs (including Directors' emoluments but excluding any contributions to pension scheme) were approximately RMB183.3 million as compared to RMB191.2 million for the year ended December 31, 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 labour dispute during the year ended December 31, 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 for further details.

Use of net proceeds from the Global Offering

The Company's Shares were listed on the Stock Exchange on September 14, 2018. The net proceeds from the Company's issue of new Shares amounted to RMB747.2 million (including the issue of additional Shares pursuant to the partial exercise of the over-allotment option on October 5, 2018), which have been, and will continue to be, applied according to the intentions set out in the section headed "Future Plans and Use of Proceeds" in the Prospectus. We expect that a portion of the net proceeds will be carried forward and utilized in financial year 2021 due to a slight adjustment to the timeline for the development of our manufacturing capabilities.

The following table sets forth the status of the Company’s use of proceeds raised in the Global Offering as of December 31, 2020:

	% of use of proceeds	Net proceeds from the Global Offering <i>RMB million</i>	Actual usage up to December 31, 2020 <i>RMB million</i>	Unutilized net proceeds as of December 31, 2020 <i>RMB million</i>
(a) Dorzagliatin research and development	39%	291.4	291.4	–
(b) Dorzagliatin lifecycle management and additional indications	9%	67.2	33.1	34.1
(c) Dorzagliatin launch and commercialization	27%	201.8	31.5	170.3
(d) New product and diabetes care technology development	11%	82.2	13.7	68.5
(e) Product licensing and partnership	4%	29.9	–	29.9
(f) General working capital	10%	74.7	74.7	–
Total	<u>100%</u>	<u>747.2</u>	<u>444.4</u>	<u>302.8</u>

Final dividend

The Board has resolved not to declare any final dividend for the year ended December 31, 2020 (December 31, 2019: NIL).

Securities transactions by the Directors

The Company has adopted the Model Code for Securities Transactions by Directors of Listed Issuers (the “**Model Code**”) as the guidelines for regulating the directors’ dealings in the securities of the Company. 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 throughout the year ended December 31, 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 set out in the Corporate Governance Code and Corporate Governance Report (the “**CG Code**”) as set out in Appendix 14 to the Listing Rules as its own code of corporate governance.

The Board is of the view that the Company has complied with all applicable code provisions of the CG Code throughout the year ended December 31, 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.

Review of annual results

The consolidated financial results of the Group for the year ended December 31, 2020 has been audited by the Company's auditor, Deloitte Touche Tohmatsu, and reviewed by the Audit Committee of the Company, which consists of Mr. Walter Teh-ming Kwauk, Mr. William Robert Keller and Mr. Yiu Wa Alec Tsui.

Scope of Work of Messrs. Deloitte Touche Tohmatsu

The figures in respect of the Group's consolidated statement of financial position, consolidated statement of profit or loss and other comprehensive income and the related notes thereto for the year ended 31 December 2020 as set out in this announcement have been agreed by the Group's auditor, Messrs. Deloitte Touche Tohmatsu, to the amounts set out in the Group's audited consolidated financial statements for the year. The work performed by Messrs. Deloitte Touche Tohmatsu in this respect did not constitute an assurance engagement in accordance with Hong Kong Standards on Auditing, Hong Kong Standards on Review Engagements or Hong Kong Standards on Assurance Engagements issued by the Hong Kong Institute of Certified Public Accountants and consequently no assurance has been expressed by Messrs. Deloitte Touche Tohmatsu on this announcement.

Annual general meeting and closure of register of shareholders

The annual general meeting ("AGM") of the Company is scheduled to be held on June 29, 2021. A notice convening the AGM will be published and dispatched to the shareholders of the Company in the manner required by the Listing Rules in due course.

For determining the entitlement to attend and vote at the AGM, the register of shareholders of the Company will be closed from June 24, 2021 to June 29, 2021, both days inclusive, during which period no transfer of shares of the Company will be registered. In order to be eligible to attend and vote at the AGM, all transfer of shares of the Company, accompanied by the relevant share certificates, must be lodged with the Company's Hong Kong share registrar, Tricor Investor Services Limited, located at Level 54, Hopewell Centre, 183 Queen's Road East, Hong Kong for registration not later than 4:30 pm on June 23, 2021.

Publication of the annual results and 2020 annual report on the websites of the Stock Exchange and the Company

This annual results announcement is published on the respective websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.huamedicine.com). The Company's annual report for the year ended December 31, 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.

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

Hong Kong, March 19, 2021

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