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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, 2021

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, 2021 (the “**Reporting Period**”), together with comparative figures for the year ended December 31, 2020. 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

- In March 2021, we submitted a new drug application (“**NDA**”) for dorzagliatin for the treatment of Type 2 diabetes (“**T2D**”) to the National Medical Products Administration of the People’s Republic of China (the “**NMPA**”), and we received notification from the NMPA that our NDA was accepted in April 2021. The NDA is currently under active review by the NMPA.
- In September 2021 at the 6th China BioMed Innovation and Investment Conference, select principal investigators from our SEED Phase III trial presented the results from the extensive clinical study called DREAM. The main objective of the DREAM study was to evaluate the ability of T2D patients who participated in our SEED Trial and achieved glycemic control as defined by investigators, to maintain normal to near-normal HbA1c levels (i.e., remission of T2D), without any glucose-lowering medication after the completion of the SEED Trial for a minimum follow-up period of 52-weeks. The results showed that the subjects had a 52-week diabetes remission rate of 65.2% (applying the Kaplan- Maier methodology) during the research period.
- We presented data from our 52-week SEED and DAWN Phase III registration trials, as well as Phase I trial HMM0112 of dorzagliatin in combination with empagliflozin (a SGLT-2 inhibitor) at the 2021 American Diabetes Association’s Scientific Sessions, demonstrating glucose control benefit using the combination of dorzagliatin and empagliflozin.

- We presented additional data from our Phase I trial HMM0111 of dorzagliatin in combination with sitagliptin (a DPP-IV inhibitor) at the 2021 American Diabetes Association's Scientific Sessions, demonstrating that dorzagliatin regulates GLP-1 secretion and providing additional benefit in glucose control in T2D patients in the United States.
- In anticipation of dorzagliatin commercialization, we continue to work with Bayer, our commercialization partner in China, on launch strategy and commercialization preparation.
- In September 2021, we entered into a strategic agreement with Sinopharm Group Co., Ltd. (Hong Kong Stock Code: 1099), to cooperate in logistics warehousing, supply chain management and channel data analysis, and to jointly promote the commercialization of dorzagliatin for its anticipated market launch in China.
- In October 2021, we enhanced our existing collaboration with WuXi STA for the commercial supply of dorzagliatin by entering into an expanded agreement with WuXi STA, and for which we held a signing ceremony and announced the agreement in February 2022.
- We established Hua Medicine drug manufacturing company at Shanghai Lingang Special Area for ensuring adequate dorzagliatin commercial supply, and we also secured land for the construction of a manufacturing facility.
- We continue to make filings and applications regarding IP rights globally around our discoveries in glucokinase, including for fixed dose combinations with dorzagliatin, as well as a second generation glucokinase activator.

FINANCIAL HIGHLIGHTS

- Cash position was approximately RMB675.2 million as of December 31, 2021
- Total expenditures incurred by the Company for the year ended December 31, 2021 was approximately RMB327.2 million, of which approximately RMB186.8 million was research and development expenses
- For the year ended December 31, 2021, research and development expenses decreased by approximately RMB34.1 million or approximately 15% to approximately RMB186.8 million
- For the year ended December 31, 2021, loss before tax decreased by approximately RMB67.4 million or approximately 17% to approximately RMB325.7 million
- For the year ended December 31, 2021, total comprehensive expense for the year decreased by approximately RMB68.3 million or approximately 17% to approximately RMB325.3 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 T2D. We filed an Investigational New Drug (“IND”) application with the NMPA for dorzagliatin under Category 1.1 (New Drug) in 2012 and initiated a Phase Ia clinical study of our novel glucokinase activator dorzagliatin in September 2013. We also filed an IND application with the U.S. Food and Drug Administration (“FDA”) for dorzagliatin in March 2015. We have completed eight Phase I trials in China, four Phase I trials in the United States, one Phase II trial in China, and two Phase III trials in China. Our two Phase III trials enrolled 1,230 patients across 110 sites throughout China. Both Phase III trials (also known as the SEED and DAWN trials) met their primary endpoints, and the safety and tolerability profile of dorzagliatin was good during the trial period. The final 52-week results of both Phase III trials were announced and published in 2020. In March 2021, we submitted a NDA for dorzagliatin for the treatment of T2D to the NMPA, and we received notification from the NMPA that our NDA was accepted in April 2021. The NDA is currently under active review by the NMPA.

In September 2021 at the 6th China BioMed Innovation and Investment Conference, select principal investigators from our SEED Phase III trial presented the extensive results from the clinical study called DREAM. The main objective of the DREAM study was to evaluate the ability of T2D patients who participated in our SEED Study and achieved glycemic control as defined by investigators, to maintain normal to near-normal HbA1c levels¹ (i.e., remission of T2D), without any glucose-lowering medication after the completion of the SEED study for a minimum follow-up period of 52-weeks. The results showed that the subjects had a 52-week diabetes remission rate of 65.2% at week 52 (95% CI, 53.4%, 77.0%)² during the research period.

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

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

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

¹ HbA1c levels < 7.0%.

² Calculated using the Kaplan-Meier methodology.

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.

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, 2021, 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.

Product pipeline

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

Product Name	Indication	Development phase	Pre-clinical	IND	Phase I	Phase II	Phase III	NDA
Dorzagliatin HMS5552	T2D	NDA Filed (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	IND-enabling						
	T1D	IND-enabling						
mGLUR5 NAM	PD-L1D	Pre-clinical						
Fructose Kinase Inhibitor	Metabolic Disease	Pre-clinical						
2 nd Generation GKA	Metabolic Disease	Pre-clinical						

Business outlook

At present, the NDA for dorzagliatin is under active review by the NMPA, and we are actively working to obtain approval for our NDA as soon as possible. If approved, we plan to commercialize dorzagliatin in China with our partner, Bayer, to seek entry into the National Reimbursement Drug List (the “NRDL”), and to expand its use as a cornerstone treatment for T2D as monotherapy or in combination with other approved antidiabetic drugs. We also plan to publicize the results of our SENSITIZE Trial in 2022, and are planning to initiate clinical trials in the United States for Type 1 diabetes with dorzagliatin. We are also advancing development of our fixed dose combinations with dorzagliatin, as well as our second generation glucokinase activator.

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, government grants and rental concession. Our other income decreased by RMB4.0 million to RMB11.9 million for the year ended December 31, 2021 from RMB15.9 million for the year ended December 31, 2020, which was mainly attributable to a decrease of RMB2.2 million in government grants and a decrease of RMB2.5 million in rental concessions for the year ended December 31, 2021, adjusted for an increase of RMB0.7 million in bank interest income from short-term time deposits. We received RMB5.5 million government grants and RMB0.3 million rental concession from the local governments for research and development and operating activities for the year ended December 31, 2021 and recognized other income of RMB1.0 million from deferred revenue which we received in the past.

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 RMB31.4 million to a loss of RMB10.4 million in the year ended December 31, 2021 from a loss of RMB41.8 million in the year ended December 31, 2020, 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 small depreciation of the U.S. dollar and HK dollar against the Renminbi in the year ended December 31, 2021, compared to the large depreciation of the U.S. dollar and HK dollar against the Renminbi in the year ended December 31, 2020.

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. Conversion of our assets and liabilities for financial statement presentation purposes 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 of the Company (the “**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) (the “**Global Offering**”) 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 RMB5.3 million to RMB134.8 million in the year ended December 31, 2021 from RMB140.1 million in the year ended December 31, 2020, which was mainly attributable to i) decrease in labour costs which was attributable to the decrease of RMB9.2 million in share-based payment under the accelerated amortization method, adjusted for an increase of RMB8.2 million in cash compensation, ii) decrease of RMB4.2 million in marketing and PR costs, mainly due to the digital program and national and regional congress conducted in the year of 2020 and less such cost in the year of 2021 under our marketing strategy, iii) decrease in consulting fee of RMB5.5 million mainly associated with the commercialization strategy consulting and legal service to realize qualified collaboration with Bayer in the year of 2020 and no such cost in the year of 2021, and iv) adjusted for the depreciation and amortization expense increase of RMB4.7 million, mainly due to the decoration and additional equipment purchased for our new headquarter.

Other expenses

Our other expenses consist of expense associated with a donation of RMB1.6 million (equivalent to USD250,000) for the year ended December 31, 2021 and RMB1.7 million (equivalent to USD250,000) for the year ended December 31, 2020 to establish the T2D 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 RMB4.0 million for the year ended December 31, 2021 as compared to RMB4.4 million for the year ended December 31, 2020, which was mainly attributable to the surrender of old offices after moving into our new headquarter at the end of 2020.

Research and development expenses

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

	For the year ended December 31,			
	2021		2020	
	<i>RMB'000</i>	<i>%</i>	<i>RMB'000</i>	<i>%</i>
Dorzagliatin Clinical Trials	22,162	11.9%	79,964	36.2%
Dorzagliatin Non-clinical Studies	3,670	2.0%	3,996	1.8%
Chemical, Manufacturing and Control	31,288	16.7%	9,780	4.4%
Labor Cost	98,064	52.5%	110,133	49.9%
Dorzagliatin Licensing and Patent Fee	2,549	1.4%	5,189	2.3%
Others	29,102	15.5%	11,900	5.4%
Total	<u>186,835</u>	<u>100.0%</u>	<u>220,962</u>	<u>100.0%</u>

Research and development expenses decreased by RMB34.2 million to RMB186.8 million for the year ended December 31, 2021 from RMB221.0 million for the year ended December 31, 2020. The decrease in research and development expenses included:

- a decrease of RMB57.8 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;
- an increase of RMB21.5 million in chemical, manufacturing, and control (CMC) expenses, which was primarily attributable to the chemical and process research for our fructose kinase inhibitor candidates and manufacture-dynamic process validation batch production for our NDA approval conducted in the year of 2021;
- a decrease of RMB12.1 million for labor costs, which was primarily attributable to a decrease of share-based payment under the accelerated amortization method;
- a decrease of RMB2.6 million for dorzagliatin licensing and patent fee, which was primarily attributable to a Patent Cooperation Treaty (PCT) application for the fixed-dosed combination associated with dorzagliatin in the year of 2020 and no such cost in the year of 2021;
- an increase of RMB17.2 million for others, which was primarily attributable to the allocation of rental fee, depreciation and amortization expense, property costs, utility cost and other cost related to our new headquarter which came into operation at the end of 2020.

Income tax expense

We recognized no income tax expenses for the year ended December 31, 2021 and the year ended December 31, 2020.

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 RMB273.0 million for the year ended December 31, 2021. As of December 31, 2021, we had cash and cash equivalents of RMB675.2 million.

As of December 31, 2021, 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 2021), 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,	
	2021	2020
	RMB'000	RMB'000
Research and development costs	159,904	161,388
Administrative costs		
– Workforce employment	50,500	48,094
– Others	62,577	111,424
	<u>113,077</u>	<u>159,518</u>
	<u>272,981</u>	<u>320,906</u>

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2020 and 2021:

	For the year ended December 31,	
	2021	2020
	RMB'000	RMB'000
Net cash used in operating activities	(272,981)	(20,906)
Net cash used in investing activities	(68,219)	(14,086)
Net cash used in financing activities	(6,134)	(7,262)
Effect of exchange rate changes	(9,518)	(31,256)
Change in cash and cash equivalents	<u>(356,852)</u>	<u>(73,510)</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, 2021, our operating activities used RMB273.0 million of cash, which resulted principally from our loss before tax of RMB325.7 million, adjusted for non-cash charges and non-operating cash charges of RMB71.9 million, and by cash used in our operating assets and liabilities of RMB19.2 million. Our net non-cash charges and non-operating cash charges during the year ended December 31, 2021 primarily consisted of RMB12.0 million of depreciation of equipment, RMB18.8 million of depreciation for right-of-use assets, RMB0.7 million of intangible assets amortization, RMB4.0 million of interest on lease liabilities; RMB32.7 million of share option expenses, RMB5.0 million of bank interest income, RMB1.0 million of income from government grants; RMB0.3 million of rent concession and RMB10.0 million net foreign exchange losses.

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 of 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.

Net Cash used in Investing Activities

Net cash used in investing activities was RMB68.2 million for the year ended December 31, 2021, which resulted primarily from the purchase of equipment, land and construction of Lingang project, partially offset by the interest received from bank. 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 Financing Activities

Net cash used in financing activities was RMB6.1 million for the year ended December 31, 2021, which resulted from payments relating to lease liabilities, offset by proceeds from exercise of share options. 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.

Financial position

Our net current assets decreased from RMB938.7 million as of December 31, 2020 to RMB597.7 million as of December 31, 2021. Current assets decreased from RMB1,045.3 million as of December 31, 2020 to RMB704.6 million as of December 31, 2021, primarily due to a decrease in bank balances and cash from RMB1,032.1 million as of December 31, 2020 to RMB675.2 million as of December 31, 2021, 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, 2021 and 2020, our lease liabilities amounted to RMB71.5 million and RMB80.7 million, respectively. The following table sets forth our lease liabilities as of the dates indicated:

	As of December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
Current portion	13,296	11,503
Non-current portion	58,232	69,212
Total	71,528	80,715

Our lease liabilities as of December 31, 2021 were from leased properties lease contracts with lease terms of two to five years. As of December 31, 2021, 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 on loss for the year.

	As of December 31,	
	2021	2020
	RMB'000	RMB'000
Impact on profit or loss		
US\$	(18,134)	(22,228)
HK\$	(2,057)	(2,210)

Interest Rate Risk

The Group is primarily exposed to fair value interest rate risk in relation to fixed-rate short-term bank deposits and pledged 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, 2021 and 2020, we recorded net current assets of RMB597.7 million and RMB938.7 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,	
	2021	2020
Current ratio ⁽¹⁾	6.6	9.8
Quick ratio ⁽²⁾	6.6	9.8
Gearing ratio ⁽³⁾	15.9%	11.0%

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

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

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

The current ratio and quick ratio as of December 31, 2021 decreased by 3.2 compared with that as of December 31, 2020, which was mainly due to the cost of research activities and daily operation.

Charge of the Group's assets

Save as disclosed in this announcement, as of December 31, 2021, RMB7.8 million of the Group's bank deposits were charged by the bank to secure commencement and completion of the factory construction and launch of production.

Capital commitments

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

	As of December 31,	
	2021	2020
	RMB'000	RMB'000
Capital expenditure in respect of the acquisition of construction contracted for but not provided in the consolidated financial statements	4,381	–

Future plans for material investments or capital assets

Save as disclosed in this announcement, as of December 31, 2021, we plan to continually invest in the Hua Medicine drug manufacturing company which was established at Shanghai Lingang Special Area for ensuring adequate dorzaglatin commercial supply.

Contingent liabilities

Save as disclosed in this announcement, the Group had no material contingent liabilities as at 31 December 2021.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

		For the year ended December 31,	
	<i>NOTES</i>	2021 RMB'000 (audited)	2020 RMB'000 (audited)
Other income	3	11,871	15,859
Other gains and losses	4	(10,373)	(41,827)
Administrative expenses		(134,835)	(140,084)
Finance cost	5	(3,950)	(4,396)
Other expenses		(1,612)	(1,724)
Research and development expenses		<u>(186,835)</u>	<u>(220,962)</u>
Loss before tax	6	(325,734)	(393,134)
Income tax expense	7	<u>–</u>	<u>–</u>
Net loss		<u>(325,734)</u>	<u>(393,134)</u>
Other comprehensive income (expense)			
Items that may be reclassified subsequently to profit or loss:			
– Exchange differences on translation of foreign operations		<u>454</u>	<u>(453)</u>
Total comprehensive expense for the year		<u>(325,280)</u>	<u>(393,587)</u>
LOSS PER SHARE	9	RMB	RMB
Basic and diluted		<u>0.34</u>	<u>0.41</u>

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	<i>NOTES</i>	As of December 31, 2021 <i>RMB'000</i> (audited)	As of December 31, 2020 <i>RMB'000</i> (audited)
Non-current assets			
Plant and equipment		57,942	49,341
Right-of-use assets	10	98,658	74,177
Intangible assets		9,026	3,387
Pledged bank deposits	12	3,130	–
Prepayments and other receivables	11	30,197	26,339
		198,953	153,244
Current assets			
Prepayments and other receivables	11	24,666	13,187
Pledged bank deposits	12	4,696	–
Bank balances and cash	12	675,238	1,032,090
		704,600	1,045,277
Current liabilities			
Trade and other payables	13	79,738	80,794
Lease liabilities		13,296	11,503
Deferred income		13,850	14,250
		106,884	106,547
Net Current Assets		597,716	938,730
Total Assets Less Current Liabilities		796,669	1,091,974
Non-current liabilities			
Lease liabilities		58,232	69,212
Contract liabilities	14	283,019	283,019
Deferred income		5,087	7,248
		346,338	359,479
Net Assets		450,331	732,495

	As of December 31, 2021	As of December 31, 2020
<i>NOTES</i>	<i>RMB'000</i>	<i>RMB'000</i>
	(audited)	(audited)
Capital and reserves		
Share capital	7,211	7,209
Treasury shares held in trust	(626)	(690)
Reserves	443,746	725,976
	<u>450,331</u>	<u>732,495</u>
Equity attributable to owners of the Company		
	<u>450,331</u>	<u>732,495</u>
Total Equity	<u>450,331</u>	<u>732,495</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

For the year ended December 31, 2021

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, Uglund 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,	
	2021	2020
	RMB'000	RMB'000
	(audited)	(audited)
Bank interest income	5,036	4,370
Government grants and subsidies (<i>Note</i>)	6,490	8,664
Rental concessions	345	2,825
	<u>11,871</u>	<u>15,859</u>

Note:

Government grant related to income received as compensation for future research and development costs expected to be incurred and require the Group to comply with conditions attached to the grants and the government to acknowledge the compliance of these conditions. These grants related to 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 acknowledge 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.

The government grants related to assets are received to compensate the right of use assets. The grants shall be recognised in profit or loss on a systematic basis.

4. Other gains and losses

Other gains and losses mainly represent the foreign exchange losses and gains during the years ended December 31, 2021 and 2020.

5. Finance cost

	For the year ended December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
	(audited)	(audited)
Interest on lease liabilities	<u>3,950</u>	<u>4,396</u>

6. Loss before tax

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

	For the year ended December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
	(audited)	(audited)
Depreciation for equipment	11,984	4,949
Depreciation of right-of-use assets	19,189	20,132
Amortization for intangible assets	<u>752</u>	<u>322</u>
	31,925	25,403
Capitalized in construction in progress	<u>(336)</u>	<u>(6,955)</u>
	<u>31,589</u>	<u>18,448</u>
Other expenses	1,612	1,724
Staff cost (including directors' emoluments):		
– Salaries and other benefits	130,579	124,339
– Retirement benefit scheme contributions	11,162	4,071
– Share option expenses	<u>32,695</u>	<u>58,942</u>
	<u>174,436</u>	<u>187,352</u>
Covid-19-related rent concessions	(345)	(2,825)
Auditors' remuneration		
– Audit services	1,670	1,720
– Non-audit services	<u>906</u>	<u>1,280</u>
	<u>2,576</u>	<u>3,000</u>
Expenses relating to short-term leases	<u>1,316</u>	<u>1,686</u>

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, 2021.

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

8. License agreement

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

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

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

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

9. 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,	
	2021	2020
	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	(325,734)	(393,134)

Number of shares:

	For the year ended December 31,	
	2021	2020
	(audited)	(audited)
Weighted average number of ordinary shares for the purpose of basic and diluted loss per share	<u>957,488,541</u>	<u>950,508,749</u>

The computation of basic and diluted loss per share for the years ended December 31, 2021 and 2020 respectively excluded the unvested restricted shares and unvested restricted stock units of the Company.

The computation of diluted loss per share for the years ended December 31, 2021 and 2020 did not assume the exercise of share options and vesting of restricted stock units since their assumed exercise would result in a decrease in loss per share.

10. Right-of-use assets

The Group entered into several new lease or lease modifications agreements for the use of leased properties for two to fifty years, and the net book value of right-of-use assets as of December 31, 2021 and 2020 is RMB98,658,000 and RMB74,177,000.

11. Prepayments and other receivables

	As of December 31, 2021 RMB'000 (audited)	As of December 31, 2020 RMB'000 (audited)
Prepayments for research and development services	14,303	2,146
Utility and rental deposits		
– current	662	1,814
– non-current	4,609	4,194
Value add tax recoverable – non-current	24,942	21,910
Interest receivables	52	704
Other receivables for considerations of options exercised	359	287
Others		
– current	9,290	8,236
– non-current	646	235
	<u>54,863</u>	<u>39,526</u>
Analysis as		
– current	24,666	13,187
– non-current	30,197	26,339
	<u>54,863</u>	<u>39,526</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 1.95% per annum as of December 31, 2021 (December 31, 2020: from 0.001% to 2.30% per annum).

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

Deposits amounting to RMB4,696,000 (2020: nil) carry fixed interest rate of 1.50% and have been pledged to secure commencement of the factory construction. These deposits will be released within 10 working days upon the commencement of the factory construction, if such commencement is before May 13, 2022. Deposits amounting to RMB1,565,000 (2020: nil) carry fixed interest rate of 2.75% and have been pledged to secure completion of the factory construction. These deposits will be released within 10 working days upon the completion of the factory construction if such completion is before May 13, 2024. The remaining deposits amounting to RMB1,565,000 (2020: nil) carry fixed interest rate of 2.75% and have been pledged to secure production of the factory. These deposits will be released within 10 working days upon the launch of production, if such launch is before November 12, 2024.

13. Trade and other payables

	As of December 31, 2021 <i>RMB'000</i> (audited)	As of December 31, 2020 <i>RMB'000</i> (audited)
Trade payables	23,785	25,821
Other payables	4,071	4,179
Payroll and bonus payables	32,149	32,285
Accrued leasehold improvement expenditure	1,604	12,383
Construction expenditure	10,982	–
Others	7,147	6,126
	<u>79,738</u>	<u>80,794</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, 2021 <i>RMB'000</i> (audited)	As of December 31, 2020 <i>RMB'000</i> (audited)
Uninvoiced or within 30 days	<u>23,785</u>	<u>25,821</u>
	<u>23,785</u>	<u>25,821</u>

14. Contract liabilities

	As of December 31, 2021 <i>RMB'000</i> (audited)	As of December 31, 2020 <i>RMB'000</i> (audited)
Advance from a customer for exclusive distribution rights	<u>283,019</u>	<u>283,019</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, 2021.

Employees and remuneration policy

As of December 31, 2021, the Group employed a total of 146 employees, as compared to a total of 162 employees as of December 31, 2020. The majority of the employees are employed in mainland China. For the year ended December 31, 2021, staff costs (including Directors' emoluments but excluding any contributions to pension scheme) were approximately RMB163.3 million as compared to RMB183.3 million for the year ended December 31, 2020.

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, 2021.

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 of Hong Kong Limited (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 2022 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, 2021:

	% of use of proceeds	Net proceeds from the Global Offering <i>RMB million</i>	Unutilized net proceeds as of January 1, 2021 <i>RMB million</i>	Utilization during the year ended December 31, 2021 <i>RMB million</i>	Actual usage up to December 31, 2021 <i>RMB million</i>	Unutilized net proceeds as of December 31, 2021 <i>RMB million</i>	Expected time frame for unutilized amount
(a) Dorzagliatin research and development	39%	291.4	-	-	291.4	-	N/A
(b) Dorzagliatin lifecycle management and additional indications	9%	67.2	34.1	7.3	40.4	26.8	By the end of year 2022
(c) Dorzagliatin launch and commercialization	27%	201.8	170.3	21.5	53.0	148.8	By the end of year 2023
(d) New product and diabetes care technology development	11%	82.2	68.5	8.2	21.9	60.3	By the end of year 2023
(e) Product licensing and partnership	4%	29.9	29.9	6.4	6.4	23.5	By the end of year 2023
(f) General working capital	10%	74.7	-	-	74.7	-	N/A
Total	100%	747.2	302.8	43.4	487.8	259.4	By the end of year 2023

Final dividend

The Board has resolved not to declare any final dividend for the year ended December 31, 2021 (December 31, 2020: 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, 2021.

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 (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, 2021. 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, 2021 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 December 31, 2021 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 23, 2022. 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 20, 2022 to June 23, 2022, 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 17, 2022.

Publication of the annual results and 2021 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, 2021 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 16, 2022

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.

On March 16, 2022, subsequent to this announcement's approval, Dr. Lian Yong Chen resigned as a Company non-executive director and Ms. Zhao Wei was appointed by the Board as a Company non-executive director.