

* For identification purpose only

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 2017



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 2017, together with the comparative figures for the corresponding period in 2016. 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 2017 before recommending it to the board of Directors for approval.

BUSINESS REVIEW

The operating environment in the pharmaceutical sector continued to be challenging during the quarter under review with pricing pressure and rising active pharmaceutical ingredients (API) cost. Although the Group managed to maintain revenue growth in the positive territory, the gross profit margin was squeezed by rising raw material costs. Nevertheless, the streamlined cost structure of the Group has remained intact during the quarter under review which enabled the Group to achieve savings from selling and distribution activities which in turn has been channeled to fund its research and development projects and the additional spending arising from its business expansion.

Revenue of the Group for the first quarter of this year reached HK\$226,200,000, achieved 0.3% increase compared to the same period last year when Renminbi currency has been weakened by 4.7% year-on-year. During the period under review, revenue of *Ferplex*[®] has recorded a mild growth of 12.4%, and the sales downtrend of *Carnitene*[®] and *Zanidip*[®] were bottomed out. Nevertheless, with the underperformance of *Slounase*[®] and the devaluation of the Renminbi against Hong Kong Dollar, the Group’s revenue growth was only flat for the quarter.

Sales of licensed-in products accounted for 54.9% (For the three months ended 31 March 2016: 53.5%) of the Group’s revenue while sales of proprietary products contributed 45.1% (For the three months ended 31 March 2016: 46.5%) of the Group’s revenue.

During the period under review, the Group’s overall gross profit margin of 66.1% was 4.1 percentage points lower versus 70.2% for the same period last year, mainly as a result of the selling price pressure exerted on *Carnitene*[®] as well as the increased production costs of *Livaracine*[®] because of rising low-molecular-weight heparins costs.

Despite the stagnant revenue growth during the quarter under review, the Group continued its improvements in sales and marketing efficiency brought down the selling expenses to revenue ratio to 18.9%, reduced by 3.9 percentage points as compared to the same quarter last year. The savings therefrom aided the Group's plan to invest heavily in the research and development (“R&D”) activities. The investment in R&D expenses increased 41.6% to HK\$20,903,000 from HK\$14,765,000 of the same period last year, which represented 9.2% 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 expansion. Net profit attributable to the owners of the Company for the period was HK\$46,380,000, decreased by 12.7% over the same period last year.

The Group's solid dose production facility in its Nansha manufacturing site is already in place and the application for a Good Manufacturing Practice (GMP) certification in mid-2017 is expected. The construction work of the Group's ophthalmic drugs production facility in its Nansha manufacturing site is in good progress and is on target for completion in mid-2017.

During the quarter under review, the Group has successfully launched a new licensing product – *Mictonorm*[®]. *Mictonorm*[®] is a type of medicine called an anti-cholinergic or anti-muscarinic muscle relaxant and is used for the treatment of urinary incontinence as well as urgency and frequency in unstable bladder conditions. The Group has created a separate business unit to focus on sales and marketing of this product as well as other new products in the future.

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

Phase Ib/IIa clinical study of Adapalene and Clindamycin combination hydrochloride gel for acne vulgaris has been completed and the analytics work to the topline data is currently in progress. Phase III study is envisaged to initiate in mid-2017.

Natulan[®] registration study for the treatment of advanced Hodgkin's lymphoma in the PRC is in progress. This is a study targeting a total of 184 patients in total and around 10% of the patients has been enrolled so far.

Phase IIb study of Anfibatide is in good progress. The study involved a total of 12 centers across China and is expected to enroll a total of 240 patients and standard dual antiplatelet strategy is employed with or without Anfibatide, and to date, around 65% of the patients has been enrolled.

The development of the two cardiovascular assets, namely Rostafuroxin and Istaroxime, under CVie Therapeutics Limited, a non-wholly owned subsidiary of the Group, has made significant progress during the year under review.

Phase IIb clinical study (Protocol No. CVTCV-001) in Taiwan for Rostafuroxin capsule 50, 500ug with antihypertensive effect is in full swing. The study involved a total of 17 centers and 18 centers respectively across Italy and Taiwan. To date, the Italian arm of the study was substantially completed, and to date, over 60% of the patients required have been enrolled for Taiwan study (MOHW's Approval Notice No. 1046044455).

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 substantially completed, and 23 patients have been enrolled in China. The study in China is expected to be completed by end of 2017.

As a result of good progress in the development of Rostafuroxin and Istaroxime, CVie Taiwan has managed to attract a good set of Taiwan-based investors. Subsequent to the end of the period under review, on 24 May 2017, CVie Taiwan successfully raised US\$7.5 million (approximately HK\$58,500,000 equivalent) by mean of the issuance of Series A Preferred Shares thereof to finance the ongoing clinical trials. Before the completion of the Series A Shares Purchase Agreement (the “**Completion**”), the Group owned 11,478,991 ordinary shares of CVie Taiwan, which represented 56.26% of the total issued share capital thereof. Immediately after the Completion, the Group's equity interest in CVie Taiwan will be reduced to 49.58% of the total issued share capital of CVie Taiwan (on as an enlarged basis by taking into account the issuance of the Series A Shares on an as if converted basis). CVie Taiwan will cease to be an indirect non-wholly owned subsidiary and will become an associated company of the Group.

The development of *Zingo*[®] under Powder Pharmaceuticals Incorporated (“**PPI**”), an associated company of the Group, has also achieved positive progress during the year under review. In March 2017, *Zingo*[®], has been granted by China Food and Drug Administration (CFDA) priority review for its clinical trial application. The clinical program will be commenced soon and is targeted to be approved by CFDA in this year.

Overall, the Group has more than 13 clinical studies in either operational or preparatory stage. Several of those clinical studies are registration enabling study and successful conclusion of those studies is the Group's priority. And the Group will continue to commit in these new drugs development to facilitate sustainable growth in the future.

PROSPECT

As foreseen at the beginning of the year, persistent changes and challenges will be in place in this industry. In view of the Group's existing product range is yet to be improved, raw material inflation and selling price pressure will remain the headwind in the coming quarters.

Meanwhile, the Group firmly believes that, with its effort in building a comprehensive drug development pipeline, it could become one of main beneficiaries from the recent regulatory reforms in China. The announcement made by the State Council in February 2017 has already demonstrated the determination of Chinese Government to accelerate approvals for new drugs and encouraging innovative products to be launched in China earlier. In collaboration to the State Policy, CFDA has also issued draft guidelines in March 2017 that would allow pharmaceutical companies to run Phase I trials in China for the first time, which means if the draft is implemented, CFDA would accept multi-regional clinical trial data to support new drug applications as long as the trial settings are in compliance to the technical guidelines in China. Another policy from CFDA intended to speed up the approval timeline is the expansion of its fast-track pathway, or "Green Channel". Pediatric and geriatric drugs, imported innovative drugs manufactured in China, and drugs which target high unmet medical needs, among others, are the examples which can have access to the expanded Green Channel.

The recent experience from the obtaining of the Phase III clinical trial approval of the Group's oncology product, namely JX-594, has further underlined the new standard under the regulatory reform. The advisory committee meeting for this approval was held by CFDA Center for Drug Evaluation (CDE) and, for the first time ever, invited public and media representatives to attend and granted the chance to speak. Towards the end of the meeting, the experts come to a decision by ballot and the results was announced by the chairman of the meeting at the scene.

With these positive signs from the regulatory angle, the Group will stay calm and remain the focus on the drug development efforts in order to shorten the time-to-market of its pipeline products. The recent launch of *Mictonorm*[®] in the first quarter of this year is a good start, and the Group is expected more new products launch, such as *Sancuso*[®], soon to boost revenue growth.

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

CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS*For the three months ended 31 March 2017*

	<i>Notes</i>	For the three months ended 31 March	
		2017 HK\$'000 (unaudited)	2016 HK\$'000 (unaudited)
Revenue	(3)	226,200	225,538
Cost of sales		(76,730)	(67,127)
Gross profit		149,470	158,411
Other income	(4)	10,470	9,308
Impairment of intangible assets		(511)	(3,706)
Selling and distribution expenses		(42,722)	(51,429)
Administrative expenses		(41,268)	(35,037)
Research and development expenses		(20,903)	(14,765)
Profit from operations		54,536	62,782
Finance costs		(1,262)	(916)
Share of results of associates		(2,664)	(2,570)
Profit before taxation		50,610	59,296
Taxation	(5)	(8,655)	(10,088)
Profit for the period		41,955	49,208
Attributable to:			
Owners of the Company		46,380	53,107
Non-controlling interests		(4,425)	(3,899)
		41,955	49,208
		HK cents	HK cents
Earnings per share			
Basic	(6)	7.86	9.05
Diluted	(6)	7.83	8.98

CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the three months ended 31 March 2017

	For the three months ended 31 March	
	2017 HK\$'000 (unaudited)	2016 HK\$'000 (unaudited)
Profit for the period	41,955	49,208
Other comprehensive income (expense):		
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of financial statements of overseas subsidiaries	13,254	23,653
Fair value changes of available-for-sale financial assets	(5,333)	(10,328)
Other comprehensive income for the period, net of tax	7,921	13,325
Total comprehensive income for the period	49,876	62,533
Total comprehensive income (expense) for the period attributable to:		
Owners of the Company	53,497	66,199
Non-controlling interests	(3,621)	(3,666)
	49,876	62,533

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY*For the three months ended 31 March 2017*

	Attributable to the owners of the Company								Attributable to non-controlling interests		Total
	Share capital	Share premium	Merger difference	Share-based compensation reserve	Other reserves	Investments revaluation reserve	Exchange reserve	Retained profits	Sub-total	interests	
	HKS'000	HKS'000	HKS'000	HKS'000	HKS'000	HKS'000	HKS'000	HKS'000	HKS'000	HKS'000	HKS'000
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
At 1 January 2016 (audited)	29,340	717,925	9,200	8,718	59,344	(899)	(47,540)	691,350	1,467,438	49,390	1,516,828
Employee share option benefits	-	-	-	895	-	-	-	-	895	-	895
Exercise of share options	25	131	-	(73)	-	-	-	-	83	-	83
Share of share-based compensation reserve of a subsidiary	-	-	-	6	-	-	-	-	6	4	10
Profit (loss) for the period	-	-	-	-	-	-	-	53,107	53,107	(3,899)	49,208
Other comprehensive income for the period	-	-	-	-	-	(10,328)	23,420	-	13,092	233	13,325
Total comprehensive income (expense) for the period	-	-	-	-	-	(10,328)	23,420	53,107	66,199	(3,666)	62,533
At 31 March 2016 (unaudited)	29,365	718,056	9,200	9,546	59,344	(11,227)	(24,120)	744,457	1,534,621	45,728	1,580,349

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

For the three months ended 31 March 2017

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 2016.

The accounting policies and method of computation used in preparing the unaudited condensed consolidated results for the three months ended 31 March 2017 are consistent with those used in the Group’s annual financial statements for the year ended 31 December 2016 except as described below.

In the current interim 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:

Amendments to HKAS 7	Disclosure Initiative
Amendments to HKAS 12	Recognition of Deferred Tax Assets for Unrealised Losses

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 revised HKFRSs that have been issued but are not yet effective:

HKFRS 9	Financial Instruments ¹
HKFRS 15	Revenue from Contracts with Customers ¹
HKFRS 16	Leases ²
Amendments to HKAS 40	Transfer of Investment Property ¹
Amendments to HKFRS 2	Classification and Measurement of Share-based Payment Transactions ¹
Amendments to HKFRS 4	Applying HKFRS 9 Financial Instruments with HKFRS 4 Insurance Contracts ¹
Amendments to HKFRS 10 and HKAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture ⁴
Amendments to HKFRSs	Annual Improvement to HKFRSs 2014-2016 Cycle ³

¹ Effective for annual periods beginning on or after 1 January 2018, with earlier application permitted

² Effective for annual periods beginning on or after 1 January 2019, with earlier application permitted

³ Effective for annual periods beginning on or after 1 January 2017 or 1 January 2018, as appropriate

⁴ 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 revised HKASs and HKFRSs but is not yet in a position to state whether these new and revised 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	
	2017 HK\$'000 (unaudited)	2016 HK\$'000 (unaudited)
Proprietary products	102,023	104,949
Licensed-in products	124,177	120,589
	226,200	225,538

Geographical segments

During the three months ended 31 March 2017 and 2016, 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	
	2017 HK\$'000 (unaudited)	2016 HK\$'000 (unaudited)
Interest income on:		
Bank deposits	814	214
Held-to-maturity financial assets	42	42
Advance to an associate	200	216
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Total interest income	1,056	472
Sales of research materials	1,862	–
Development grants	1,157	3,996
Development milestone income	–	4,501
Exchange gain	5,961	–
Sundry income	434	339
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	10,470	9,308
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5. TAXATION

	For the three months ended 31 March	
	2017 HK\$'000 (unaudited)	2016 HK\$'000 (unaudited)
Current tax		
Hong Kong Profits Tax	2,782	45,882
PRC Enterprise Income Tax	4,169	4,668
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	6,951	50,550
Under-provision		
Hong Kong Profits Tax	18	–
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Deferred tax		
Origination and reversal of temporary differences	1,686	(40,462)
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	8,655	10,088
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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	
	2017	2016
	<i>HK\$'000</i>	<i>HK\$'000</i>
	(unaudited)	(unaudited)
<i>Earnings:</i>		
Net profit attributable to the owners of the Company for the purpose of basic and diluted earnings per share	46,380	53,107

	For the three months ended 31 March	
	2017	2016
	<i>Share(s)'000</i>	<i>Share(s)'000</i>
	(unaudited)	(unaudited)
<i>Number of shares:</i>		
Weighted average number of ordinary shares for the purpose of basic earnings per share	590,093	586,883
Effect of dilutive potential ordinary shares:		
Options	1,944	4,795
Weighted average number of ordinary shares for the purpose of diluted earnings per share	592,037	591,678

7. RELATED PARTY TRANSACTIONS

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

During the three months ended 31 March 2017, the Group received approximate HK\$200,000 (31 March 2016: HK\$216,000) 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 management during the period was as follows:

	For the three months ended 31 March	
	2017 HK\$'000 (unaudited)	2016 HK\$'000 (unaudited)
Short-term employee benefits	11,985	3,719
Share-based payments	318	199
Retirement and other post-employment benefits	3,100	3,000
	15,403	6,918

(c) Issue of subsidiary’s shares to Perfect Concept Holdings Limited (“Perfect Concept”)

During the period under review, China Oncoby Focus Limited (“COF”), on a pro rata basis, issued 2,800 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\$201,600 (approximately HK\$1,563,000).

(d) Donation to Lee’s Pharmaceutical – Kanya Lee Scholarship Limited (“Kanya Lee Scholarship”)

During the three months ended 31 March 2017, total 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 2017	31 December 2016
	<i>HK\$'000</i>	<i>HK\$'000</i>
	(unaudited)	(audited)
Capital commitments in respect of:		
Investment in available-for-sale financial assets	16,040	15,760
Intangible assets – license fee and development cost	110,893	89,763
Property, plant and equipment	26,131	23,370
Construction contract	29,977	41,649
	183,041	170,542
Authorised but not contracted for:		
Intangible assets – license fee and development cost	20,027	21,890

9. SUBSEQUENT EVENT REVIEW

On 24 May 2017, CVie Therapeutics Limited (“CVie Taiwan”), an indirect non-wholly owned subsidiary of the Company which focused on the development of the two cardiovascular assets, namely Rostafuroxin and Istaroxime, entered into the Series A Shares Purchase Agreement with two independent third parties (the “Investors”), pursuant to which the Investors will subscribe for 2,750,387 Series A Preferred Shares of CVie Taiwan at the consideration of US\$7.5 million (approximately HK\$58,500,000 equivalent). Before the completion of the Series A Shares Purchase Agreement (the “Completion”), the Group owned 11,478,991 ordinary shares of CVie Taiwan, which represented 56.26% of the total issued share capital thereof. Immediately after the Completion, the Group’s equity interest in CVie Taiwan will be reduced to 49.58% of the total issued share capital of CVie Taiwan (on an enlarged basis by taking into account the issuance of the Series A Shares on an as if converted basis). CVie Taiwan will cease to be an indirect non-wholly owned subsidiary and will become an associated company of the Group.

DIVIDEND

The Board does not recommend payment of dividend for the three months ended 31 March 2017 (For the three months ended 31 March 2016: 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 2017.

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

Hong Kong, 31 May 2017

As at the date of this report, Ms. Lee Siu Fong (Chairman), Ms. Leelalertsuphakun Wanee and Dr. Li Xiaoyi are executive Directors, Dr. Marco Maria Brughera 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.

