LEE'S PHARM.
李氏大藥廠

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 Report 2018

* 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 2018, together with the comparative figures for the corresponding period in 2017. 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 ("**HKICPA**"). The audit committee of the Company has also reviewed with the management and the Auditor this unaudited report for the three months ended 31 March 2018 before recommending it to the board of Directors for approval.

BUSINESS REVIEW

The Group started the year with the same vigor as in the past several quarters of 2017, and achieved accelerated growth momentum in both revenue and net profit during the first quarter of 2018. Although persistent inflationary pressure in the operating environment in China remains a concern, pricing pressure and active pharmaceutical ingredients (API) cost pressure have eased off during the quarter under review. In addition, the Group continued to achieve savings from its streamlined cost structure on the selling and distribution side during the quarter under review, which enabled the Group to devote more resources along the lines of increasing research and development efforts and business expansions.

Revenue growth of the Group in the first quarter of 2018 registered an increase of over 20% for the first time over the past three years, generated revenue of HK$281,905,000 during the period under review and achieved an increase of 24.6% over the same period last year. Sales of licensed-in products were mixed. On one hand, revenue growth of Carnitene® remained stagnant. However, sales of Remodulin®, Ferplex® and Zanidip® surged 120.3%, 72.2% and 65.5%, respectively, and become the key drivers of the growth of licensed-in products. Sales of major proprietary products also maintained strong growth momentum with sales of Eyprotor®, Yallaferon®, Slounase® and Livaracine® increased by 180.0%, 28.8%, 28.1% and 22.1%, respectively, over the same period last year.

Sales of licensed-in products accounted for 53.7% (For the three months ended 31 March 2017: 54.9%) of the Group's revenue while sales of proprietary products contributed 46.3% (For the three months ended 31 March 2017: 45.1%) of the Group's revenue. The contribution of newer products like Remodulin® to the growth of revenue, the return of Zanidip® to over 50% growth and the double digit growth of Slounase® were encouraging signs that the Group are making headway in broadening its revenue base for more sustainable growth.

During the period under review, the Group's overall gross profit margin held at 68.3%, improved by 2.2 percentage points as to 66.1% achieved in the same quarter of 2017.

Net profit attributable to the owners of the Company in the first quarter of 2018 was HK$70,178,000, significantly increased by 51.3% over the same period last year. The Group continued its improvements in sales and marketing efficiency and maintained a healthy selling expenses to revenue ratio of 22.2%. The cost saving practices there continually supported the Group's plan to invest heavily in research and development ("R&D") activities. The investment in R&D expenses increased 50.5% to HK$31,449,000 from HK$20,903,000 of the same period last year, which represented 11.2% of revenue during the quarter under review. In addition, the savings from selling and distribution activities also supported the increased administrative expenses in the quarter for its business expansions.

The Group's solid dose production facility in Nansha is already fully operational with valid manufacturing license. To date, the Good Manufacturing Practice ("GMP") certificate for its outer packaging operations for Mictonorm® has been obtained, while the applications for the GMP certificates in respect of manufacturing of Azilsartan and Sodium Phenylbutyrate are still underway. Ophthalmology product production facility in Nansha had completed installation and commissioning. The manufacturing license has been obtained for topical formulation in April 2018 and additional formulation for multi-dose eyedrops shall be obtained soon. This is a significant milestone for Zhaoke (Guangzhou) Ophthalmology Company Limited, a company positioned to become a leading domestic fully integrated ophthalmology company and the first China contracted manufacturer for ophthalmology products for international market.

The Group's commitment to R&D persisted in the quarter and measurable progress has been made during the period.

In January 2018, China Oncology Focus Limited ("COFL"), a 65% owned subsidiary of the Group, has been granted the approval to proceed with the clinical trials for ZKAB001, an anti PD-L1 monoclonal antibody, in three separate cancer indications. The trials will be anticipated to use a 3+3 design with 5mg/kg, 10mg/kg and 15mg/kg dosing regimens. Once the Maximum Tolerated Dose ("MTD") has been established, addition patients are expected to be recruited in an expanded Phase I protocol. Clinical data from these studies is expected to be available by the end of 2019, and positive results could lead to conditional approval of the antibody prior to a confirmatory Phase III study.

Following the approval of the registration enabling global Phase III clinical trial for advanced liver cancer using its oncolytic immunotherapy called Pexa-Vec (formerly JX-594), the PHOCUS study, by the China Food and Drug Administration ("CFDA") (Approval No. 2017L04441), the preparation work has been closed to completion. The study in China will be led by world-renowned oncologist Professor Qin and 26 major cancer centers around China have been confirmed to participate. The first China patient is expected to enroll in second quarter of 2018. This clinical study will globally enroll 600 patients (300 in China, 300 in the rest of the world) and over 250 of the patients required from the rest of the world have been enrolled to date.

In May 2018, CFDA approved the clinical trials for Gimatecan, a novel oral lipophilic camptothecin. The trials will be anticipated to use a 3+3 design with 0.4mg/kg, 0.6mg/kg and 0.8mg/kg dosing regimens to determine the MTD in Chinese population. Clinical data from these studies is expected to be available by the end of 2019, and positive results could lead to the following extensive Phase III clinical trial in China.

The development of the two cardiovascular assets, namely Rostafuroxin and Istaroxime, under CVie Therapeutics Limited, an associate of the Group, has made significant progress during the period under review.

Phase IIb clinical study (Protocol No. CVTCV-001) in Taiwan for Rostafuroxin capsule 50, 500ug with antihypertensive effect has been completed and the analytics work to the data is currently in progress.

Istaroxime is a first-in-class luso-inotropic agent for the treatment of acute decompensated heart failure and is currently in its Phase IIb clinical study in Italy (24 patients) and China (96 patients). Istaroxime possesses a dual mode of action, combining inotropic (myocyte contraction) and lusotropic (myocyte relaxation) effects. To date, the Italian arm of the study has been completed and the first cohort of 36 patients in China has also been completed. Over 50% enrolment has been achieved for the second cohort. The study is expected to complete enrolment in the third quarter of 2018.

With over 50 projects in the pipeline, the Group continues to prioritise its resources and focus on the near term projects. Overall, the Group will continue to commit in new drugs development to facilitate sustainable growth in the future.

PROSPECT

Persistent changes and challenges will be in place in this industry, such as raw material inflation and selling price pressure will remain the headwind in the coming quarters. However, the Group is cautiously optimistic to maintain the sales growth momentum of the past several quarters in order to compensate the potential profit squeezed that is the result continuing expansion of the Group R&D efforts.

With the new listing rules for pre-revenue biotech companies finalised in April 2018, the capital market for the pharmaceutical industry has turned a new page. It is expected that a growing number of firms will decide to tap the equity market in Hong Kong to raise funds for the development of new drugs and innovative medical products. The Group has already stay alert and get prepared so as to face up to the challenges. Nevertheless, the opening of the new arena for biotech companies could also mean the Group's efforts in building a comprehensive drug development pipeline may become one of the beneficiaries under this new wave in which the value of the Group can be better reflected.

As always, the operation and management team will continue to make its unremitting efforts to attain additional uplift on the performance in the upcoming period.

CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS

For the three months ended 31 March 2018

		For the three months ended 31 March	
	Notes	**2018** **HK$'000** **(unaudited)**	2017 *HK$'000* (unaudited)
Revenue	(3)	**281,905**	226,200
Cost of sales		**(89,351)**	(76,730)
Gross profit		**192,554**	149,470
Other income	(4)	**32,650**	10,470
Impairment of intangible assets		**–**	(511)
Selling and distribution expenses		**(62,597)**	(42,722)
Administrative expenses		**(44,073)**	(41,268)
Research and development expenses		**(31,449)**	(20,903)
Profit from operations		**87,085**	54,536
Finance costs		**(655)**	(1,262)
Share of results of associates		**(4,465)**	(2,664)
Profit before taxation		**81,965**	50,610
Taxation	(5)	**(18,784)**	(8,655)
Profit for the period		**63,181**	41,955
Attributable to:			
Owners of the Company		**70,178**	46,380
Non-controlling interests		**(6,997)**	(4,425)
		63,181	41,955
		HK cents	*HK cents*
Earnings per share			
Basic	(6)	**11.87**	7.86
Diluted	(6)	**11.77**	7.83

CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the three months ended 31 March 2018

	For the three months ended 31 March	
	2018	2017
	HK$'000	*HK$'000*
	(unaudited)	(unaudited)
Profit for the period	**63,181**	41,955
Other comprehensive income (expense):		
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of financial statements of overseas subsidiaries	**24,145**	13,254
Fair value changes of available-for-sale financial assets	**–**	(5,333)
Share of associate's exchange reserve	**1,355**	–
Items that will not be reclassified subsequently to profit or loss:		
Fair value changes of financial assets at fair value through other comprehensive income	**(11,489)**	–
Other comprehensive income for the period, net of tax	**14,011**	7,921
Total comprehensive income for the period	**77,192**	49,876
Total comprehensive income (expense) for the period attributable to:		
Owners of the Company	**84,205**	53,497
Non-controlling interests	**(7,013)**	(3,621)
	77,192	49,876

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

For the three months ended 31 March 2018

	Attributable to the owners of the Company										
	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$'000	Attributable to non-controlling interests HK$'000	Total HK$'000
At 1 January 2018 (audited)	29,547	724,868	9,200	15,368	41,407	(30,421)	(31,809)	1,046,186	1,804,346	(7,414)	1,796,932
Employee share option benefits	–	–	–	1,136	–	–	–	–	1,136	–	1,136
Exercise of share options	40	5,014	–	(1,184)	–	–	–	–	3,870	–	3,870
Share of share-based compensation reserve of a subsidiary	–	–	–	6	–	–	–	–	6	4	10
Share of reserve of associates	–	–	–	–	14	–	–	–	14	–	14
Capital contribution from non-controlling interests	–	–	–	–	–	–	–	–	–	1,954	1,954
Profit (loss) for the period	–	–	–	–	–	–	–	70,178	70,178	(6,997)	63,181
Other comprehensive income (expense) for the period	–	–	–	–	1,355	(11,489)	24,161	–	14,027	(16)	14,011
Total comprehensive income (expense) for the period	–	–	–	–	1,355	(11,489)	24,161	70,178	84,205	(7,013)	77,192
At 31 March 2018 (unaudited)	29,587	729,882	9,200	15,326	42,776	(41,910)	(7,648)	1,116,364	1,893,577	(12,469)	1,881,108
At 1 January 2017 (audited)	29,503	721,154	9,200	11,671	59,512	(12,716)	(96,842)	880,244	1,601,726	32,990	1,634,716
Employee share option benefits	–	–	–	966	–	–	–	–	966	–	966
Exercise of share options	8	1,090	–	(200)	–	–	–	–	898	–	898
Share of share-based compensation reserve of a subsidiary	–	–	–	6	–	–	–	–	6	4	10
Share of reserve of associates	–	–	–	–	15	–	–	–	15	–	15
Capital contribution from non-controlling interests	–	–	–	–	–	–	–	–	–	1,564	1,564
Profit (loss) for the period	–	–	–	–	–	–	–	46,380	46,380	(4,425)	41,955
Other comprehensive income for the period	–	–	–	–	–	(5,333)	12,450	–	7,117	804	7,921
Total comprehensive income (expense) for the period	–	–	–	–	–	(5,333)	12,450	46,380	53,497	(3,621)	49,876
At 31 March 2017 (unaudited)	29,511	722,244	9,200	12,443	59,527	(18,049)	(84,392)	926,624	1,657,108	30,937	1,688,045

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

For the three months ended 31 March 2018

1. BASIS OF PREPARATION

The unaudited condensed consolidated results 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 (the "**Listing Rules**").

2. PRINCIPAL ACCOUNTING POLICIES

The unaudited condensed consolidated results 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 results 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 2017.

The accounting policies and methods of computation used in preparing the unaudited condensed consolidated results for the three months ended 31 March 2018 are consistent with those used in the Group's annual financial statements for the year ended 31 December 2017 except as described below.

In the current period, the Group has applied, for the first time, the following new amendments to HKASs and Hong Kong Financial Reporting Standards (the "**HKFRSs**") issued by the HKICPA that are relevant for the preparation of the Group's unaudited condensed consolidated results:

HKFRS 9	Financial Instruments
HKFRS 15	Revenue from Contracts with Customers
HK(IFRIC) – Int 22	Foreign Currency Transactions and Advance Consideration
Amendments to HKAS 40	Transfers of Investment Property
Amendments to HKFRS 2	Classification and Measurement of Share-based Payment Transactions
Amendments to HKFRS 4	Applying HKFRS 9 Financial Instruments with HKFRS 4 Insurance Contracts
Amendments to HKFRSs	Annual Improvement to HKFRSs 2014 – 2016 Cycle except Amendments to HKFRS 12

Available-for-sale financial assets were reclassified to financial assets at fair value through other comprehensive income upon adoption of HKFRS 9 on 1 January 2018. Except this, the application of the above amendments to HKASs and HKFRSs in the current period 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 HKASs and HKFRSs that have been issued but are not yet effective:

HKFRS 16	Leases[1]
HKFRS 17	Insurance Contracts[2]
HK(IFRIC) – Int 23	Uncertainty over Income Tax Treatments[1]
Amendments to HKAS 19	Plan Amendment, Curtailment or Settlement
Amendments to HKAS 28	Long-term Interests in Associates and Joint Ventures[1]
Amendments to HKFRS 9	Prepayment Features with Negative Compensation[1]
Amendments to HKFRS 10 and HKAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture[3]
Amendments to HKFRSs	Annual Improvement to HKFRSs 2015–2017 Cycle[1]

[1] Effective for annual periods beginning on or after 1 January 2019, with earlier application permitted

[2] Effective for annual periods beginning on or after 1 January 2021, with earlier application permitted

[3] Effective for annual periods beginning on or after a date to be determined

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

3. REVENUE

The principal activities of the Group are the development of, manufacturing of 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 recognised as follows:

Business segments

	For the three months ended 31 March	
	2018	2017
	HK$'000	*HK$'000*
	(unaudited)	(unaudited)
Proprietary products	**130,419**	102,023
Licensed-in products	**151,486**	124,177
	281,905	226,200

Geographical segments

During the three months ended 31 March 2018 and 2017, more than 90% of the Group's revenue was derived from activities conducted in the People's Republic of China (the "**PRC**"), no geographical segment information is presented.

4. OTHER INCOME

	For the three months ended 31 March	
	2018	2017
	HK$'000	*HK$'000*
	(unaudited)	(unaudited)
Interest income on:		
Bank deposits	**1,752**	814
Held-to-maturity financial assets	**42**	42
Advance to an associate	**200**	200
Total interest income	**1,994**	1,056
Sales of research materials	**–**	1,862
Development grants	**4,605**	1,157
Exchange gain	**20,460**	5,961
Sundry income	**5,591**	434
	32,650	10,470

5. TAXATION

	For the three months ended 31 March	
	2018	2017
	HK$'000	*HK$'000*
	(unaudited)	(unaudited)
Current tax		
Hong Kong Profits Tax	**1,465**	2,782
PRC Enterprise Income Tax	**12,644**	4,169
	14,109	6,951
Under-provision		
Hong Kong Profits Tax	**–**	18
Deferred tax		
Origination and reversal of temporary differences	**4,675**	1,686
	18,784	8,655

Hong Kong Profits Tax is calculated at 16.5% of the estimated assessable profits. Tax arising in the PRC is calculated at the rates of tax prevailing in the PRC. Taxation arising in other jurisdictions is calculated at the rates 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	
	2018	2017
	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	**70,178**	46,380

	For the three months ended 31 March	
	2018	2017
	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	**591,422**	590,093
Effect of dilutive potential ordinary shares:		
Options	**4,713**	1,944
Weighted average number of ordinary shares for the purpose of diluted earnings per share	**596,135**	592,037

7. RELATED PARTY TRANSACTIONS

(a) Interest income from shareholder loans to Powder Pharmaceuticals Incorporated ("PPI")

During the three months ended 31 March 2018, the Group received approximate HK$200,000 (31 March 2017: HK$200,000) interest income from loans to PPI. PPI is an associate to the Group.

(b) Compensation of key management personnel

The remuneration of directors and other members of key managements during the period was as follows:

	For the three months ended 31 March	
	2018	2017
	HK$'000	*HK$'000*
	(unaudited)	(unaudited)
Short-term employee benefits	**9,404**	11,971
Share-based payments	**497**	318
Retirement and other post-employment benefits		
– Defined contribution plan	**14**	14
– Retirement benefits	**3,500**	3,100
	13,415	15,403

(c) Issue of subsidiary's shares to Perfect Concept Holdings Limited ("Perfect Concept")

During the period under review, China Oncology Focus Limited ("COFL"), a subsidiary of the Company, issued total 3,500 shares to Perfect Concept. Dr. Li Xiaoyi, Ms. Lee Siu Fong and Ms. Leelalertsuphakun Wanee, directors of the Company, are the majority of the beneficial owners of Perfect Concept and Perfect Concept is considered as a related party to the Group. Total consideration received for the issue of shares is US$252,000 (HK$1,968,000 approximately).

Ms. Leelalertsuphakun Wanee, Ms. Lee Siu Fong and Dr. Li Xiaoyi are the directors and substantial shareholders of the Company who are connected persons of the Company under the Listing Rules. They hold 90% of the equity interest in Perfect Concept and therefore, Perfect Concept is the associate of Ms. Leelalertsuphakun Wanee, Ms. Lee Siu Fong and Dr. Li Xiaoyi, and is then a connected person of the Company under the Listing Rules. Lee's International is a shareholder of COFL and at the same time, Perfect Concept, is also a shareholder of COFL. Perfect Concept, being a connected person of the Company, is holding 35% of the issued share capital of COFL, and therefore, the issue of COFL's shares to Perfect Concept constitutes a connected transaction pursuant to Rule 14A.27 of the Listing Rules.

(d) Service income from CVie Therapeutics Limited ("CVTW")

During the three months ended 31 March 2018, total HK$5,337,000 (31 March 2017: nil) was received from CVTW, an associate to the Group, for providing research and development services.

(e) Donation to Lee's Pharmaceutical – Kanya Lee Scholarship Limited ("Kanya Lee Scholarship")

During the three months ended 31 March 2018, total HK$150,000 (31 March 2017: HK$150,000) 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 of the Group.

8. CAPITAL COMMITMENTS

	31 March 2018	31 December 2017
	HK$'000	*HK$'000*
	(unaudited)	(audited)
Capital commitments in respect of:		
Investment in available-for-sale financial assets	**16,962**	16,552
Intangible assets – license fee and development cost	**85,373**	76,760
Property, plant and equipment	**45,581**	38,427
	147,916	131,739
Authorised but not contracted for:		
Intangible assets – license fee and development cost	**19,891**	28,653

DIVIDEND

The Board does not recommend payment of dividend for the three months ended 31 March 2018 (three months ended 31 March 2017: 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 2018.

By order of the Board
Lee's Pharmaceutical Holdings Limited
Lee Siu Fong
Chairman

Hong Kong, 24 May 2018

As at the date of this report, Ms. Lee Siu Fong (Chairman), Ms. Leelalertsuphakun Wanee and Dr. Li Xiaoyi are executive Directors, Mr. Simon Miles Ball is a non-executive Director, Dr. Chan Yau Ching, Bob, Mr. Lam Yat Cheong and Dr. Tsim Wah Keung, Karl are independent non-executive Directors.