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 2016

* 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 2016, together with the comparative figures for the corresponding period in 2015. 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 2016 before recommending it to the board of Directors for approval.

BUSINESS REVIEW

Despite considerable challenges remained in the pharmaceutical sector during the quarter under review, the Group managed to reverse the negative revenue growth trend and delivered significant growth in profit. Improvement of revenue growth of major products during the quarter under review indicated the beginning of a turnaround on the Group's top line growth. Meanwhile, the streamlined cost structure of the Group since last year has been demonstrated to be sustainable which enabled its achievement of a decent bottom line growth with growing investment in R&D during the quarter under review.

Revenue of the Group for the first quarter of this year reached HK$225,538,000, a 6.4% increase compared to that of fourth quarter of 2015, reversing the downward movement of the preceding two quarters. Even more encouraging is the fact that the sales was only slightly decreased by HK$4,785,000 or 2.1% against a backdrop of RMB devaluation of 4% compared to the same period last year.

	2015Q3	2015Q4	**2016Q1**
Revenue *(HK$'000)*	232,262	211,985	**225,538**
Quarter-over-Quarter Change *(%)*	-6.2	-8.7	**+6.4**

All six major products registered significant improvement in sales performance over the fourth quarter of 2015. During the period under review, revenue growth of *Ferplex*® went back to 51.9% quarter-on-quarter upon the successful renewal of its Import Drug License in early 2016. Other flagship products such as *Yallaferon*® and *Livaracin*® have returned to revenue growth of 16.0% and 17.2%, respectively, compared with same quarter last year. Overall revenue growth momentum was still dragged down marginally by the underperformance of *Carnitene*® and *Zanidip*®, as well as other undesirable factors such as the devaluation of the Renminbi against Hong Kong Dollar and the unfavourable product selling price variances on a quarter-on-quarter basis during the quarter under review. Nevertheless, as sales of *Carnitene*® regained the momentum with sequential improvement of 6.5%, the revenue decline has been significantly reduced which displayed positive signs of improvement on the top line through the contributions from newer products.

Sales of licensed-in products accounted for 53.5% (For the three months ended 31 March 2015: 57.3%) of the Group's revenue while sales of proprietary products contributed 46.5% (For the three months ended 31 March 2015: 42.7%) of the Group's revenue.

During the period under review, the gross profit margin held steadily at 70.2%, slightly decreased by 0.8 percentage point as to the 71.0% achieved in the same quarter of 2015.

Despite the stagnant revenue growth during the quarter under review, the Group managed to achieve remarkable growth in both operating profit (+40.1%) and net profit (+31.3%) respectively, compared to the same quarter last year. The continuous improvements in sales and marketing efficiency brought down the selling expenses to revenue ratio to 22.8%, reduced by 8.6 percentage points as compared to the same quarter last year, and contributed a significant part to the profit growth during the quarter under review. As part of our plan to intensify our research and development ("**R&D**") activities through the cost savings from selling expenses, the investment in R&D expenses has been increased 48.8% to HK$18,471,000 from HK$12,413,000 of the same period last year, which represented 8.2% of revenue during the quarter under review. With administrative expenses were kept in line in the quarter, net profit attributable to the owners of the Company for the period increased by 31.3% over the same period last year and reached HK$53,107,000.

The Group's solid dose production facility in Guangzhou Nansha continued to make progress on its final stage of construction and equipment installation and is expected to be fully operational by end of June 2016. The design work of the Group's ophthalmic drugs production facility in Nansha is close to completion and is expected to commence the construction in June 2016.

The Group stands firm on its effort in knowledge-based promotion and leverage on new media to support physician education and to disseminate scientific information for its products, along with the determination to transform its sales and marketing organisation to improve operation efficiency and extract more value. The efforts made so far have proven to be sustainable and have produced tangible results. In addition, new business unit has been created to focus on sales and marketing of new and newer products. A separate unit provides the necessary drive and motivation that are crucial to the success in the market place. The resulted reallocation of resources help new products gain traction quicker and provide new catalyst for future growth.

The Group's commitment to R&D had been intensified 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 progressed on schedule. The phase IIa component of the study has since been completed and the remaining phase Ib study is expected to be completed by June 2016.

For *Natulan*® registration study, the Group has worked together with the principle investigator in developing the study protocol that has been confirmed by the China Food and Drug Administration ("**CFDA**"). The preparation for the study is underway and first enrollment is expected in June 2016.

Anfibatide has reached a significant milestone in its indication of Thrombotic Thrombocytopenic Purpura (TTP) and its application to the US FDA for orphan drug designation for Anfibatide on TTP has been approved in March 2016.

Phase IIb clinical study (Protocol No. CVTCV-001) in Taiwan for Rostafuroxin capsule 50, 500ug with antihypertensive effect is in full swing. The Phase IIb multi-centers, randomised, comparator-controlled, dose-finding clinical study and the study aims to evaluate the anti-hypertensive effects indifferent doses of Rostafuroxin in comparison with *Losartan*®, assessed by office and ambulatory blood pressure monitoring in a hypertensive population selected according to specific genetic profiles. The study involved a total of 17 centers and 18 centers respectively across Italy and Taiwan. To date, the Italian arm of the study has been substantially completed, and the patient enrolment for Taiwan study (MOHW's Approval Notice No. 1046044455) has continued to make good progress.

Istaroxime, a first-in-class luso-inotropic agent for the treatment of acute decompensated heart failure, is currently in its Phase IIb clinical study in Italy and China. 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 the first patient enrollment in China is expected in June 2016.

The Group is one of the regional partners of SillaJen, Inc., a South Korean based biotechnology company headquartered in Busan South Korea, for Pexa-Vec (formerly JX-594). The product is undergone a phase III registration enabling clinical study at the moment. The first patient for the multinational randomised Phase III open-label study of Pexa-Vec, in patients with advanced liver cancer, also known as hepatocellular carcinoma (HCC) was enrolled in January 2016 in New Zealand. Subsequently, patients have been enrolled in the US and Europe. The clinical trial certificate from CFDA is expected in June 2016. As one of the former partners of JX-594, the Group has received a milestone payment from SillaJen, Inc. of approximately HK$4.5 million with the aforesaid achievement during the quarter under review.

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 as the engines for sustainable growth.

PROSPECT

The Group has made encouraging start of the year by reversing the downward trend of revenue growth during the quarter under review. However, it remains cautiously optimistic about the prospect in 2016 and beyond.

Continued decent volume growth and steadfast improvement in major product performance such as *Carnitene*® are expected to drive better overall results in revenue growth. But the structural headwinds to revenue growth, such as lower pricing flexibility and currency volatility, may persist.

Besides the six major products, the Group has been focusing on the growth of newer products such as *Remodulin*®, *Gaslon N*® and oral carnitine. Although the contribution of these products to the overall revenue may be still marginal at the moment, they have started to generate the momentum that could serve as new catalyst for overall growth in the near future.

While continuing its efforts to streamline the cost structure in order to achieve sustainable profitability, the Group will gallop ahead with more investment in R&D. The Group's myriad of clinical and preclinical programs is the strength and foundation that will drive decent organic growth in future.

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 2016

	Notes	For the three months ended 31 March 2016 HK$'000 (unaudited)	2015 HK$'000 (unaudited)
Revenue	2	**225,538**	230,323
Cost of sales		**(67,127)**	(66,710)
Gross profit		**158,411**	163,613
Other revenue		**9,308**	2,269
Fair value changes of derivative financial instruments		**–**	(1,054)
Selling and distribution expenses		**(51,429)**	(72,424)
Administrative expenses		**(35,037)**	(35,171)
Research and development expenses		**(18,471)**	(12,413)
Profit from operations		**62,782**	44,820
Finance costs		**(916)**	(754)
Share of results of associates		**(2,570)**	(2,244)
Profit before taxation		**59,296**	41,822
Taxation	3	**(10,088)**	(5,660)
Profit for the period		**49,208**	36,162
Attributable to:			
Owners of the Company		**53,107**	40,446
Non-controlling interests		**(3,899)**	(4,284)
		49,208	36,162
		HK cents	*HK cents*
Earnings per share			
Basic	4	**9.05**	7.32
Diluted	4	**8.98**	7.20

CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the three months ended 31 March 2016

	For the three months ended 31 March	
	2016	2015
	HK$'000	*HK$'000*
	(unaudited)	(unaudited)
Profit for the period	**49,208**	36,162
Other comprehensive income (expense):		
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of financial statements of overseas subsidiaries	**23,653**	3,768
Fair value changes of available-for-sale financial assets	**(10,328)**	4,621
Other comprehensive income for the period, net of tax	**13,325**	8,389
Total comprehensive income for the period	**62,533**	44,551
Total comprehensive income (expense) for the period attributable to:		
Owners of the Company	**66,199**	47,032
Non-controlling interests	**(3,666)**	(2,481)
	62,533	44,551

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

For the three months ended 31 March 2016

	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 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
At 1 January 2015 (audited)	27,236	301,196	9,200	7,782	59,344	3,319	7,793	518,471	934,341	64,526	998,867
Employee share option benefits	–	–	–	963	–	–	–	–	963	–	963
Exercise of share options	140	12,523	–	(1,548)	–	–	–	–	11,115	–	11,115
Share of share-based compensation reserve of a subsidiary	–	–	–	6	–	–	–	–	6	4	10
Issue of shares pursuant to Shareholders' Agreement	345	12,035	–	–	–	–	–	–	12,380	–	12,380
Capital contribution from non-controlling interests	–	–	–	–	–	–	–	–	–	391	391
Profit (loss) for the period	–	–	–	–	–	–	–	40,446	40,446	(4,284)	36,162
Other comprehensive income for the period	–	–	–	–	–	4,621	1,965	–	6,586	1,803	8,389
Total comprehensive income (expense) for the period	–	–	–	–	–	4,621	1,965	40,446	47,032	(2,481)	44,551
At 31 March 2015 (unaudited)	27,721	325,754	9,200	7,203	59,344	7,940	9,758	558,917	1,005,837	62,440	1,068,277

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

For the three months ended 31 March 2016

1. BASIS OF PREPARATION AND PRINCIPAL ACCOUNTING POLICIES

The unaudited condensed consolidated results have been prepared in accordance with Hong Kong Accounting Standards ("**HKASs**") and Hong Kong Financial Reporting Standards ("**HKFRSs**") issued by the Hong Kong Institute of Certified Public Accountants (the "**HKICPA**") and applicable disclosure requirements of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited. They have been prepared on the historical cost basis, except for certain financial instruments that are measured at fair values as appropriate.

The accounting policies and method of computation used in preparing the unaudited condensed consolidated results are consistent with those used in the audited consolidated financial statements for the year ended 31 December 2015 except as described below.

In the current interim period, the Group has applied, for the first time, the following new amendments to HKASs and HKFRSs issued by the HKICPA that are relevant for the preparation of the Group's unaudited condensed consolidated financial statements:

Amendments to HKAS 1	Disclosure Initiative
Amendments to HKAS 16 and HKAS 38	Clarification of Acceptable Methods of Depreciation and Amortisation
Amendments to HKAS 16 and HKAS 41	Agriculture: Bearer Plants
Amendments to HKAS 27	Equity Method in Separate Financial Statements
Amendment to HKFRS 10, HKFRS 12 and HKAS 28	Investment Entities: Applying the Consolidation Exemption
Amendments to HKFRS 11	Accounting for Acquisitions of Interests in Joint Operations
Amendments to HKFRSs	Annual Improvements to HKFRSs 2012-2014 Cycle

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 HKFRS 10 and HKAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture[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 a date to be determined

The Group is in the process of making an assessment of what the impact of these new and revised HKASs and HKFRSs is expected to be in the period of initial application. So far it has concluded that the adoption of them is unlikely to have a significant impact on the unaudited condensed consolidated financial statements of the Group.

2. 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	
	2016	2015
	HK$'000	*HK$'000*
	(unaudited)	(unaudited)
Proprietary products	**104,949**	98,289
Licensed-in products	**120,589**	132,034
	225,538	230,323

Geographical segments

During the three months ended 31 March 2016 and 2015, 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.

3. TAXATION

	For the three months ended 31 March	
	2016	2015
	HK$'000	*HK$'000*
	(unaudited)	(unaudited)
Current tax		
Hong Kong Profits Tax	**45,882**	3,988
PRC Enterprise Income Tax	**4,668**	3,617
	50,550	7,605
Deferred tax		
Origination and reversal of temporary differences	**(40,462)**	(1,945)
	10,088	5,660

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.

4. 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	
	2016	2015
	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	**53,107**	40,446

	For the three months ended 31 March	
	2016	2015
	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	**586,883**	552,365
Effect of dilutive potential ordinary shares:		
Options	**4,795**	9,151
Weighted average number of ordinary shares for the purpose of diluted earnings per share	**591,678**	561,516

5. RELATED PARTY TRANSACTIONS

(a) Purchase from Sigma-Tau Industrie Farmaceutiche Riunite S.p.A.

Name of related party	*Note*	**Nature of transaction**	For the three months ended 31 March **2016** ***HK$'000*** **(unaudited)**	2015 *HK$'000* (unaudited)
Sigma-Tau Industrie Farmaceutiche Riunite S.p.A ("**STIFR**")	1	Purchase of pharmaceutical products	–	27,202
STIFR	1	Purchase of experimental products for use in research & development	–	2,899
			–	30,101

Note:

1. The amount represented the transactions made on or before 31 May 2015. STIFR ceased to be the related party of the Group from 1 June 2015 because it has ceased as an associate (as defined in the Listing Rules) of a substantial shareholder of the Company due to the restructuring of Sigma-Tau Group. As a result, STIFR is no longer a connected person of the Company and the transaction made between STIFR and any members of the Group thereafter will no longer constitute related party transactions and continuing connected transactions of the Company.

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

During the three months ended 31 March 2016, the Group received approximate HK$216,000 (31 March 2015: HK$89,000) interest income from loans to PPI. PPI is an associate to the Group.

(c) 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	
	2016	2015
	HK$'000	*HK$'000*
	(unaudited)	(unaudited)
Short-term employee benefits	**3,719**	3,382
Share-based payments	**199**	214
Retirement and other post-employment benefits	**3,000**	2,182
	6,918	5,778

6. CAPITAL COMMITMENTS

	31 March 2016	31 December 2015
	HK$'000	*HK$'000*
	(unaudited)	(audited)
Capital commitments in respect of:		
Investment in available-for-sale financial assets	**36,515**	36,431
Intangible assets – license fee and development cost	**94,645**	71,147
Property, plant and equipment	**8,636**	20,020
Construction contract	**17,046**	22,081
	156,842	149,679
Authorised but not contracted for:		
Intangible assets – license fee and development cost	**41,148**	–

DIVIDEND

The Board does not recommend payment of dividend for the three months ended 31 March 2016 (For the three months ended 31 March 2015: 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 2016.

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

Hong Kong, 26 May 2016

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.