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華領醫藥

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

ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED DECEMBER 31, 2018

BUSINESS HIGHLIGHTS

- Advanced our two Phase III trials for dorzagliatin in China, with total randomized enrollment of 752 patients as of December 31, 2018.
 - o Our monotherapy Phase III trial (HMM0301) completed enrollment as of February 28, 2019.
 - o As of February 28, 2019, enrollment for our combination with metformin Phase III trial (HMM0302) was 489 patients.
- Aggregate financing of US\$231 million was successfully raised in calendar year 2018, with US\$117 million raised in a pre-IPO equity financing in March 2018 and HK\$892 million (approximately US\$114 million) raised in an IPO on the Hong Kong Stock Exchange in September 2018.
 - o Cash position was approximately RMB1,443.3 million as of December 31, 2018.
- Total expenditures incurred by the Company for the year ended December 31, 2018 was approximately RMB411.9 million, of which approximately RMB269.1 million was attributable to R&D expenses.

FINANCIAL HIGHLIGHTS

- Research and development expenses increased by approximately RMB143.7 million or approximately 114.7% to approximately RMB269.1 million.
- Loss on changes in fair value of financial liabilities at fair value through profit or loss ("FVTPL") increased by approximately RMB3,139.8 million or approximately 2,482.9% to approximately RMB3,266.2 million.
- Loss before tax increased by approximately RMB3,323.3 million or approximately 1,184.0% to approximately RMB3,604.0 million.
- Loss and total comprehensive expense for the year increased by approximately RMB3,323.3 million or approximately 1,184.0% to approximately RMB3,604.0 million.
- Adjusted loss* increased by approximately RMB129.4 million or approximately 86.3% to approximately RMB279.3 million.
- * Adjusted loss is not a financial measure defined under IFRS. It is calculated by taking loss before tax for the year and adding back (a) share-based payment; and (b) loss on changes in fair value of financial liabilities at FVTPL.

MANAGEMENT DISCUSSION AND ANALYSIS

Business overview

We are a pre-revenue China-based drug development company currently focused on developing dorzagliatin, a first-in-class oral drug for the treatment of Type 2 diabetes. We filed an Investigational New Drug (IND) application with the National Medical Products Administration (NMPA) for dorzagliatin under Category 1.1 (New Drug) in 2012 and initiated a Phase Ia clinical study of our novel glucokinase activator dorzagliatin in September 2013. We also filed an IND application with the U.S. Food and Drug Administration (FDA) for dorzagliatin in March 2015. Since then, we have completed five Phase I trials in China, two Phase I trials in the United States, and one Phase II trial in China. During the year ended December 31, 2018 (being the reporting period), the results from our Phase II trial were published in the May 2018 edition of *The Lancet Diabetes & Endocrinology*. We also published the results of our personalized medicine Phase Ic trial, demonstrating effective glycemic control in Type 2 diabetes patients when using our proprietary biomarker-guided patient selection approach in the April 2018 edition of *Diabetes*, *Obesity and Metabolism*. We are currently conducting two Phase III trials in China and two Phase I trials in the United States. Our Phase III registration trials began in July 2017, with dorzagliatin both as a monotherapy (HMM0301) and in combination with metformin (HMM0302). Our two Phase I trials began in early 2019, and are studying the pharmacokinetic (PK) and pharmacodynamic (PD) characteristics of dorzagliatin in combination with sitagliptin (DPP-4) and empagliflozin (SGLT-2), respectively.

In preparation for our eventual new drug application (NDA) submission for dorzagliatin with the NMPA, we completed the required API commercial manufacturing process validation of up to one ton of material. In addition, in the second half of 2018, we established the leadership team for our China commercialization, sales and marketing (CSM) team for dorzagliatin.

We will also continue to develop mGLUR5, a potential novel drug candidate for the treatment of Parkinson's disease levodopa-induced dyskinesia, or PD-LID.

Product pipeline

Trial No.	Products	Pre-clinical	Phase 1	Phase 2	Phase 3
HMM0301	Dorzagliatin (HMS5552)	Drug Naive T2D			
HMM0302	Dorzagliatin + Metformin	T2D with Metforr	nin Tolerance		
HMM0111	Dorzagliatin + DPP-4	Obese T2D			
HMM0112	Dorzagliatin + SGLT-2	Metabolic Syndrome			
	Dorzagliatin + Insulin	T2D Basal Insulin User			
	Dorzagliatin + GLP-1	Obese T2D			
	mGLUR5	PD-LID			

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

Trial HMM0301 is a dorzagliatin monotherapy Phase III trial in drug-nave T2D patients in China. We completed enrollment with over 450 patients as of February 28, 2019 and we expect to announce top-line 24-week results by the fourth quarter of 2019. Trial HMM0302 is a dorzagliatin combination with metformin Phase III trial in metformin tolerant T2D patients in China. We expect to complete enrollment by mid-year 2019, and announce top-line 24-week result by the first quarter of 2020. Trial HMM0111 is a dorzagliatin combination with DPP-4 (sitagliptin) Phase I trial in T2D patients in the United States. We announced first patient dosed in January 2019 and expect to complete and announce results by year end 2019. Trial HMM0112 is a dorzagliatin combination with SGLT-2 (empagliflozin) Phase I trial in T2D patients in the United States. We have activated our clinical site and expect to dose first patient in the first half of 2019. We expect to complete and announce results by year end 2019. We are planning to conduct additional dorzagliatin combination trials with insulin and GLP-1, respectively. We expect to initiate these clinical studies later in 2019. We continue to conduct preclinical studies on our mGLUR5 program for levodopa-induced dyskinesia in Parkinson disease patients. Based on the results of these studies, we plan to make a Go/No GO decision later in 2020.

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

To date, we have not yet generated any revenue from the sale of goods or from the rendering of services, recognizing only limited income in the form of government grants and investment income. As of December 31, 2018, we expect to continue to incur significant losses for the foreseeable future with no product revenues prior to obtaining marketing approval for dorzagliatin from the NMPA and commercializing dorzagliatin.

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

Business outlook

We expect to complete patient enrollment for both of our Phase III trials by the middle of calendar year 2019, announce top-line 24-week Phase III trial results for our monotherapy trial (HMM0301) by the fourth quarter of 2019, announce top-line 24-week Phase III results for our combination with metformin trial (HMM0302) by the first quarter of 2020, file for new drug application (NDA) approval on a rolling basis with the NMPA shortly thereafter, and obtain NMPA approval by the end of 2020 or the first half of 2021. Upon receipt of positive Phase III data, we plan to partner with international pharmaceutical companies to make dorzagliatin available to patients outside of China. This will include partnerships for conducting clinical trials and navigating the drug approval process, as well as for the marketing and commercialization of dorzagliatin outside of China. In preparation for our eventual NDA submission with the NMPA, we plan to complete all required research and studies as well as commercialization, manufacturing and control (CMC) process validations by the end of 2019. We also plan to expand our CSM team in anticipation of China launch of dorzagliatin by the end of 2020 or early 2021. As part of the strategy to establish dorzagliatin as a cornerstone therapy for the treatment of Type 2 diabetes globally, we would expect to collaborate with global experts in Type 2 diabetes to further understand the potential of dorzagliatin.

Key events after the reporting period

On January 23, 2019, the China National Intellectual Property Administration (CNIPA) issued to our Company a patent on a controlled release formulation of dorzagliatin. This new patent would extend the exclusivity of dorzagliatin to 2037 in China.

On January 31, 2019, we dosed our first patient for our Phase I DPP-4 combination trial (HMM0111) in the United States. We have activated a clinical trial site for our Phase I SGLT-2 combination trial (HMM0112) in the United States. and expect to dose first patient in the first half of 2019. We expect to complete and publish results of both Phase I combination trials (HMM0111 & HMM0112) by year end 2019.

In February 2019, we announced the appointment of Dr. Ralph DeFronzo as our Global Consultant – Distinguished Scientific Consultant. Dr. DeFronzo is currently a Professor and Division Chief of Diabetes Division at the University of Texas Health Science Center and Deputy Director of Texas Diabetes Institute. He has contributed to several significant milestones in diabetes medicine, including leading the U.S. development of metformin, and its FDA approval in 1995. Since then, he discovered a new approach to diabetes treatment that targets glucose reabsorption in the kidneys, which led to the development and approval of SGLT-2.

On February 28, 2019, our Phase III monotherapy trial (HMM0301) had completed patient enrollment and our Phase III combination trial (HMM0302) had enrolled 489 patients.

Financial review

Other income

Our other income consisted primarily of bank interest income and government grants and subsidies. Our other income decreased by RMB1.3 million to RMB10.4 million for the year ended December 31, 2018 from RMB11.7 million for the year ended December 31, 2017, which was mainly attributable to a decrease of RMB1.4 million in government grants.

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. Our other gains and losses increased by RMB70.4 million to a gain of RMB63.8 million in the year ended December 31, 2018 from a loss of RMB6.6 million in the year ended December 31, 2017, which was mainly attributable to foreign exchange gains in connection with bank balances and cash denominated in U.S. dollars and HK dollars and the appreciation of the U.S. dollars and HK dollars against the Renminbi in the year ended December 31, 2018 compared to the minor depreciation of the U.S. dollar against the Renminbi in the year ended December 31, 2017.

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

Administrative expenses

Our administrative expenses consisted primarily of employee compensation and related costs. Our administrative expenses increased by RMB69.3 million to RMB100.4 million in the year ended December 31, 2018 from RMB31.1 million in the year ended December 31, 2017, which was mainly attributable to i) increase in labor costs which is attributable to the increase of RMB29.3 million in share-based payment including share options and restricted share units that were granted, and increase of RMB29.1 million in cash compensation due to increased headcount of 40 new employees for the year ended December 31, 2018 for the establishment of our finance and corporate development team and commercial strategy and marketing team, ii) consulting fee associated with marketing strategy in 2018, and iii) overhead costs associated with the headcount increases.

Finance cost

Our finance cost consisted of expenses associated with the issue of redeemable convertible preferred shares. Our finance cost was RMB3.5 million for the year ended December 31, 2018 as compared to RMB3.0 million for the year ended December 31, 2017, which was attributable to the Series D and Series E preferred shares financings completed in March 2018.

Listing expenses

Our listing expenses mainly include sponsor fee, underwriting fees and commissions, and professional fees paid to legal advisers and the reporting accountants for their services rendered in relation to the HK IPO. The total listing expenses for the HK IPO are approximately RMB72.4 million. We incurred listing expenses of approximately RMB38.9 million for the year ended December 31, 2018, which were recognized as expenses and the remaining amount of approximately RMB33.5 million were recognized directly as a deduction from equity upon the successful completion of the HK IPO.

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,			
	2018	%	2017	%
	RMB'000		RMB'000	
Dorzagliatin Clinical Trials	133,619	49.7%	51,816	41.3%
Dorzagliatin Non-clinical Studies	2,295	0.9%	7,708	6.2%
Chemical, Manufacturing and Control	44,733	16.5%	22,947	18.3%
Labor Cost	76,854	28.6%	29,339	23.4%
Dorzagliatin Licensing Fee	137	0.1%	6,757	5.4%
Others	11,427	4.2%	6,770	5.4%
Total	269,065	100.0%	125,337	100.0%

Research and development expenses increased by RMB143.8 million to RMB269.1 million for the year ended December 31, 2018 from RMB125.3 million for the year ended December 31, 2017. The increase in research and development expenses included:

- an increase of RMB81.8 million for dorzagliatin clinical trials, which was primarily attributable to increased costs associated with the progress of our Phase III clinical trials and additional Phase I clinical trials conducted in 2018;
- a decrease of RMB5.4 million in dorzagliatin non-clinical studies, which was primarily attributable to certain toxicology trials completed in 2017, and that were not conducted in 2018;
- an increase of RMB21.8 million in chemical, manufacturing, and control expenses, which was primarily attributable to process validation for API manufacturing completed in 2018;
- an increase of RMB47.5 million for increased labor costs, which was primarily attributable to an increase of RMB22.7 million in cash compensation with headcount increasing from 55 as of December 31, 2017 to 75 as of December 31, 2018 and an increase of RMB24.8 million in sharebased payment;
- a decrease of RMB6.6 million for decreased licensing milestone payments, which was primarily attributable to a US\$1.0 million milestone payment paid to Roche under our licensing agreement due to the initiation of our Phase III trials in 2017, and that did not recur in 2018; and
- an increase of RMB4.7 million for others, which was primarily attributable to increased travelling, consulting and meeting costs, and increased rental cost.

Loss on changes in fair value of financial liabilities at FVTPL

Our loss on changes in fair value of convertible redeemable preferred shares consisted primarily of the increase in fair value per share. Loss on changes in fair value of financial liabilities at FVTPL increased by RMB3,139.8 million to RMB3,266.2 million for the year ended December 31, 2018 from RMB126.5 million for the year ended December 31, 2017, which was mainly attributable to the increase in valuation of the Company due to the launch of our Phase III clinical trials in the third quarter of 2017 and the successful completion of the HK IPO in the third quarter of 2018.

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

Income tax expense

We recognized no income tax expenses for the year ended December 31, 2018 and the year ended December 31, 2017.

Adjusted net loss

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

	For the year ended December 31		
	2018 RMB'000	2017 RMB'000	
Loss before tax for the period Adjust for:	(3,603,998)	(280,688)	
Loss on changes in fair value of financial liabilities at FVTPL Share-based payment	3,266,216 58,500	126,456 4,354	
Adjusted net loss	(279,282)	(149,878)	

Liquidity and capital resources

Since our inception, we have incurred net losses and negative cash flows from operations. Our primary use of cash is to fund R&D expenses. Our operating activities utilized RMB269.4 million for the year ended December 31, 2018. As of December 31, 2018, we had cash and cash equivalents of RMB1,443.3 million.

As of December 31, 2018, there were no significant investments held by the Company, nor were there any material acquisitions or disposals of subsidiaries, associates and joint ventures during the reporting period.

Cash Operating Cost

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

	For the year ended December 31,		
	2018 RMB'000	2017 RMB'000	
R&D costs Administrative costs	169,938	166,148	
– Workforce employment	40,262	11,419	
– Others	59,223	23,925	
	99,485	35,344	
	269,423	201,492	

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2017 and 2018:

	For the year ended December 31,	
	2018	2017
	RMB '000	RMB '000
Net cash (used in) operating activities	(269,423)	(198,694)
Net cash from investing activities	12,492	14,475
Net cash from financing activities	1,464,856	172,904
Effect of exchange rate changes	62,652	(8,853)
Net increases (decrease) in cash and cash equivalents	1,270,577	(20,168)

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, 2018, our operating activities used RMB269.4 million of cash, which resulted principally from our loss before tax of RMB3,604.0 million, adjusted for non-cash charges and non-operating cash charges of RM3,255.9 million, and by cash used in our operating assets and liabilities of RMB78.7 million. Our net non-cash charges during the year ended December 31, 2018 primarily consisted of RMB3,266.2 million of loss on changes in fair value of financial liabilities at FVTPL, depreciation of plant and equipment, amortization for intangible assets, share-based payments expenses, and net foreign exchange loss.

During the year ended December 31, 2017, our operating activities used RMB198.7 million of cash, which resulted principally from our loss before tax of RMB280.7 million, adjusted for non-cash charges and non-operating cash charges of RMB130.5 million, and by cash used in our operating assets and liabilities of RMB48.5 million. Our net non-cash charges during the year ended December 31, 2017 primarily consisted of loss on changes in fair value of financial liabilities at FVTPL of RMB126.5 million, depreciation of plant and equipment, amortization for intangible assets, share-based payments expenses, and net foreign exchange loss.

Net Cash from Investing Activities

Net cash provided by investing activities was RMB12.5 million for the year ended December 31, 2018, which resulted primarily from the disposal of other financial assets and purchase of plant and equipment. Net cash provided by investing activities was RMB14.5 million for the year ended December 31, 2017, which resulted primarily from the net impact of purchases and disposals of other financial assets and purchases of plant and equipment.

Net Cash from Financing Activities

Net cash from financing activities was RMB1,464.9 million for the year ended December 31, 2018, which resulted primarily from proceeds from the issue of our Series D and E preferred shares and net proceeds from the HK IPO. Net cash from financing activities was RMB172.9 million for the year ended December 31, 2017, which resulted primarily from prepayments from investors and proceeds from the issue of our convertible redeemable preferred shares and proceeds from the issue of a subsidiary's ordinary shares and the written put options of certain subsidiaries.

Financial position

Our net current assets increased from RMB189.3 million as of December 31, 2017 to RMB1,396.9 million as of December 31, 2018. Current assets increased from RMB232.3 million as of December 31, 2017 to RMB1,474.5 million as of December 31, 2018, primarily due to an increase in bank balances and cash from RMB172.7 million as of December 31, 2017 to RMB1,443.3 million as of December 31, 2018, which was due primarily to the proceeds from the issue of the Company's ordinary shares through our HK IPO, issue of convertible redeemable preferred shares for our Series D and Series E pre-IPO financing, and the issue of subsidiary's ordinary shares and a written put option over subsidiary.

Contractual Obligations

The following table sets forth our contractual obligations as of December 31, 2018. Amounts we pay in future periods may vary from those reflected in the table.

	Payments due by period				
	Less than			More than	
	Total RMB'000	a year RMB'000	1-3 years RMB'000	3-5 years RMB'000	5 years RMB'000
Operating Lease Obligation	6,056	3,991	2,065	_	_

Indebtedness

As of December 31, 2018, we did not have any indebtedness, including but not limited to mortgages, charges, debentures, other issued and outstanding debt capital, bank overdrafts, borrowings, liabilities under acceptance or acceptance credits, hire purchase commitments, unutilized banking facilities or other similar indebtedness, any guarantees or other material contingent liabilities. Accordingly, the gearing ratio is not applicable.

Qualitative and Quantitative Disclosures About Market Risk

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

Currency Risk

Our business mainly operates in the PRC with most of our transactions settled in RMB, and our financial statements are presented in RMB. RMB 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 RMB into foreign currencies. The value of RMB 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 RMB. We convert a portion of those funds to RMB immediately and place the remaining amount in time deposits. We convert additional amounts to RMB as needed. The value of the RMB 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 RMB for our operations, or if any of our arrangements with other parties are denominated in U.S. dollars and need to be converted into RMB, appreciation of the RMB against the U.S. dollar or other currencies would have an adverse effect on the RMB amount we receive from the conversion. Conversely, if we decide to convert RMB into U.S. dollar or other currencies for business purposes, appreciation of the U.S. or HK dollar against the RMB 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 RMB against US\$ and HK\$, the foreign currencies with which we may have material exposure. No sensitivity analysis has been disclosed for the TWD 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 RMB strengthens 5% against US\$ and HK\$. For a 5% weakening of RMB against US\$ and HK\$ there would be an equal and opposite impact or loss for the year.

	2018 RMB'000	2017 RMB'000
Impact on profit or loss		
US\$	(50,411)	50,844
HK\$	(20,438)	

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 of the Company consider that the exposure of cash flow interest rate risk arising from variable-rate bank balances is insignificant, therefore no sensitivity analysis on such risk has been prepared.

Liquidity Risk

As of December 31, 2018 and 2017, we recorded net current assets of RMB1,396.9 million and RMB189.3 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 L	As of December 31,	
	2018	2017	
Current ratio ⁽¹⁾	19.0	5.4	
Quick ratio ⁽²⁾	19.0	5.4	

⁽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, 2018 increased by 13.6 compared with that as of December 31, 2017 was mainly due to the Series D and Series E Preferred Shares financing and HK IPO for the year ended December 31, 2018.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

		For the yea Decembe	
	NOTES	2018 RMB'000 (audited)	2017 RMB'000 (audited)
Other income Other gains and losses	3 4	10,355 63,778	11,706 (6,557)
Administrative expenses Finance cost Listing expenses	5	(100,398) (3,534) (38,918)	(31,086) (2,958)
Research and development expenses Loss on changes in fair value of financial liabilities at fair value through profit or loss ("FVTPL")		(269,065) (3,266,216)	(125,337) (126,456)
Loss before tax Income tax expense	6 7	(3,603,998)	(280,688)
Loss and total comprehensive expense for the year		(3,603,998)	(280,688)
Loss and total comprehensive expense for the year attributable to:			
Owners of the CompanyNon-controlling interests		(3,602,726) (1,272)	(272,714) (7,974)
		(3,603,998)	(280,688)
LOSS PER SHARE Basic and diluted	9	RMB (10.07)	RMB (2.64)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	NOTES	As of December 31, 2018 RMB'000 (audited)	As of December 31, 2017 RMB'000 (audited)
Non-current assets			
Plant and equipment		5,328	2,641
Intangible assets		859	
Prepayments and other receivables	10	9,552	10,855
		15,739	13,496
Current assets			
Prepayments and other receivables	10	24,337	23,364
Prepayments to related parties		6,863	20,090
Other financial assets			16,101
Bank balances and cash	11	1,443,310	172,733
		1,474,510	232,288
Current liabilities			
Trade and other payables	12	76,033	12,377
Amounts due to related parties		_	23,320
Deferred income		1,600	7,300
		77,633	42,997
Net Current Assets		1,396,877	189,291
Total Assets Less Current Liabilities		1,412,616	202,787
Non-current liabilities			
Deferred income		9,128	6,528
Financial liabilities at FVTPL			1,138,789
		9,128	1,145,317
Net Assets/(Liabilities)		1,403,488	(942,530)

		As of December 31,	As of December 31,
	NOTES	2018	2017
		RMB'000	RMB'000
		(audited)	(audited)
Capital and reserves			
Share capital		7,209	48
Treasury shares held in trust		(797)	
Reserves		1,397,076	(953,928)
Equity/(deficit) attributable to owners of the Company		1,403,488	(953,880)
Non-controlling interests			11,350
Total Equity/(Deficit)		1,403,488	(942,530)

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

For the year ended December 31, 2018

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, Ugland House, Grand Cayman, KY1-1104, Cayman Islands. The principal place of business of the Company is 275 Ai Di Sheng Road, Shanghai 201203, PRC.

The Company is an investment holding company. The Company and its subsidiaries (collectively referred to as "**Group**") are principally engaged in developing a global first-in-class oral drug, dorzagliatin or HMS5552, for the treatment of 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 except for certain financial instruments which are measured at fair values 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 RMB, which is the same as the presentation currency of the consolidated financial statements.

3. Other income

	For the year ended December 31,	
	2018 RMB'000 (audited)	2017 RMB'000 (audited)
Bank interest income	1,226	1,191
Government grants and subsidies related to income (note)	9,129	10,515
	10,355	11,706

Note:

The government grants and subsidies related to income have been received to compensate for the expenses of Group's R&D. Some of the grants related to income have future related costs expected to be incurred and require the Group to comply with conditions attached to the grants and the government to acknowledge the compliance of these conditions. These grants related to incomes were recognized in profit or loss when related costs are subsequently incurred and the Group received government 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 receivable.

4. Other gains and losses

	For the year ended December 31,	
	2018 RMB'000 (audited)	2017 RMB'000 (audited)
(Loss)/gain on disposal of plant and equipment	(7)	24
Net foreign exchange gain/(loss)	63,479	(8,315)
Gain from changes in fair value of other financial assets		
- realized	259	1,660
- unrealized		101
Others	47	(27)
	63,778	(6,557)

5. Finance cost

	For the year ended December 31,	
	2018 RMB'000 (audited)	2017 RMB'000 (audited)
Transaction cost for the issue of the Company's convertible redeemable preferred shares, subsidiary's ordinary		
shares and written put option over subsidiary	3,534	2,958

6. Loss before tax

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

	For the year ended	
	December 31,	
	2018 RMB'000 (audited)	2017 RMB'000 (audited)
Depreciation for plant and equipment	1,534	637
Amortization for intangible assets	7	—
Staff cost (including directors' emoluments):		
- Salaries and other benefits	78,348	29,623
- Retirement benefit scheme contributions	6,177	3,070
– Share-based payment	58,500	4,354
	143,025	37,047
Auditors' remuneration	2,000	493
Minimum operating lease payment in respect of rented premises	4,677	2,358

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.

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

8. License agreement

In December 2011, the Company entered into a research, development and commercialization agreement ("GKA Agreement") with Hoffman-La Roche Inc., and F. Hoffman-La Roche AG (collectively referenced as "Roche") under which Roche granted the Company an exclusive license of patent rights, know-how and regulatory filings with respect to a compound which is a glucokinase activator to research, develop and commercialize products ("Licensed Product") in the field of diabetes in the licensed territory ("Licensed Territory"). Pursuant to the GKA Agreement, the Company made a US\$2.0 million non-refundable upfront payment to Roche which was recorded as research and development expenses in 2012.

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

The Company is obligated to make a US\$4.0 million milestone payment upon the approval of the Licensed Product in the 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 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 in the high single digits (as a percentage of net sales) 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,	
	2018	2017
	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	(3,602,726)	(272,714)
Number of shares:		
	For the yea	r ended
	December 31,	
	2018	2017
	(audited)	(audited)
Weighted average number of ordinary shares for the		
purpose of basic and diluted loss per share	357,864,458	103,486,850

The computation of basic and diluted loss per share for the years ended December 31, 2018 and 2017 respectively excluded the unvested restricted shares and unvested restricted stock units of the Company.

The weighted average numbers of shares for the purpose of basic and diluted loss per share for the years ended December 31, 2018 and 2017 is calculated based on the assumption that the Capitalization Issue of the share allotment has been adjusted retrospectively.

The computation of diluted loss per share for the year ended December 31, 2018 did not assume the exercise of share options, the overallotment options, the restricted shares or the restricted stock units since their assumed conversion or exercise would result in a decrease in loss per share. The computation of diluted loss per share for the year ended December 31, 2017 did not assume conversion of the convertible redeemable preferred shares, the exercise of share options or the restricted shares, since their assumed conversion or exercise would result in a decrease in loss per share.

10. Prepayments and other receivables

	As of December 31, 2018 RMB'000 (audited)	As of December 31, 2017 RMB'000 (audited)
Prepayments for research and development services	21,157	21,795
Utility and rental deposits	1,530	608
Value add tax recoverable – non-current (note)	9,552	10,855
Others	1,650	961
	33,889	34,219
Analysis as		
– current	24,337	23,364
- non-current	9,552	10,855
	33,889	34,219

Note: Value added tax recoverable represent amounts paid by the Group for purchases. Value added tax recoverable was recorded as other non-current assets as at December 31, 2017 since it was expected to be deducted from future value added tax payables arising on the Group's revenue which are not expected to be generated within the next 12 months from December 31, 2017. In June 2018, the General Tax Bureau of the Ministry of Finance announced a new tax policy, 《關於2018年退還部分行業增值税留抵税額有關税收政策的通知》(Caishui [2018] No. 70), that allows the refund of non-deductible valued added tax recoverable from local tax bureaus for companies in qualified industries including pharmaceuticals. Pursuant to Caishui [2018] No. 70, the value added tax recoverable as at December 31, 2017 was refunded during the year ended December 31, 2018. The value added tax recoverable generated in 2018, which is not in the scope of the above said rule, is recorded as prepayments and other receivables as non-current assets as at December 31, 2018.

11. Bank balances and cash

Bank balances and cash carry interests at market rates which ranged from 0.01% to 0.30% per annum as of December 31, 2018 (December 31, 2017: from 0.001% to 1.956% per annum).

12. Trade and other payables

	As of December 31, 2018 RMB'000 (audited)	As of December 31, 2017 RMB'000 (audited)
Trade payables	55,676	4,022
Payroll and bonus payables	14,867	8,000
Accrued expense	4,652	—
Others	838	355
	76,033	12,377

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

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

	As of	As of
	December 31,	December 31,
	2018	2017
	RMB'000	RMB'000
	(audited)	(audited)
Within 30 days	35,118	3,974
31 to 60 days	6,411	_
61 to 180 days	14,147	
181 to 365 days		48
	55,676	4,022

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 from the Listing Date to December 31, 2018.

Employees and remuneration policy

As of December 31, 2018, the Group employed a total of 115 employees, as compared to a total of 75 employees as of December 31, 2017. The majority of the employees are employed in mainland China. For the year ended December 31, 2018, the staff costs (including Directors' emoluments but excluding any contributions to pension scheme) were approximately RMB136.8 million as compared to RMB34.0 million for the year ended December 31, 2017.

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, 2018.

Share incentive plan

The Company conditionally adopted a share option scheme (the "Share Option Scheme") on August 26, 2018, which became effective on the Listing Date. The total number of Shares which may be issued upon exercise of all options to be granted under the Share Option Scheme cannot exceed 105,191,330 Shares. As of February 28, 2019, the Company granted 1,225,000 options to subscribe for Shares and 150,000 forfeited for resignation under the Share Option Scheme.

The Company has also adopted the Pre-IPO Share Incentive Scheme and established an employee trust to administer the scheme. A total of 117,000,000 Shares, representing all the Shares underlying the options and awards granted under the Pre-IPO Share Incentive Scheme, were issued to HLYY Limited, the nominee under the trust, to hold the Shares to satisfy the options and awards granted upon

exercise/vesting. No further Shares will be allotted and issued to the HLYY Limited or the trustee for the purpose of the Pre-IPO Share Incentive Scheme (other than pursuant to capitalization issue, rights issue, sub-division or consolidation of shares in accordance with the Pre-IPO Share Incentive Scheme), and no further option or award will be granted under the Pre-IPO Share Incentive Scheme. As the Pre-IPO Share Incentive Scheme does not involve the grant of options to subscribe for any new Shares of the Company, it is not required to be subject to the provisions under Chapter 17 of the Listing Rules.

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), have been applied in compliance with the intended use of proceeds set out in the section headed "Future plans and use of proceeds" contained in the Prospectus.

The following table sets forth the status of use of proceeds from the HK IPO as of December 31, 2018:

		% of use of proceeds (Approximately)	Net proceeds from the HK IPO RMB million	Actual usage up to 31 December, 2018 RMB million	Unutilized net proceeds as of December 31, 2018 RMB million
(a)	Dorzagliatin research and				
	development	39%	291.4	26.2	265.2
(b)	Dorzagliatin lifecycle				
	management and				
	additional indications	9%	67.2	2.9	64.3
(c)	Dorzagliatin launch and				
	commercialization	27%	201.8	1.5	200.3
(d)	New product and diabetes care				
	technology development	11%	82.2	0.5	81.7
(e)	Product licensing and partnership	4%	29.9	—	29.9
(f)	General working capital	10%	74.7	12.6	62.1
	Total	100%	747.2	43.7	703.5

Final dividend

The Board has resolved not to declare any final dividend for the year ended December 31, 2018 (December 31, 2017: NIL)

Securities transactions by the Directors

The Company has adopted the Model Code as its own code of conduct regarding securities transactions by the Directors.

As the Shares were listed on the Stock Exchange on September 14, 2018, the Model Code was not applicable to the Company during the period from January 1, 2018 to September 13, 2018.

Having made specific enquiry of all Directors, all of them have confirmed that they have complied with the Model Code throughout the period from the Listing Date to December 31, 2018.

Corporate governance

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

The Company has adopted the code provisions of the CG Code as set out in Appendix 14 to the Listing Rules as its own code of corporate governance. The CG Code has been applicable to the Company with effect from the Listing Date and was not applicable to the Company during the period from January 1, 2018 to September 13, 2018.

The Board is of the view that the Company has complied with all applicable code provisions of the CG Code since the Listing Date up to the date of this announcement. The Board will review the corporate governance structure and practices from time to time and shall make necessary arrangements when the Board considers appropriate.

Changes to information in respect of the Directors

Since the Listing Date, there was no change to the information required to be disclosed by the Directors pursuant to Rule 13.51B of the Listing Rules where applicable.

Review of annual results

The consolidated financial results of the Group for the year ended December 31, 2018 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 Dr. Lian Yong Chen.

Annual general meeting and closure of register of shareholders

The annual general meeting (AGM) of the Company is scheduled to be held on June 24, 2019. 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 19, 2019 to June 24, 2019, 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 22, Hopewell Centre, 183 Queen's Road East, Hong Kong for registration not later than 4:30 pm on June 18, 2019.

Publication of the annual results and 2018 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, 2018 containing all the information required under the Listing Rules will be published on the respective websites of the Stock Exchange and the Company and will be dispatched to the shareholders of the Company in due course.

DEFINITIONS

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

"Board"	the board of Directors of the Company
"NMPA"	National Medical Products Administration (國家藥品監督管理局), and its predecessor, the China Food and Drug Administration (國家食品藥品 監督管理總局)
"Company"	Hua Medicine (華領醫藥), an exempt limited liability company incorporated under the laws of the Cayman Islands on November 10, 2009 and whose Shares are listed on the Stock Exchange
"CG Code"	the Corporate Governance Code as set out in Appendix 14 to the Listing Rules
"Director(s)"	the director(s) of the Company
"Group"	the Company and its subsidiaries
"HK\$" or "HK dollars"	Hong Kong dollars, the lawful currency of Hong Kong

"HK IPO"	the global offering of the Shares, comprising the Hong Kong public offering of 10,476,000 Shares, and the international offering of 94,280,000 Shares and 2,980,500 Shares pursuant to the partial exercise of the over-allotment option granted by the Company
"Listing"	listing of our Shares on the Stock Exchange
"Listing Date"	September 14, 2018, being the date on which the Shares were listed on the Main Board of the Stock Exchange
"Listing Rules"	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited
"Model Code"	the Model Code for the Securities Transactions by Directors of Listed Issue's contained in Appendix 10 to the Listing Rules
"PRC"	the People's Republic of China, excluding, for the purposes of this announcement, the Hong Kong Special Administrative Region of the People's Republic of China, the Macau Special Administrative Region of the People's Republic of China and Taiwan
"Pre-IPO Share Incentive Scheme"	the share incentive scheme approved and adopted by the Company on March 25, 2013 as amended from time to time, for the benefit of any director, employee, adviser or consultant of the Company or any of its subsidiaries
"Prospectus"	the prospectus issued by the Company on August 31, 2018 in connection with the Hong Kong public offering of the Shares
"R&D"	research and development
"RMB" or "Renminbi"	Renminbi, the lawful currency of the PRC
"Shareholder(s)"	holder of the Shares
"Share(s)"	ordinary share(s) with nominal value of US\$0.001 each in the share capital of the Company
"Stock Exchange"	The Stock Exchange of Hong Kong Limited
"US\$" or "U.S. dollars"	United States dollars, the lawful currency of the United States of America

The United States of America

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

Hong Kong, March 7, 2019

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