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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 ANNOUNCEMENT FOR THE THREE MONTHS ENDED 31 MARCH 2013

BUSINESS REVIEW

Having experienced a deceleration of growth momentum in sales in the second half of 2012 due to the adjustment and adaption of the industry that resulted in a sluggish 13% increase in revenue in the fourth quarter of 2012 over the corresponding quarter in 2011, the Group had successfully reversed the trend in the first quarter of 2013 with turnover increased by 35% compared to the first quarter of last year and reached HK\$148,447,000, a new historical height of quarterly sales. More encouraging is the fact that this reacceleration of growth momentum was achieved during a traditionally weakest quarter when the Chinese New Year is celebrated. The disperse of industry wide uncertainty allowed the Group to focus on products again and major products like *Ferplex*[®], *Carnitene*[®] and *Livaracine*[®] continued to be the key drivers of the growth with strong performance of 63%, 55%, and 28% increase in sales amount respectively for this quarter compared with same period last year.

Net profit attributable to shareholder for the first quarter also attained a new historical height of HK\$32,310,000, representing an increase of 31% over same period last year and an increase of 15% over the last quarter of 2012. Gross profit margin for the first quarter was 71.96%, represented a slight improvement compared with the average of 71.27% for the twelve-month period of last year. Selling expenses to turnover ratio for the first quarter was 31.6%, a steadfast reduction over the improved average of 33.6% for the year 2012 that was attributable to the relentless effort in enhancing marketing efficiency. Administrative expenses grew only 5% compared with the fourth quarter of 2012 which was mainly resulted from the staff salary adjustment and was much tamer than the 70% increase for the year 2012. Consequently, net profit margin for the first quarter was improved slightly to 21.8%, compared with 21.3% for the whole year of 2012.

* *For identification purposes only*

In the area of manufacturing, the Group had completed the construction work for its Hefei new facility building during the period under review. The focus is now shifting to erect the clean room production area and install production equipment. As now, the Group is on schedule to have the new facility inspected and certified by the CFDA on or before the end of 2013. The investment will undoubtedly bolster the Group's competitiveness in the market place.

The first quarter of 2013 was also monumental for the Group's research and development. The proprietary drug Anfibatide has successfully completed the first cohort of the phase I/II study. The Data Monitoring Committee has reviewed the safety data of the study and given a green light for moving into second cohort study. The preliminary data showed that Anfibatide is a very safe agent with no noticeable bleeding effect. The second cohort study is expected to start in the second quarter and patient enrollment should be faster after the initial positive experiences with the study drug. It is expected the phase I/II study of Anfibatide be completed by end of year and top line data be available in the first quarter of 2014.

The phase IIb study of JX-594 for advanced Hepatic Cellular Carcinoma (TRAVERSE) had progressed satisfactorily during the first quarter of 2013. Following the publication of JX-594's phase IIa study results in prestige peer review journal Nature Medicine in late March, the enrollment of TRAVERSE study has experienced an exponentially jump and targeted 120 patient recruitment has been reached in earlier May. Top line data of the study is expected by the end of 2013 that could validate the therapeutic potential of this innovative product and provide new treatment option to patients suffered from advanced liver cancer.

Other research and development milestones reached during the quarter included the completion of 380 patients phase IV study of Zanidip. The results will be ready in the second quarter and could provide a catalyst for the growth of Zanidip sales.

In the partnership front, the Group had a most prolific quarter with signing of four partnership agreements that have colossal implication to the future growth of the company. In January 2013, the Group entered into agreement with Portola Pharmaceuticals, Inc. to jointly expand the Phase 3 APEX study of Betrixaban into China, with an option for the Group to negotiate for the commercial rights to the drug in China. Betrixaban is a novel, oral small molecule that directly inhibits the activity of Factor Xa, an important validated target in the blood coagulation pathway. The ongoing phase III pivotal trial involves 6,800 patients in over 50 countries and is to address a highly unmet medical need for critically ill patients. The study is expected to complete in 2014 with US, Europe and China registration filing in 2015. This collaboration is a manifestation of Group's step up effort to be in the forefront of global drug development.

Also in January, the Group entered licensing agreement with Spanish company GP Pharm for exclusive marketing and distribution of a long acting Leuprolide, a drug indicated for prostate cancer. The agreement augments the Group's oncology pipeline and boosts its competitiveness in the area.

In February 2013, CVie Therapeutics Company Limited ("CVie"), a subsidiary of the Group, concluded a strategic partnership with Dyax Corp. for the development and commercialization of *Kalbitor*[®] (ecallantide) in the treatment of hereditary angioedema (HAE) in China, Hong Kong and Macau. *Kalbitor*[®] is currently marketed in United States for the treatment of acute attacks of HAE in patients 16 years of age and older. HAE is a rare and deadly disease and no effective therapy is currently available in China. *Kalbitor*[®] will be the second orphan drug after *Remodulin*[®] that the Group has committed to bring into China and the effort is reflection of the Group's dedication to neglected diseases and neglected patients in China.

In March 2013, the venture partner of CVie, the Group's subsidiary that focuses on cardiovascular drug development, agreed to increase its presence in the joint venture. The new fund will help to accelerate the development of both Rostafuroxin and Istaroxime and to prepare for the launch of *Remodulin*[®] in the third quarter. It will also pave the way for further participation of strategic investors.

The Group also entered into agreement with Jennerex in March to expand the rights on additional indications of JX-594 to all cancer types beyond hepatocellular carcinoma. JX-594 is the only oncolytic virus under development that can be administered intravenously. This unique feature has significantly enlarged the therapeutic potential of this agent to many different cancer types. In exploratory phase I studies, JX-594 has exhibited promising results in colorectal and kidney cancers. The new agreement will allow the Group to fully capture the enormous potential of this exciting therapeutic agent.

PROSPECT

Having encountered somewhat unexpected turbulences during the second half of 2012, the Group had managed to get back to its growth trajectory in the first quarter of 2013 and is buoyant about the growth prospect in the future.

After few years of hiatus in pharmaceuticals tender process due to various reasons, many provinces in China have started to reopen the process, providing new opportunity for both “old” and “new” products of the Group. For “old” products that have been launched for more than three years, the new tender process could reshape the competition landscape and create opportunity for hospital formulary entry that will improve the products’ market penetration and market share. As to the “new” products that have been launched for less than three years, the new tender process may present the only chance to commence actual selling in the targeted province, expanding the Group’s revenue sources. It is expected that tender process activity will intensify in the second half of year, bring more dynamic into the market place.

The Group has also heightened its expectation on new drug approval for 2013. In April, the Group successfully obtained the Import Drug Licenses from the China Food and Drug Administration for *Remodulin*[®] (treprostinil) injection, for the treatment of patients with pulmonary arterial hypertension (PAH). *Remodulin*[®] is a prostacyclin vasodilator that is indicated for treatment of PAH (WHO Group 1) by intravenous and subcutaneous administration, to diminish symptoms associated with exercise. *Remodulin*[®], a license-in drug of CVie, will be launched in the fourth quarter of this year and will fill a major void in treatment options that could result in better care for pulmonary arterial hypertension patients in China. The approval of *Remodulin*[®] could be the start of series approvals anticipated by the Group as registrations of several products are in the final reviewing stage. The new approvals would lay a solid foundation for future growth.

With resilience and agility, the Group will continue to fortify its core competent in product development and differentiation, maintaining a sustainable growth momentum.

UNAUDITED CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS

For the three months ended 31 March 2013

	Notes	For the three months ended 31 March	
		2013 HK\$'000	2012 HK\$'000
Turnover	(2)	148,447	109,889
Cost of sales		<u>(41,618)</u>	<u>(31,824)</u>
Gross profit		106,829	78,065
Other revenue		1,791	5,102
Selling and distribution expenses		(46,939)	(40,872)
Research and development expenses		(4,464)	(2,750)
Administrative expenses		<u>(19,131)</u>	<u>(10,557)</u>
Profit from operations		38,086	28,988
Finance costs		<u>(291)</u>	<u>(249)</u>
Profit before taxation		37,795	28,739
Taxation	(3)	<u>(5,676)</u>	<u>(4,129)</u>
Profit for the period		<u><u>32,119</u></u>	<u><u>24,610</u></u>
Attributable to:			
Shareholders of the Company		32,310	24,609
Non-controlling interests		<u>(191)</u>	<u>1</u>
		<u><u>32,119</u></u>	<u><u>24,610</u></u>
		<i>HK cents</i>	<i>HK cents</i>
Earnings per share			
Basic	(4)	<u><u>6.20</u></u>	<u><u>5.24</u></u>
Diluted	(4)	<u><u>5.84</u></u>	<u><u>5.13</u></u>

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

For the three months ended 31 March 2013

	For the three months ended 31 March	
	2013	2012
	HK\$'000	HK\$'000
Profit for the period	32,119	24,610
Other comprehensive income (expenses):		
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of:		
– Financial statements of overseas subsidiaries	731	712
– Revaluation of overseas buildings	10	(3)
	<hr/>	<hr/>
Other comprehensive income for the period, net of tax	741	709
	<hr/>	<hr/>
Total comprehensive income for the period	32,860	25,319
	<hr/> <hr/>	<hr/> <hr/>
Total comprehensive income (expenses) attributable to:		
Shareholders of the Company	33,051	25,317
Non-controlling interests	(191)	2
	<hr/>	<hr/>
	32,860	25,319
	<hr/> <hr/>	<hr/> <hr/>

UNAUDITED CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

For the three months ended 31 March 2013

	Attributable to the shareholders of the Company							Attributable to non-controlling interests		Total HK\$'000	
	Share capital HK\$'000	Share premium HK\$'000	Merger difference HK\$'000	Share-based compensation reserve HK\$'000	Other reserves HK\$'000	Revaluation reserve HK\$'000	Exchange reserve HK\$'000	Retained profits HK\$'000	Sub-total HK\$'000		Attributable to non-controlling interests HK\$'000
At 1 January 2013	26,055	260,656	9,200	3,292	17,038	4,036	14,636	247,243	582,156	11,123	593,279
Employee share option benefits	-	-	-	701	-	-	-	-	701	-	701
Exercise of share options	22	547	-	(109)	-	-	-	-	460	-	460
Share of share-based compensation reserve of a subsidiary	-	-	-	8	-	-	-	-	8	2	10
Deemed partial disposal of interest in a subsidiary (Note 5)	-	-	-	-	11,592	-	-	-	11,592	11,670	23,262
Profit (loss) for the period	-	-	-	-	-	-	-	32,310	32,310	(191)	32,119
Other comprehensive income for the period	-	-	-	-	-	10	731	-	741	-	741
Total comprehensive income (expenses) for the period	-	-	-	-	-	10	731	32,310	33,051	(191)	32,860
At 31 March 2013	<u>26,077</u>	<u>261,203</u>	<u>9,200</u>	<u>3,892</u>	<u>28,630</u>	<u>4,046</u>	<u>15,367</u>	<u>279,553</u>	<u>627,968</u>	<u>22,604</u>	<u>650,572</u>
At 1 January 2012	23,489	105,533	9,200	2,440	-	3,980	10,372	156,900	311,914	417	312,331
Employee share option benefits	-	-	-	322	-	-	-	-	322	-	322
Exercise of share options	23	146	-	(42)	-	-	-	-	127	-	127
Profit for the period	-	-	-	-	-	-	-	24,609	24,609	1	24,610
Other comprehensive income for the period	-	-	-	-	-	(3)	711	-	708	1	709
Total comprehensive income for the period	-	-	-	-	-	(3)	711	24,609	25,317	2	25,319
At 31 March 2012	<u>23,512</u>	<u>105,679</u>	<u>9,200</u>	<u>2,720</u>	<u>-</u>	<u>3,977</u>	<u>11,083</u>	<u>181,509</u>	<u>337,680</u>	<u>419</u>	<u>338,099</u>

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

For the three months ended 31 March 2013

1. BASIS OF PREPARATION AND PRINCIPAL ACCOUNTING POLICIES

The unaudited consolidated results have been prepared in accordance with accounting principles generally accepted in Hong Kong, Accounting Standards and Hong Kong Financial Reporting Standards issued by the Hong Kong Institute of Certified Public Accountants and the disclosure requirements of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited. They have been prepared under the historical cost convention, as modified by the revaluation of leasehold buildings.

The accounting policies and method of computation used in preparing the unaudited consolidated results are consistent with those used in the audited financial statements for the year ended 31 December 2012 except as described below.

In the current period, the Group has applied the following new and revised standards, amendments and interpretations (the “HKFRSs”) issued by the Hong Kong Institute of Certified Public Accountants (the “HKICPA”), which are or have become effective.

HKFRS 10	Consolidated Financial Statements
HKFRS 11	Joint Arrangements
HKFRS 12	Disclosure of Interests in Other Entities
HKFRS 13	Fair Value Measurement
HKAS 19 (2011)	Employee Benefits
HKAS 27 (2011)	Separate Financial Statements
HKAS 28 (2011)	Investments in Associates and Joint Ventures
Amendments to HKFRS 1	Government Loans
Amendments to HKFRS 7	Disclosures – Offsetting Financial Assets and Financial Liabilities
Amendments to HKFRS 10, HKFRS 11 and HKFRS 12	Consolidated Financial Statements, Joint Arrangements and Disclosure of interests in Other Entities: Transition Guidance
Amendments to HKAS 1	Presentation of Items of Other Comprehensive Income
HK(IFRIC) – Int 20	Stripping Costs in the Production Phase of a Surface Mine
Amendments to HKFRSs	Annual Improvements to HKFRSs 2009 – 2011 Cycle except for the amendments to HKAS 1

The adoption of the new and revised HKFRSs had no material effect on how the results and financial position for the current or prior accounting periods have been prepared and presented. Accordingly, no prior period adjustment has been required.

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 ²
Amendments to HKFRS 10, HKFRS 12 and HKAS 27 (2011)	Investment Entities ¹
Amendments to HKAS 32	Offsetting Financial Assets and Financial Liabilities ¹

¹ Effective for annual periods beginning on or after 1 January 2014

² Effective for annual periods beginning on or after 1 January 2015

HKFRS 9 Financial Instruments

HKFRS 9 issued in 2009 introduces new requirements for the classification and measurement of financial assets. HKFRS 9 amended in 2010 includes the requirements for the classification and measurement of financial liabilities and for derecognition.

Key requirements of HKFRS 9 are described as follows:

- HKFRS 9 requires all recognised financial assets that are within scope of HKAS 39 *Financial Instruments: Recognition and Measurement* to be subsequently measured at amortised cost or fair value. Specifically, debt investments that are held within a business model whose objective is to collect the contractual cash flows, and that have contractual cash flows that are solely payments of principal and interest on the principal outstanding are generally measured at amortised cost at the end of subsequent reporting periods. In addition, under HKFRS 9, entities may make an irrevocable election to present subsequent changes in the fair value of an equity investment (that is not held for trading) in other comprehensive income, with only dividend income generally recognised in profit or loss.
- The most significant effect of HKFRS 9 regarding the classification and measurement of financial liabilities relates to the accounting for changes in the fair value of a financial liability (designated as at fair value through profit or loss) attributable to changes in the credit risk of that liability. Specifically, under HKFRS 9, for financial liabilities that designated as at fair value through profit or loss, the amount of change in the fair value of the financial liability that is attributable to changes in the credit risk of that liability is presented in other comprehensive income, unless the recognition of the effects of changes in the liability's credit risk in other comprehensive income would create or enlarge an accounting mismatch in profit or loss. Changes in fair value attributable to a financial liability's credit risk are not subsequently reclassified to profit or loss. Previously, under HKAS 39, the entire amount of the change in fair value of the financial liability designated as at fair value through profit or loss was presented in profit or loss.

HKFRS 9 is effective for annual periods beginning on or after 1 January 2015, with earlier application permitted.

The directors anticipate that the adoption of HKFRS 9 in the future may have an impact on amounts reported in respect of the Group's consolidated financial assets and financial liabilities. Regarding the Group's financial assets, it is not practicable to provide a reasonable estimate of that effect until a detailed review has been completed.

Amendments to HKFRS 10, HKFRS 12 and HKAS 27 (2011) Investment Entities

The amendments to HKFRS 10 introduce an exception to consolidating subsidiaries for an investment entity, except where the subsidiaries provide services that relate to the investment entity's investment activities. Under the amendments to HKFRS 10, an investment entity is required to measure its interests in subsidiaries at fair value through profit or loss.

To qualify as an investment entity, certain criteria have to be met. Specifically, an entity is required to:

- obtain funds from one or more investors for the purpose of providing them with professional investment management services;
- commit to its investor(s) that its business purpose is to invest funds solely for returns from capital appreciation, investment income, or both; and
- measure and evaluate performance of substantially all of its investments on a fair value basis.

Consequential amendments to HKFRS 12 and HKAS 27 have been made to introduce new disclosure requirements for investment entities.

The amendments to HKFRS 10, HKFRS 12 and HKAS 27 are effective for annual periods beginning on or after 1 January 2014, with early application permitted. The directors anticipate that the application of the amendments may have impact on amounts reported in the Group's consolidated financial statements.

Amendments to HKAS 32 Offsetting Financial Assets and Financial Liabilities

The amendments to HKAS 32 clarify existing application issues relating to the offset of financial assets and financial liabilities requirements. Specifically, the amendments clarify the meaning of "currently has a legally enforceable right of set-off" and "simultaneous realisation and settlement".

The amendments to HKAS 32 are not effective until annual periods beginning on or after 1 January 2014, with retrospective application required.

The directors anticipate that the application of these amendments to HKAS 32 may have impact on amounts reported in the Group's consolidated financial statements.

2. TURNOVER

The principal activities of the Group are development, manufacturing and sales of pharmaceutical products. During the period, turnover 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	
	2013 HK\$'000	2012 HK\$'000
Proprietary products	62,495	54,443
License-in products	85,952	55,446
	<u>148,447</u>	<u>109,889</u>

Geographical segments

During the period ended 31 March 2013 and 2012, more than 90% of the Group's turnover was derived from activities conducted in the People's Republic of China (the "PRC"), no geographical segmental information is presented.

3. TAXATION

	For the three months ended 31 March	
	2013 HK\$'000	2012 HK\$'000
Current tax		
Hong Kong	3,963	1,305
PRC Enterprise Income Tax	1,343	2,645
Over-provision in prior year	(139)	–
	<u>5,167</u>	<u>3,950</u>
Deferred tax		
Provision of current period	509	179
	<u>5,676</u>	<u>4,129</u>

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.

4. EARNINGS PER SHARE

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

	For the three months ended 31 March	
	2013	2012
Net profit attributable to shareholders for the purpose of basic and diluted earnings per share	HK\$32,310,000	HK\$24,609,000
Number of shares:		
Weighted average number of ordinary shares for the purpose of basic earnings per share	521,371,104	469,926,701
Effect of dilutive potential ordinary shares:		
Options	11,747,018	9,684,207
Contingent share arrangement	20,162,391	–
Weighted average number of ordinary shares for the purpose of diluted earnings per share	553,280,513	479,610,908

5. DEEMED PARTIAL DISPOSAL OF INTEREST IN A SUBSIDIARY

On 4 March 2013, CVie Therapeutics Company Limited (“CVie”) issued 1,200,000 shares to Ivy Blue Holdings Limited, a third party to the Group, at consideration of USD3 million. After the issue of shares, the Group’s shareholding in CVie was reduced by 8.97% to 70.98%. As the Group retained control over CVie, the Group recognised a gain on deemed partial disposal of interests in CVie of approximate HK\$11,592,000 in the equity attributable to the shareholders of the Company, and an increase in non-controlling interests of approximate HK\$11,670,000 for the shares in CVie at time of deemed partial disposal during the reporting period.

6. CAPITAL COMMITMENTS

	31 March 2013 HK\$'000	31 December 2012 HK\$'000
Capital commitments in respect of:		
Intangible assets – license fee and development cost	30,197	20,603
Property, plant and equipment	15,470	9,083
Construction contract	72,879	98,363
	118,546	128,049

DIVIDEND

The Board does not recommend payment of dividend for the three months ended 31 March 2013. (2012: 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 period ended 31 March 2013.

REVIEW OF INTERIM FINANCIAL STATEMENTS

The results for the three months ended 31 March 2013 are unaudited, but have been reviewed by auditors 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 reviewed with the management and auditors this unaudited report for the three months ended 31 March 2013 before recommending it to the Board for approval.

On behalf of the Board
Lee Siu Fong
Chairman

Hong Kong, 20 May 2013

As at the date thereof, Ms. Lee Siu Fong (Chairman of the Company), Ms. Leelalertsuphakun Wanee and Dr. Li Xiaoyi are executive Directors; Mr. Mauro Bove is non-executive Director, Dr. Chan Yau Ching, Bob, Mr. Lam Yat Cheong and Dr. Tsim Wah Keung, Karl are independent non-executive Directors.