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# Lee's Pharmaceutical Holdings Limited 李氏大藥廠控股有限公司\*

(incorporated in the Cayman Islands with limited liability)
(Stock Code: 950)

## FIRST QUARTERLY RESULTS FOR THE THREE MONTHS ENDED 31 MARCH 2022

FINANCIAL HIGHLIGHT			
	Three months ende	ed 31 March	
	2022	2021	Change
	HK\$'000	HK\$'000	
Revenue	324,750	283,142	+14.7%
Gross profit	215,826	192,411	+12.2%
Profit attributable to the owners			
of the Company	20,307	41,048	-50.5%
	HK cents	HK cents	
Earnings per share			
Basic	3.45	6.98	-50.6%
Diluted	3.45	6.97	-50.5%

<sup>\*</sup> For identification purpose only

### **QUARTERLY FINANCIAL STATEMENTS**

The directors (the "Directors") of Lee's Pharmaceutical Holdings Limited (the "Company") present herewith the unaudited consolidated quarterly financial results (the "Quarterly Results") of the Company and its subsidiaries (collectively, the "Group") for the three months ended 31 March 2022, together with the comparative figures for the corresponding period in 2021. The Quarterly Results are unaudited, but have been reviewed by the Company's auditor, HLM CPA Limited (the "Auditor") in accordance with Hong Kong Standard on Review Engagements 2410 "Review of Interim Financial Information Performed by the Independent Auditor of the Entity" issued by the Hong Kong Institute of Certified Public Accountants. The audit committee of the Company has also reviewed with the management and the Auditor this unaudited Quarterly Results for the three months ended 31 March 2022 before recommending it to the board of Directors ("Board") for approval.

### **BUSINESS REVIEW**

### **Revenue and Profit**

COVID-19 and its economic consequences continue to affect the market environment as 2022 begins. First-quarter 2022 revenue of the Group totaled HK\$324,750,000 (First-quarter 2021: HK\$283,142,000), an increase of 14.7% compared to the prior-year quarter. First-quarter 2022 growths was primarily driven by the sales contributed from chronic disease medications such as the newly launched Bredinin<sup>TM</sup>, as well as Carnitene® and Treprostinil Injection which grew by 18.0% and 70.4%, respectively, and offset lower sales of out-patient drugs such as Ferplex® and surgical drugs such as Livaracine® and Slounase®.

Sales of licensed-in products in the first-quarter 2022 accounted for 61.8% (First-quarter 2021: 55.6%) of the Group's revenue while sales of proprietary and generic products in the first-quarter 2022 contributed 38.2% (First-quarter 2021: 44.4%) of the Group's revenue.

First-quarter 2022 gross profit of the Group was HK\$215,826,000 (First-quarter 2021: HK\$192,411,000). The Group's overall gross profit margin was 66.5%, decreased by 1.5 percentage points as to 68.0% achieved in the first-quarter 2021 due to increase in proportion of revenue generated from the sales of licensed-in products.

Research and development ("**R&D**") expenses represented new drugs development in major therapeutic areas such as cardiovascular, woman health, paediatrics, rare diseases, dermatology and obstetrics, as well as in oncology under a separate R&D arm within the Group. An aggregate of HK\$103,801,000 (First-quarter 2021: HK\$76,530,000) has been spent in the first-quarter 2022, represented 32.0% (First-quarter 2021: 27.0%) to the corresponding quarterly revenue. Among which HK\$61,634,000 (First-quarter 2021: HK\$47,865,000) has been recognised as expenses and HK\$42,167,000 (First-quarter 2021: HK\$28,665,000) has been capitalised as intangible assets. Several clinical trials were embarking to the latter development stage which expediting the finalisation of accounts of completed works contracts and led to an increase in R&D spending in the first-quarter 2022. Nevertheless, it remains the

objective of the Group to optimise the resources allocation among prioritised R&D projects and to keep the expenditures within the limits of revenues in the fiscal year ending December 2022.

The Group's selling and distribution expenses was HK\$81,966,000, representing an increase of HK\$9,397,000 or 12.9% compared to HK\$72,569,000 in the same quarter last year. Overall, the selling expenses to revenue ratio during the first-quarter 2022 was 25.2%, slightly decreased by 0.4 percentage point as to 25.6% same quarter last year. Adequate resources have been deployed to support the works for strengthening the distribution channels, preparing for the roll-out of new and upcoming products, as well as transforming the brand of selected products of the Group. In March 2022, the Group has launched its own flagship online stores on e-commerce platform of Alibaba.com and JD.com to strengthen its brand awareness and expand its sales channels.

As a result of higher expenses incurred in the abovementioned areas, net profit attributable to the owners of the Company in the first-quarter 2022 was HK\$20,307,000, decreased by 50.5% over the same quarter in 2021.

### **Manufacturing Facilities and Production Capability**

Over the years, there have been considerable changes and upgrades in the Group's manufacturing and production capability. To date, the Group's Hefei site has completed the production capacity expansion and process scale up facility upgrades of Yallaferon®, same line production facility upgrades for new pre-filled syringe injection products before introduction to the market, and the making of registration batch of new product in the form of oral lyophilised powder used as sensitiser in surgery for tumor. In Nansha site, the process scale up equipment installation and commission for the manufacturing of inhaled pharmaceutical aerosols has been completed and will have the process scale up pilot run soon, the production process upgrades for oral dose antihypertension drug is in progress, and the making of three pivotal registration batches of the oral cytotoxic drugs in the special workshop has been completed.

## **Drug Development**

To date, the Group has over 40 projects in its pipeline from early- to late-stage development. The applications made in the prior year for Import Drug License ("IDL"), such as Teglutik®, and for Abbreviated New Drug Application ("ANDA"), namely Azilsartan, Epinastine Hydrochloride tablet, and Apremilast tablet (阿普米司特片), are under review by the Centre for Drug Evaluation (the "CDE"). The New Drug Application ("NDA") for Adasuve® made in the prior year has been officially accepted by the China's National Medical Products Administration ("NMPA").

## **Major Therapeutic Areas**

The Group is currently developing several assets in major therapeutic areas, such as cardiovascular, woman health, paediatrics, rare diseases, dermatology and obstetrics, which includes late-stage programs such as (1) Cetraxal® Plus for acute otitis externa (AOE) and acute otitis media with tympanostomy tubes (AOMT); and (2) Intrarosa® in the treatment of vulvovaginal atrophy (VVA), both of which are already in Phase III clinical trial stage.

## **Oncology Pipeline**

China Oncology Focus Limited ("COF"), a 65% owned subsidiary of the Group, is a clinical development stage company and the Group's R&D arm focused on oncology with emphasis in immuno-oncology. To date, COF has built a pipeline of 10 oncology assets, including 6 innovative and 4 generics, through internal development and in-licensing, and is currently developing several assets, including (1) Socazolimab (an anti-PD-L1 antibody) in recurrent or metastatic cervical cancer in new drug application stage in China; (2) Socazolimab in osteosarcoma in Phase III clinical trial; (3) Socazolimab combined with chemotherapy in small cell lung cancer in Phase III clinical trial and has completed the patient enrollment in May 2022; (4) Zotiraciclib, an oral multi-kinase inhibitor in Phase I clinical trial for glioblastoma; (5) Gimatecan, a topoisomerase I inhibitor in Phase II clinical trial for ovarian cancer and in Phase Ib/II clinical trial for small cell lung cancer and a Phase I clinical trial for pancreatic cancer in China; and (6) Socazolimab combined with Pexa-vec (oncolytic virus) which is in Phase Ib clinical trial for melanoma.

During the quarter under review and up to date, the Group obtained 4 ANDA and IDL approvals from NMPA.

## Zingo®

On 1 March 2022, the Drug Registration Certificate for Zingo® (Lidocaine Hydrochloride Powder Intradermal Injection System) has been obtained from the NMPA. Zingo® is an amide local anesthetic indicated for use on intact skin to provide local analgesia prior to venipuncture or peripheral intravenous cannulation in children 3–18 years of age and to provide topical local analgesia prior to venipuncture in adults. The rapid onset of analgesia in 1–3 minutes provides care givers and patients the opportunity for a pain-free and needle-free access procedure.

### INOmax®

On 8 March 2022, the Drug Registration Certificate for INOmax® (nitric oxide gas for inhalation) has been obtained from the NMPA. INOmax® is a therapy for the treatment of hypoxic respiratory failure ("HRF") associated with pulmonary hypertension ("PPHN") in term and near-term infants greater than 34 weeks gestational age. PPHN is a serious condition in which blood vessels in the lungs constrict, making it difficult to oxygenate blood, often resulting in HRF. INOmax® is a vasodilator which selectively relaxes pulmonary blood vessels and, in conjunction with ventilatory support and other appropriate agents, improves oxygenation in this fragile newborn population.

## High Concentration Treprostinil Injection

On 9 March 2022, the Drug Registration Certificate for High Concentration Treprostinil Injection (specification: 20ml: 50mg) developed and manufactured by Zhaoke Pharmaceutical (Hefei) Company Limited, a wholly-owned subsidiary of the Company, has been obtained from the NMPA.

### Natulan®

On 21 April 2022, the Drug Registration Certificate for Natulan® (Procarbazine Hydrochloride Capsules) has been obtained from the NMPA. Natulan® has been approved for combining with chemotherapy to treat Hodgkin's lymphoma (HL) in adult.

### **PROSPECT**

As mentioned earlier this year, the Group remains of the view that the long-term prospect for the China pharmaceutical market is promising in terms of the growth of total health spending in the region but the tough business environment due to regulatory changes will be persisted in 2022. The recent outbreak of COVID-19 in Shanghai which resulted a month-long lockdown of nearly 25 million people has added to the uncertainties to the trade environment.

Nevertheless, the Group has implemented a series of measures to adapt to the "new normal" and to emphasis efficiency at every step of the value chain, particularly in key areas such as sales and R&D, after taking the present conditions into consideration, and the effect has begun to show.

On the other hand, more NDA approvals are expected in the year ending 2022, such as Teglutik® (Riluzole Oral Suspension) for the treatment of Amyotrophic Lateral Sclerosis (ALS) and Nadroparin Calcium Injection which are expected to be approved soon. The Group aims at advancing its product portfolio to create growth opportunities.

The Group firmly believes that all these works to be done will eventually drive growth therefor and will eventually create more value for the shareholders.

## CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS

For the three months ended 31 March 2022

## For the three months ended 31 March

		enaea 31 N	larcn
		2022	2021
	Notes	HK\$'000	HK\$'000
		(unaudited)	(unaudited)
Revenue	3	324,750	283,142
Cost of sales		(108,924)	(90,731)
Gross profit		215,826	192,411
Other income	4	24,621	31,581
Other gains and losses, net		119	2,349
Selling and distribution expenses		(81,966)	(72,569)
Administrative expenses (Provision for)/reversal of expected credit		(57,279)	(58,871)
losses on financial assets		(4,184)	330
Research and development expenses		(61,634)	(47,865)
Research and development expenses		(01,034)	(47,803)
Profit from operations		35,503	47,366
Finance costs		(1,737)	(1,271)
Share of results of associates		(255)	(2,264)
Profit before taxation		33,511	43,831
Taxation	5	(12,846)	(7,475)
Profit for the period		20,665	36,356
Attributable to:			
Owners of the Company		20,307	41,048
Non-controlling interests		358	(4,692)
		20,665	36,356
		HK cents	HK cents
Earnings per share:			
Basic	6	3.45	6.98
Diluted	6	3.45	6.97
	5		0.71

## CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the three months ended 31 March 2022

	For the three months ended 31 March	
	2022	2021
	HK\$'000	HK\$'000
	(unaudited)	(unaudited)
Profit for the period Other comprehensive income/(expense): Items that may be reclassified subsequently to profit or	20,665	36,356
loss:		
<ul> <li>Exchange differences on translation of financial statements of overseas subsidiaries</li> </ul>	7,827	(7,062)
<ul> <li>Share of other comprehensive expense of associates</li> </ul>	_	(54)
Item that will not be reclassified subsequently to profit or loss:		,
- Fair value changes of financial assets at fair value		
through other comprehensive income	(332,695)	(91,196)
Other comprehensive expense for the period, net of tax	(324,868)	(98,312)
Total comprehensive expense for the period	(304,203)	(61,956)
Total comprehensive expense for the period attributable to:		
Owners of the Company	(303,862)	(53,047)
Non-controlling interests	(341)	(8,909)
_		
<u> </u>	(304,203)	(61,956)

## CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

For the three months ended 31 March 2022

				Attributable t	o the owners of	the Company				Attributable	
	Share capital HK\$'000	Share premium HK\$'000	Merger difference HK\$'000	Share-based compensation reserve HK\$'000	Other reserves HK\$'000	Investments revaluation reserve HK\$'000	Exchange reserve HK\$'000	Retained profits HK\$'000	Sub- total HK\$'000	to non- controlling interests HK\$'000	Total HK\$'000
At 1 January 2022 (audited) Employee share option benefits	29,442	720,091 -	9,200	55,964 3,051	65,302	(1,948,815)	22,838	3,510,556	2,464,578 3,051	(73,416) -	2,391,162 3,051
Profit for the period Other comprehensive income/(expense) for the period - Exchange differences on translation of financial statements of overseas	-	-	-	-	-	-	-	20,307	20,307	358	20,665
of financial statements of overseas subsidiaries  - Fair value changes of financial assets at fair value through other	-	-	-	-	-	-	7,791	-	7,791	36	7,827
comprehensive income						(331,960)			(331,960)	(735)	(332,695)
Total comprehensive (expense)/income for the period						(331,960)	7,791	20,307	(303,862)	(341)	(304,203)
At 31 March 2022 (unaudited)	29,442	720,091	9,200	59,015	65,302	(2,280,775)	30,629	3,530,863	2,163,767	(73,757)	2,090,010
At 1 January 2021 (audited) Employee share option benefits Share of reserve of an associate	29,406	714,813	9,200	40,847 3,533	65,228 - 14	(254,155)	(14,843)	1,559,299	2,149,795 3,533 14	(34,417)	2,115,378 3,533 14
Profit/(loss) for the period Other comprehensive expense for the period - Exchange differences on translation of financial statements of overseas	-	-	-	-	-	-	-	41,048	41,048	(4,692)	36,356
subsidiaries  - Share of other comprehensive	-	-	-	-	-	-	(7,006)	-	(7,006)	(56)	(7,062)
expense of associates  - Fair value changes of financial assets at fair value through other	-	-	-	-	(54)	-	-	-	(54)	-	(54)
comprehensive income						(87,035)			(87,035)	(4,161)	(91,196)
Total comprehensive (expense)/income for the period					(54)	(87,035)	(7,006)	41,048	(53,047)	(8,909)	(61,956)
At 31 March 2021 (unaudited)	29,406	714,813	9,200	44,380	65,188	(341,190)	(21,849)	1,600,347	2,100,295	(43,326)	2,056,969

## NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

For the three months ended 31 March 2022

#### 1. BASIS OF PREPARATION

The unaudited condensed consolidated financial statements have been prepared in accordance with Hong Kong Accounting Standards ("HKASs") issued by the Hong Kong Institute of Certified Public Accountants (the "HKICPA") as well as with the applicable disclosure requirements of Appendix 16 to the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited.

### 2. PRINCIPAL ACCOUNTING POLICIES

The unaudited condensed consolidated financial statements have been prepared on the historical cost basis except for certain financial instruments that are measured at fair values as appropriate.

The unaudited condensed consolidated financial statements do not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Group's annual financial statements for the year ended 31 December 2021.

The accounting policies and methods of computation used in preparing the unaudited condensed consolidated financial statements for the three months ended 31 March 2022 are consistent with those used in the Group's annual financial statements for the year ended 31 December 2021 except as described below.

In the current reporting period, the Group has applied the following amendments to HKFRS issued by the HKICPA for the first time which are mandatorily effective for the annual periods beginning on or after 1 January 2022 for the preparation of the Group's unaudited condensed consolidated financial statements. HKFRS comprise Hong Kong Financial Reporting Standards; HKASs; and HK (IFRIC) Interpretations, HK Interpretations and HK (SIC) Interpretations.

Property, Plant and Equipment – Proceeds before Intended Use
Onerous Contracts – Cost of Fulfilling a Contract
Reference to the Conceptual Framework
COVID-19-Related Rent Concessions beyond 30 June 2021
Annual Improvements to HKFRSs 2018–2020

The application of these amendments to HKFRS has had no material effect on the amounts reported in these unaudited condensed consolidated financial statements and/or disclosures set out in these unaudited condensed consolidated financial statements.

The Group has not early applied the following new and amendments to HKFRS that have been issued but are not yet effective:

HKFRS 17 Insurance Contracts and the related Amendments<sup>1</sup> Amendments to HKAS 1 Classification of Liabilities as Current or Non-current and related amendments to Hong Kong Interpretation 5

 $(2020)^{1}$ 

Amendments to HKAS 1 and HKFRS

Practice Statement 2

Amendments to HKAS 8 Definition of Accounting Estimates<sup>1</sup> Amendments to HKAS 12

Deferred Tax related to Assets and Liabilities arising from

a Single Transaction<sup>1</sup>

Amendments to HKFRS 10 and HKAS 28 Sale or Contribution of Assets between an Investor and its

Associate or Joint Venture<sup>2</sup>

Disclosure of Accounting Policies<sup>1</sup>

Effective for annual periods beginning on or after 1 January 2023, earlier application is permitted

Effective date to be determined

The Group has already commenced an assessment of the impact of these new and amendments to HKFRS but is not yet in a position to state whether these new and amendments to HKFRS would have a material impact on its results of operations and financial positions.

#### 3. REVENUE

The principal activities of the Group are the developing, manufacturing and sales and marketing of pharmaceutical products. During the period, revenue represents the net amount received and receivable for goods sold by the Group to outside customers and are recognised at point in time as follows:

### **Business segments**

	For the three months ended 31 March	
	2022	2021
	HK\$'000	HK\$'000
	(unaudited)	(unaudited)
Proprietary and generic products	124,020	125,612
Licensed-in products	200,730	157,530
	324,750	283,142

### Geographical segments

During the three months ended 31 March 2022 and 2021, more than 90% of the Group's revenue was derived from activities conducted in the People's Republic of China (the "PRC"), no geographical segmental information is presented.

### 4. OTHER INCOME

	For the three months		
	ended 31 N	<b>Aarch</b>	
	2022	2021	
	HK\$'000	HK\$'000	
	(unaudited)	(unaudited)	
Interest income on:			
Bank and pledged bank deposits	650	837	
Advance to associates		751	
Total interest income	650	1,588	
Development and government grants	14,436	4,781	
Rental and utilities income	1,859	2,815	
Research and development service income	6,330	21,671	
Sundry income	1,346	726	
	24,621	31,581	

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The Group received the development grants from local government as recognition of the Group's performance and development of high-technology pharmaceutical products.

### 5. TAXATION

	For the three months ended 31 March		
	2022	2021	
	HK\$'000	HK\$'000	
	(unaudited)	(unaudited)	
Current tax			
Hong Kong Profits Tax	7,011	7,360	
PRC Enterprise Income Tax	1,735	912	
Deferred tax	8,746	8,272	
Origination and reversal of temporary difference	4,100	(797)	
	12,846	7,475	

For a qualified entity, Hong Kong Profits Tax for the three months ended 31 March 2022 and 2021 is calculated at 8.25% on the first HK\$2 million of the estimated assessable profits and at 16.5% on the estimated assessable profits above HK\$2 million according to the two-tiered profits tax rates regime. Hong Kong Profits Tax is calculated at 16.5% for the three months ended 31 March 2022 and 2021 for all other entities.

Tax arising in the PRC is calculated at the tax rates prevailing in the PRC. Taxation arising in other jurisdictions is calculated at the tax rate prevailing in the relevant jurisdictions.

### 6. EARNINGS PER SHARE

The calculation of basic and diluted earnings per share attributable to the owners of the Company is based on the following data:

	For the three months ended 31 March	
	2022	2021
	HK\$'000	HK\$'000
	(unaudited)	(unaudited)
Earnings:		
Net profit attributable to the owners of the Company for the purpose		
of basic and diluted earnings per share	20,307	41,048
	For the three	e months
	ended 31	March
	2022	2021
	Share(s)'000	Share(s)'000
	(unaudited)	(unaudited)
Number of shares:		
Weighted average number of ordinary shares for the purpose of		
basic earnings per share	588,835	588,125
Effect of dilutive potential ordinary shares:		
Options		569
Weighted average number of ordinary shares for the purpose of		
diluted earnings per share	588,835	588,694

## 7. RELATED PARTY TRANSACTIONS

During the reporting period, the Group entered into the following transactions with related parties. In the opinion of the directors of the Company, the following transactions arose in the ordinary course of the Group's business.

### (a) Transaction with associates

	For the three months		
	ended 31 March		
	2022	2021	
	HK\$'000	HK\$'000	
	(unaudited)	(unaudited)	
Interest income	_	751	
Rental and utilities income	_	2,815	
Research and development service income	_	21,671	
Purchase of consumables	<u> </u>	1,045	

### (b) Compensation of key management personnel

The remuneration of directors of the Company and other members of key management during the reporting period was as follows:

	For the three months ended 31 March		
	2022	2021	
	HK\$'000	HK\$'000	
	(unaudited)	(unaudited)	
Short-term employee benefits	4,264	3,287	
Share-based payments	2,099	1,892	
Retirement and other post-employment benefits	1,805	3,005	
<ul> <li>Defined contribution plan</li> </ul>	5	5	
- Retirement benefits	1,800	3,000	
	8,168	8,184	

## (c) Donation to Lee's Pharmaceutical - Kanya Lee Scholarship Limited ("Kanya Lee Scholarship")

During the three months ended 31 March 2022, total HK\$1,900,000 (three months ended 31 March 2021: HK\$500,000) was donated to Kanya Lee Scholarship. Dr. Li Xiaoyi, director of the Company, is also a member of key management of Kanya Lee Scholarship and Kanya Lee Scholarship is considered as a related party to the Group.

### 8. CAPITAL COMMITMENTS

	31 March	31 December
	2022	2021
	HK\$'000	HK\$'000
	(unaudited)	(audited)
Capital commitments contracted for in respect of:		
Investment in financial assets at fair value through other		
comprehensive income	36,730	39,119
Intangible assets – license fee and development cost	143,945	125,162
Property, plant and equipment	86,274	85,567
	266,949	249,848

### **DIVIDEND**

The Board does not recommend payment of dividend for the three months ended 31 March 2022 (three months ended 31 March 2021: Nil).

## PURCHASE, SALE OR REDEMPTION OF LISTED SECURITIES

Neither the Company nor any of its subsidiaries had purchased, sold or redeemed any of the Company's listed securities during the three months ended 31 March 2022.

By order of the Board

Lee's Pharmaceutical Holdings Limited

Lee Siu Fong

Chairman

Hong Kong, 26 May 2022

As at the date of this announcement, Ms. Lee Siu Fong (Chairman) and Ms. Leelalertsuphakun Wanee are executive Directors; Dr. Li Xiaoyi and Mr. James Charles Gale are non-executive Directors; Dr. Chan Yau Ching, Bob, Mr. Lam Yat Cheong and Dr. Tsim Wah Keung, Karl, are independent non-executive Directors.