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華領醫藥

(Incorporated in the Cayman Islands with limited liability)

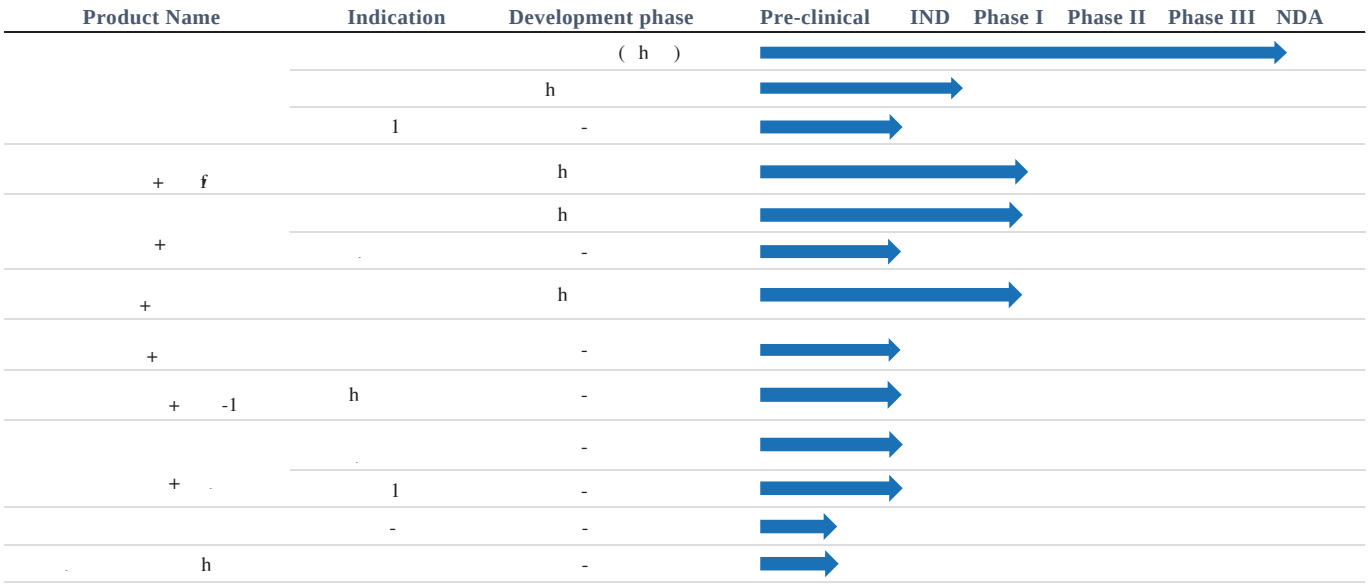
(Stock Code: 2552)

30, 2021

- In March 2021, we submitted a NDA for dorzagliatin for the treatment of Type 2 diabetes to the NMPA, and we received notification from the NMPA thalia3r NDA was accepted in April 2021.
- We presented data from o3r 52-week SEED and DAWN phase 3 registration trials, as well as phase 1 trial HMM0112 of dorzagliatin in combination with SGLT-2 at the 2021 American Diabetes Association's Scientific Sessions demonstrating glucose control benefit using the combination.
- We presented additional data from our phase 1 trial HMM0111 of dorzagliatin in combination with DPP-4 at the 2021 American Diabetes Association's Scientific Sessions, demonstrating thalidorzagliatin regulates GLP-1 secretion and providing additional benefit in glucose control in T2D patients in USA.
- In anticipation of dorzagliatin commercialization, subject to approval of its NDA, in addition to its CMO partnerships, Hua Medicine has also established Hua Medicine drug manufacture company aliShanghai Lingang Special Area for ensuring adequateidorzagliatin commercial supply.
- Cash position was approximately RMB846.9 million as of June 30, 2021.
- Total expenditures incurred by the Company for the six months ended June 30, 2021 was approximately RMB165.1 million, of which approximately RMB98.0 million was attributable to research and development expenses.
- Research and development expenses decreased by approximately RMB14.3 million or approximately 12.7% to approximately RMB98.0 million for the six months ended June 30, 2021, compared with the six months ended June 30, 2020.
- Loss before tax decreased by approximately RMB8.2 million or approximately 4.7% to approximately RMB165.3 million for the six months ended June 30, 2021, compared with the six months ended June 30, 2020.
- Loss and other comprehensive expense for the period decreased by approximately RMB8.4 million or approximately 4.8% to approximately RMB165.3 million for the six months ended June 30, 2021, compared with the six months ended June 30, 2020.

We are a pre-revenue China-based drug development company currently focusing on the development of dorzagliatin, a first-in-class oral drug for the treatment of Type 2 diabetes ("T2D"). We filed an Investigational New Drug ("IND

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



0111

We presented at the 2021 American Diabetes Association's Scientific Sessions and additional data analysis of HMM0111 which demonstrated that dorzagliatin stimulates GLP-1 release in T2D patients and is synergistic with sitagliptin, a DPP-4 inhibitor, to increase circulating active GLP-1 in T2D patients.

18 .08(3) . We may not be able to ultimately develop and market our dorzagliatin successfully.

In the second half of 2021, we plan to initiate additional studies for dorzagliatin and for dorzagliatin combinations, including with dapagliflozin, sitagliptin and GLP-1 and insulin in T2D patients for high quality blood glucose control and improved TIR, which potentially improve the standard of care of T2D mellitus, and with insulin for T1D patients as new indications. We are also advancing our fixed-dose combination pipeline for dorzagliatin.

There are no important events that have occurred since June 30, 2021 up to the date of this announcement.

Our other income consisted primarily of bank interest income, government grants and rent concession. Our other income was RMB3.6 million in the six months ended June 30, 2021 as compared to RMB3.6 million in the six months ended June 30, 2020, which was mainly attributable to an increase of RMB0.4 million in government grants and rent concession for the six months ended June 30, 2021, adjusted for a decrease of RMB0.4 million in bank interest income from short-term time deposits.

Our other gains and losses consisted primarily of losses due to fluctuations in the exchange rates between the Renminbi and the U.S. dollar and between Renminbi and the HK dollar. Our other gains and losses decreased by RMB7.3 million and were mainly attributable to foreign exchange losses in connection with bank balances and cash denominated in U.S. dollar and HK dollar and the depreciation of the U.S. dollar and HK dollar against the Renminbi for the six months ended June 30, 2021.

Our business mainly operates in the PRC, and most of our transactions settled in Renminbi. Since inception, we have financed our business principally through equity financings, with related proceeds denominated in U.S. dollar, HK dollar 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 will also expose us to currency exchange risk. We have not engaged in any foreign exchange hedging related activity.

Our administrative expenses consisted primarily of employee compensation and related costs. Our administrative expenses decreased by RMB0.7 million to RMB63.5 million in the six months ended June 30, 2021 from RMB64.2 million in the six months ended June 30, 2020, which was mainly attributable to i) decrease in labor costs which was attributable to the decrease of RMB4.0 million in share-based payment under the accelerated amortization method, ii) decrease of RMB4.7 million in rental fee, which was mainly due to the allocation method renewal after moving into our new headquarter at the end of 2020, iii) adjusted for the increase of RMB2.6 million in depreciation and amortization expense, mainly due to the decoration and additional equipment purchased for our new headquarter, iv) adjusted for the increase of RMB1.3 million in meeting fee due to more meeting activities conducted compared to the six months ended June 30, 2020 which

Our other expenses consisted of expense associated with a donation of RMB1.6 million (equivalent to USD250,000) for the six months ended June 30, 2021 and RMB1.7 million (equivalent to USD250,000) for the six months ended June 30, 2020 to establish the Type 2 Diabetes research fund at the Department of Biochemistry and Biophysics at the Raymond and Ruth Perelman School of Medicine of the University of Pennsylvania.

Our finance cost consisted primarily of interest on lease liabilities. Our finance cost was RMB2.0 million in the six months ended June 30, 2021 as compared to RMB2.2 million in the six months ended June 30, 2020, which was mainly attributable to the surrender of old offices after moving into our new headquarter at the end of 2020.

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

				30,
	2021	**%**	**2020**	**%**
	'000		**'000**	
Dorzagliatin Clinical Trials	18,564	19.0%	46,565	41.6%
Dorzagliatin Non-clinical Studies	3,236	3.3%	225	0.2%
Chemical, Manufacturing and Control	7,450	7.6%	4,652	4.1%
Labor Cost	54,271	55.3%	55,261	49.2%
Dorzagliatin Licensing and Patent Fee	–	0.0%	1,272	1.1%
Others	14,461	14.8%	4,278	3.8%
Total	97,982	100.0%	112,253	100.0%

Research and development expenses decreased by RMB14.3 million to RMB98.0 million for the six months ended June 30, 2021 from RMB112.3 million for the six months ended June 30, 2020. The decrease in research and development expenses mainly included:

- a decrease of RMB28.0 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 RMB2.8 million in chemical, manufacturing, and control expenses, which was primarily attributable to the chemical and process research for our fructose kinase inhibitor candidates conducted in the first half of 2021;

- an increase of RMB3.0 million for dorzagliatin non-clinical studies, which was primarily attributable to the ISS data and analysis expense for NDA filing, FDC efficacy study of dorzagliatin with insulin/acarbose and efficacy study of dorzagliatin in animal model of T2D complicating cognitive disorder;

- a decrease of RMB1.0 million for labor costs, which was primarily attributable to a decrease of share-based payment under the accelerated amortization method; and

- an increase of RMB10.2 million for other expenses, which was primarily attributable to the

The following table provides information regarding our cash flows for the six months ended June 30, 2021 and 2020:

	[illegible] 30, 2021 '000	30, 2020 '000
Net cash used in operating activities	(164,290)	(167,405)
Net cash (used in) from investing activities	(10,124)	2,871
Net cash used in financing activities	(5,788)	(3,832)
Effect of exchange rate changes	(4,960)	12,350
Net decrease in cash and cash equivalents	(185,162)	(156,016)

[illegible]

The primary use of our cash was to fund our research and development activities, regulatory and other clinical trial costs, and related supporting administration. Our prepayments and other current assets, accounts payable and other payables balances were affected by the timing of vendor invoicing and payments.

During the six months ended June 30, 2021, our operating activities used RMB164.3 million of cash, which resulted principally from our loss before tax of RMB165.3 million, adjusted for non-cash charges and non-operating cash charges of RMB38.8 million, and by cash used in our operating assets and liabilities of RMB37.8 million. Our net non-cash charges during the six months ended June 30, 2021 primarily consisted of share-based payments expenses, depreciation of equipment, right of use assets and amortization for intangible assets.

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

[illegible]

Net cash used in investing activities was RMB10.1 million for the six months ended June 30, 2021, which resulted primarily from the purchase of equipment and intangible assets, adjusted for interest received from bank for short-term deposit. Net cash provided by investing activities was RMB2.9 million for the six months ended June 30, 2020, which resulted primarily from the interest received from bank for short-term deposit, adjusted for purchase of equipment and intangible assets.

Net cash used in financing activities was RMB5.8 million for the six months ended June 30, 2021, which resulted from repayments of lease liabilities, adjusted for proceeds from exercise of share options. Net cash used in financing activities was RMB3.8 million for the six months ended June 30, 2020, which resulted from repayments of lease liabilities, adjusted for proceeds from exercise of share options.

Our net current assets decreased from RMB938.7 million as of December 31, 2020 to RMB791.6 million as of June 30, 2021. Current assets decreased from RMB1,045.3 million as of December 31, 2020 to RMB874.4 million as of June 30, 2021, primarily due to decrease in bank balances and cash from RMB1,032.1 million as of December 31, 2020 to RMB846.9 million as of June 30, 2021, which was due primarily to net cash expenditure during the six months ended June 30, 2021.

We have applied the Amendment to IFRS 16 "Covid-19-Related Rent Concessions beyond 30 June 2021" issued by the International Accounting Standard Board (the "IASB").

As of June 30, 2021, our lease liabilities amounted to RMB76.3 million. The following table sets forth our lease liabilities as of the dates indicated:

	30, 2021	**31, 2020**
	'000	**'000**
Current portion	11,599	11,503
Non-current portion	64,692	69,212
Total	76,291	80,715

Our lease liabilities as of June 30, 2021 were from leased properties lease contracts with lease terms of two to five years. As of June 30, 2021, we did not have any other indebtedness.

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.

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 Trade System market. We do not believe that we currently have any significant direct foreign exchange risk and have not used any derivative financial instruments to hedge our exposure to such risk.

Since our inception, we have raised funds through various rounds of offshore financings and received proceeds of such financings in U.S. dollars, HK dollars and Renminbi. We convert a portion of those funds to Renminbi immediately and place the remaining amount in time deposits. We convert additional amounts to Renminbi as needed. The value of the Renminbi against the U.S. dollars and other currencies may fluctuate and is affected by, among other things, changes in China's political and economic conditions. To the extent that we need to convert U.S. dollars or other currencies we have received in previous financings into Renminbi for our operations, or if any of our arrangements with other parties are denominated in U.S. dollars and need to be converted into Renminbi, appreciation of the Renminbi against the U.S. dollars or other currencies would have an adverse effect on the Renminbi amount we receive from the conversion. Conversely, if we decide to convert Renminbi into U.S. dollars or other currencies for business purposes, appreciation of the U.S. or HK dollars against the Renminbi would have a negative effect on the U.S. dollars or other currencies amounts available to us. We have conducted a sensitivity analysis to determine our exposure to changes in foreign currency rate.

The following table details our sensitivity to a 5% increase and decrease in the Renminbi against the U.S. dollar and the HK dollar, the foreign currencies to which we may have material exposure. No sensitivity analysis has been disclosed for the Taiwan dollar denominated assets as the impact on profit is immaterial. 5% represents management's assessment of the reasonably possible change in foreign exchange rate. The sensitivity analysis uses outstanding foreign currency denominated monetary items as a base and adjusts their translation at the end of the reporting period for a 5% change in foreign currency rate. A negative number below indicates an increase in loss where Renminbi strengthens 5% against the U.S. dollar and the HK dollar. For a 5% weakening of the Renminbi against the U.S. dollar and the HK dollar there would be an equal and opposite impact on gain for the period.

	30, 2021	**31, 2020**
	'000	**'000**
US $	(19,400)	(22,228)
HK $	(1,967)	(2,210)

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

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

As of June 30, 2021 and December 31, 2020, we recorded net current assets of RMB791.6 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.

	NOTES	30, 2021 '000	2020 '000
Other income	4	3,612	3,554
Other gains and losses		(3,788)	3,463
Administrative expenses		(63,518)	(64,248)
Finance cost	5	(1,999)	(2,247)
Research and development expenses		(97,982)	(112,253)
Other expenses		(1,617)	(1,724)
Loss before tax	6	(165,292)	(173,455)
Income tax expense	7	–	–
Loss for the period		(165,292)	(173,455)
Other comprehensive expense			
Items that may be reclassified subsequently to profit or loss:			
– Exchange differences on translation of foreign operations		(2)	(202)
Total comprehensive expense for the period		(165,294)	(173,657)
Total comprehensive expense for the period attributable to:			
– Owners of the Company		(165,294)	(173,657)
		(165,294)	(173,657)
	9		
Basic and diluted		(0.17)	(0.18)

	NOTES	30, 2021 '000	31, 2020 '000
Equipment	10	44,947	49,341
Right-of-use assets	10	66,515	74,177
Intangible assets	10	9,384	3,387
Prepayments and other receivables	11	31,910	26,339
		152,756	153,244
Prepayments and other receivables	11	27,439	13,187
Bank balances and cash	12	846,928	1,032,090
		874,367	1,045,277
Trade and other payables	13	56,899	80,794
Deferred income		14,250	14,250
Lease liabilities		11,599	11,503
		82,748	106,547
		791,619	938,730
		944,375	1,091,974
Deferred income		7,248	7,248
Contract liability		283,019	283,019
Lease liabilities		64,692	69,212
		354,959	359,479
		589,416	732,495
Share capital		7,209	7,209
Treasury shares held in trust		(669)	(690)
Reserves		582,876	725,976
		589,416	732,495

For the six months ended June 30, 2021

1.

The Company was established in the Cayman Islands as an exempted company with limited liability on November 10, 2009 and its shares have been listed on the Stock Exchange since September 14, 2018. The address of the registered office is PO Box 309, Ugland House, Grand Cayman, KY1-1104, Cayman Islands. The principal place of business of the Company is 275 Ai Di Sheng Road, Shanghai 201203, PRC.

5.

		30,
	2021	2020
	'000	'000
	( )	( )
Interest on the lease liabilities	1,999	2,247
	1,999	2,247

6.

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

		30,
	2021	2020
	'000	'000
	( )	( )
Depreciation of equipment	6,128	2,277
Depreciation of right-of-use assets	9,055	10,106
Amortization of intangible assets	395	137
Total depreciation and amortization	15,578	12,520
Covid-19-related rent concessions	345	60
Other expense (Note):	1,617	1,724
Staff cost (including directors' emoluments):		
– Salaries and other benefits	66,009	60,624
– Retirement benefit scheme contributions	5,271	1,657
– Share-based payment	19,364	30,216
	90,644	92,497
Auditors' remuneration	680	680
Expenses relating to short-term leases and lease of low-value assets	263	785

Note:

In 2021, the Company donated US Dollars ("US $") 0.25 million (equivalent to approximately RMB1,617,000)

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 current interim period.

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

8.

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 current interim period, 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. Such payment was recognized as an intangible asset as at June 30, 2021.

The Group is further obligated to make US $3,000,000 milestone payments upon the achievement of development of the Licensed Product through new drag 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.

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:

		30,
	2021	2020
	'000	'000
	( )	( )
Loss for the period attributable to the owners of the Company for the purpose of basic and diluted loss per share	(165,292)	(173,455)

Number of shares:

		30,
	2021	2020
	( )	( )
Weighted average number of ordinary shares for the purpose of basic and diluted loss per share	955,092,759	948,878,897

The computation of basic and diluted loss per share for the six months ended June 30, 2021 and 2020 respectively excluded the unvested restricted stock units of the Company.

The computation of diluted loss per share for the six months ended June 30, 2021 and 2020 respectively did not assume the exercise of share options since their assumed exercise would result in a decrease in loss per share.

10. [illegible]

During the six months ended June 30, 2021, the Group acquired RMB1,885,000 (unaudited) (six months ended June 30, 2020: RMB1,498,000 (unaudited)) of equipment. During the current interim period, the Group disposed

12.

Bank balances and cash comprise cash held by the Group and short-term bank deposits with an original maturity of six 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 June 30, 2021 (December 31, 2020: from 0.001% to 2.30% per annum).

13.

	30, 2021 '000	**31, 2020** '000
Trade payables	23,790	25,821
Payroll and bonus payables	17,305	32,285
Payable to Roche under license agreement	5,812	–
Other payables	3,392	4,179
Accrued Leasehold improvement expenditure	1,493	12,383
Others	5,107	

Neither the Company nor any of its subsidiaries had purchased, sold or redeemed any of the Company

The following table sets forth the status of the Company's use of proceeds raised in the Global Offering as of June 30, 2021:

	%		**30, 2021**	**30, 2021**
Dorzagliatin research and development	39%	291.4	291.4	–
Dorzagliatin lifecycle management and additional indications	9%	67.2	35.9	31.3
Dorzagliatin launch and commercialization	27%	201.8	33.5	168.3
New product and diabetes care technology development	11%	82.2	16.4	65.8
Product licensing and partnership	4%	29.9	–	29.9
General working capital	10%	74.7	74.7	–
Total	100%	747.2	451.9	295.3

The Board has resolved not to declare any interim dividend for the six months ended June 30, 2021 (June 30, 2020: NIL).

The Company has adopted the Model Code as the guidelines for the Directors' dealings in the securities of the Company since the Listing Date. Specific enquiry has been made of each Director and all Directors have confirmed that they have complied with the applicable standards set out in the Model Code for the six months ended June 30, 2021.

[illegible]

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 its own code of corporate governance. The CG Code has been applicable to the Company with effect from the Listing Date.

The Board is of the view that the Company has complied with all applicable code provisions of the CG Code throughout the six months ended June 30, 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.

[illegible]

Mr. Robert Taylor Nelsen had been appointed as non-executive director of Brii Biosciences Limited 騰盛博藥生物科技有限公司 (Stock Code: 2137) since June 22, 2018, a company which was listed on the Stock Exchange on July 13, 2021.

Mr. Tsui Yiu Wa, Alec had been appointed as independent non-executive director of Brii Biosciences Limited 騰盛博藥生物科技有限公司 (Stock Code: 2137) effective from July 13, 2021, being the listing date of the company.

Mr. Liu Junling had been appointed as independent non-executive director of Autohome Inc. since January 12, 2015, a company which is listed on NASDAQ (Stock Code: ATHM) and became secondary listed on the Stock Exchange (Stock Code: 2518) on March 15, 2021.

Dr. Chen Lian Yong had resigned as non-executive director of CStone Pharmaceuticals (Stock Code: 2616 2hc8cutige on Ju9 13, 2021.

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"Post-IPO Share Option Scheme"	the post-IPO share option scheme approved and adopted by the Company on August 26, 2018 for the benefit of any director, employee, adviser or consultant of the Company or any of its subsidiaries
"Pre-IPO Share Incentive Scheme"	the share incentive scheme approved and adopted by the Company on March 25, 2013 as amended from time to time, for the benefit of any director, employee, adviser or consultant of the Company or any of its subsidiaries
"Prospectus"	the prospectus of the company dated August 31, 2018
"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
"U.S." or "United States"	The United States of America

By order of the Board

Chief Executive Officer
and
Executive Director

Hong Kong, August 19, 2021

As at the date of this announcement, the Board 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.