



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
2014

* For identification purpose only

BUSINESS REVIEW

The Group had started the year 2014 with the same vigor as in 2013 that resulted in another quarter of consistent performance and strong growth momentum, breaking new ground in a slew of areas.

The growth trend in revenue edged higher during the first quarter of the year, overtaking the pace of year 2013 with turnover for the first quarter of 2014 surged by 39% compared with same quarter last year and reached new height of HK\$206,214,000. The sales of the Group's major products continued to perform well, with sales of newer product *Zanidip*[®] continued to take the pole position with a leap of 93% compared with same quarter last year. Sales of older products also grew significantly with sales of *Livaracine*[®], *Carnitene*[®], *Ferplex*[®] and *Yallaferon*[®] increased by 46%, 42%, 38% and 27% respectively over the same period last year.

Net profit attributable to shareholders also attained historical height in the first quarter of 2014, reaching the level of HK\$42,100,000 despite 122% increasing investment in drug research and development. The slight decrease in gross profit margin by 0.4 percentage point and in net profit margin by 1.4 percentage point did not dent the upward trajectory of net profit growth as it increased by 30.3% over the same quarter last year.

Regarding production and facility, preparation was continued during the quarter to make the Group more adapt to the market change. Hefei facility has been in full operation since the Chinese New Year and the transition from old facility to the new one had been smooth and successful. The highly automatic production process substantially enhances the Group's production capacity while significantly reduces quality risk for the product. The construction works of the Nansha facility have been completed. It is now ready for installation of production modules for manufacturing of a variety of dosage forms, such as solid dose, pre-filled syringe and oral solution. Upon completion, the Group will be in a position to offer a complete range of formulations to the market, greatly augmenting its competitiveness as a specialty pharmaceutical company in China.

The Group's commitment to research and development had been intensified in the quarter, illustrated by 122% spending jump in this realm over same period last year. A total of six Investigative New Drug (IND) applications have been actively under review by CFDA. One of the six IND applications was approved by CFDA in February of 2014. Adapalene and Clindamycin combination hydrochloride Gel is a proprietary product (China Patent No. 200810004156.1) developed by the Group's in-house R&D team. It is indicated for moderate to severe acne in which there is still unmet medical need. The combination formulation could bring out the synergic effect and improve patient compliance for the treatment. The Group has started the preparation for clinical study upon the approval and first patient enrollment is expected in earlier third quarter.



As up to additional five clinical studies are anticipated to start for the remaining of the year, the Group is gearing up its preparation by aggressively expanding its clinical development team. Seasoning managers were brought in and system is upgraded to improve the team's capacity and capability. A computerized clinical trial managing system CTMS has been installed to strengthen operation effectiveness and efficiency.

The sales and marketing efforts in the quarter under review mainly focused on the preparation for the launch of both oral carnitine and *Remodulin*[®]. Given the growth momentum of the Group's direct sales force, the available of oral carnitine will further boost the confidence of the team, providing new catalyst to propel it to a new level. The contribution of the Group's direct sales force to the total revenue is expected to continue to climb.

Having considered that niche nature of *Remodulin*[®], the Group, operating through its JV subsidiary CVie Therapeutics, has set up a sales and marketing team dedicated to the product only. The recruitment phase had completed and training is underway. The highly specialized team is small in number but big in knowledge of pulmonary hypertension to provide the best service to patients.

In the partnership arena, the Group remained committed to co-development model in order to leverage on both partners' strength in development. In February this year, the Group entered into a license agreement with Dilafor AB, a Swedish drug development company, to manufacture, develop and commercialize tafoxiparin for obstetrics and gynecological indications in China, Hong Kong, Macau and Taiwan. Pursuant to the terms of the agreement, the Group and Dilafor will jointly develop tafoxiparin for obstetrical and gynecological indications. The joint clinical development program of tafoxiparin will initially be focused on reducing labor times for patients who do not start labor spontaneously and are induced into labor, an indication where both the Group and Dilafor see a major medical need for the product in terms of improving outcomes for both mother and baby.

PROSPECT

The growth momentum of existing major products should carry the Group further along the trajectory of last seven years and deliver consistent results in the near future.

With many provincial tenders opening up during the remaining of the year, the newer products will have the chance to realize their potential in the market place. The activity could generate new growth momentum for the Group.

The launch of both oral carnitine and *Remodulin*[®] adds new dimension to the Group's growth path. Intensified efforts on brand building and medical promotion will create excitement in field and medical community, making a ripple effect to the sales of existing products.

The possible initiation of seven clinical studies in 2014 not only ascertains the Group's relentless pursuit of excellence in drug development, but also places it in an advantageous position to reap benefit of China's continuing growth in the healthcare industry.

UNAUDITED CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS

For the three months ended 31 March 2014

	Notes	For the three months ended 31 March	
		2014 HK\$'000	2013 HK\$'000
Turnover	(2)	206,214	148,447
Cost of sales		(58,601)	(41,618)
Gross profit		147,613	106,829
Other revenue		5,595	1,791
Selling and distribution expenses		(67,494)	(46,939)
Research and development expenses		(9,919)	(4,464)
Administrative expenses		(22,949)	(19,131)
Profit from operations		52,846	38,086
Finance costs		(786)	(291)
Share of results of associate		(1,626)	–
Profit before taxation		50,434	37,795
Taxation	(3)	(9,689)	(5,676)
Profit for the period		40,745	32,119
Attributable to:			
Shareholders of the Company		42,100	32,310
Non-controlling interests		(1,355)	(191)
		40,745	32,119
Earnings per share		HK cents	HK cents
Basis	(4)	7.79	6.20
Diluted	(4)	7.51	5.84

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

For the three months ended 31 March 2014

	For the three months ended 31 March	
	2014 HK\$'000	2013 HK\$'000
Profit for the period	40,745	32,119
Other comprehensive income:		
Items that may not be reclassified subsequently to profit or loss:		
Exchange differences on translation of revaluation of overseas buildings	–	10
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of financial statements of overseas subsidiaries	(10,379)	731
Other comprehensive (expense) income for the period, net of tax	(10,379)	741
Total comprehensive income for the period	30,366	32,860
Total comprehensive income (expense) for the period attributable to:		
Shareholders of the Company	31,708	33,051
Non-controlling interests	(1,342)	(191)
	30,366	32,860

UNAUDITED CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

For the three months ended 31 March 2014

	Attributable to the shareholders of the Company								Attributable to non-controlling interests		Total
	Share capital	Share premium	Share-based		Other reserve	Revaluation reserve	Exchange reserve	Retained profits	Sub-total	interests	
			Merger difference	compensation reserve							
	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 2014	26,912	292,326	9,200	5,392	60,312	-	23,284	368,579	786,005	66,053	852,058
Employee share option benefit	-	-	-	962	-	-	-	-	962	-	962
Exercise of share options	195	1,127	-	(404)	-	-	-	-	918	-	918
Share of share-based compensation reserve of a subsidiary	-	-	-	6	-	-	-	-	6	4	10
Profit (loss) for the period	-	-	-	-	-	-	-	42,100	42,100	(1,355)	40,745
Other comprehensive (expense) income for the period	-	-	-	-	-	-	(10,392)	-	(10,392)	13	(10,379)
Total comprehensive income (expense) for the period	-	-	-	-	-	-	(10,392)	42,100	31,708	(1,342)	30,366
At 31 March 2014	27,107	293,453	9,200	5,956	60,312	-	12,892	410,679	819,599	64,715	884,314
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 benefit	-	-	-	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	-	-	-	-	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 (expense) for the period	-	-	-	-	-	10	731	32,310	33,051	(191)	32,860
At 31 March 2013	26,077	261,203	9,200	3,892	28,630	4,046	15,367	279,553	627,968	22,604	650,572

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

For the three months ended 31 March 2014

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, Hong Kong Accounting Standards (“HKAS”) and Hong Kong Financial Reporting Standards (“HKFRS”) issued by the Hong Kong Institute of Certified Public Accountants (the “HKICPA”) and the 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.

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 2013 except as described below.

In the current period, the Group has applied the following new and revised HKFRSs issued by the HKICPA, which are or have become effective:

Amendments to HKFRS 10, HKFRS 12 and HKAS 27	Investments Entities
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The application of the new and revised HKFRSs in the current period has had no material impact on the Group’s financial performance and position for the current and prior period and/or the disclosure 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:

Amendments to HKFRSs	Annual Improvements to HKFRS 2010-2012 Cycle ¹
Amendments to HKFRSs	Annual Improvements to HKFRS 2011-2013 Cycle ¹
HKFRS 9	Financial Instruments ²
HKFRS 14	Regulatory Deferral Accounts ³
Amendments to HKFRS 9 and HKFRS 7	Mandatory Effective Date of HKFRS 9 and Transition Disclosure ²
Amendments to HKAS 19	Defined Benefit Plan: Employee Contributions ¹
Amendments to HKAS 32	Offsetting Financial Assets and Financial Liabilities ¹

Amendments to HKAS 36	Recoverable Amount Disclosures for Non-Financial Assets ¹
Amendments to HKAS 39	Novation of Derivatives and Continuation of Hedge Accounting ¹
HK(IFRIC) – Int 21	Levies ¹

¹ Effective for annual periods beginning on or after 1 July 2014, except as disclosed below. Earlier application is permitted

² Available for application – the mandatory effective date will be determined when the outstanding phase of HKFRS 9 are finalised

³ Effective for annual periods beginning on or after 1 January 2016, with earlier application permitted

Annual Improvements to HKFRS 2010 – 2012 Cycle

The *Annual Improvements to HKFRSs 2010 – 2012 Cycle* includes a number of amendments to various HKFRSs which are summarised below.

The amendments to HKFRS 2 (i) change the definitions of “vesting condition” and “market condition”, and (ii) add definitions for “performance condition” and “service condition” which were previously included within the definition of “vesting condition”. The amendments to HKFRS 2 are effective for share-based payment transactions for which the grant date is on or after 1 July 2014.

The amendments to HKFRS 3 clarify that contingent consideration that is classified as an asset or a liability should be measured at fair value at each reporting date, irrespective of whether the contingent consideration is a financial instrument within the scope of HKFRS 9 or HKAS 39 or a non-financial asset or liability. Changes in fair value (other than measurement period adjustments) should be recognised in profit and loss. The amendments to HKFRS 3 are effective for business combinations for which the acquisition date is on or after 1 July 2014.

The amendments to HKFRS 8 (i) require an entity to disclose the judgements made by management in applying the aggregation criteria to operating segments, including a description of the operating segments aggregated and the economic indicators assessed in determining whether the operating segments have “similar economic characteristics”; and (ii) clarify that a reconciliation of the total of the reportable segments’ assets to the entity’s assets should only be provided if the segment assets are regularly provided to the chief operating decision maker.

The amendments to the basis for conclusion of HKFRS 13 clarify that the issue of HKFRS 13 and consequential amendments to HKAS 39 and HKFRS 9 did not remove the ability to measure short-term receivables and payables with no stated interest rate at their invoice amounts without discounting if the effect of discounting is immaterial.

The amendments to HKAS 16 and HKAS 38 remove perceived inconsistencies in the accounting for accumulated depreciation/amortisation when an item of property, plant and equipment or an intangible asset is revalued. The amended standards clarify that the gross carrying amount is adjusted in a manner consistent with the revaluation of the carrying amount of the asset and that accumulated depreciation/amortisation is the difference between the gross carrying amount and the carrying amount after taking into account accumulated impairment losses.

The amendments to HKAS 24 clarify that a management entity providing key management personnel service to a reporting entity is a related party of the reporting entity. Consequently, the reporting entity should disclose as related party transactions the amounts incurred for the service paid or payable to the management entity for the provision of key management personnel services. However, disclosure of the components of such compensation is not required.

The directors do not anticipate that the application of the amendments included in the *Annual Improvements to HKFRS 2010 – 2012 Cycle* will have a material effect on the Group's unaudited condensed consolidated financial statements.

Annual Improvements to HKFRS 2011 – 2013 Cycle

The *Annual Improvements to HKFRSs 2011 – 2013 Cycle* includes a number of amendments to various HKFRSs which are summarised below.

The amendments to HKFRS 3 clarify that the standard does not apply to the accounting for the formation of all types of joint arrangement in the financial statements of the joint arrangement itself.

The amendments to HKFRS 13 clarify that the scope of the portfolio exception for measuring the fair value of a group of financial assets and financial liabilities on a net basis includes all contracts that are within the scope of and accounted for in accordance with HKAS 39 or HKFRS 9 even if those contracts do not meet the definitions of financial assets or financial liabilities within HKAS 32.

The amendments to HKAS 40 clarify that HKAS 40 and HKFRS 3 are not mutually exclusive and application of both standards may be required. Consequently, an entity acquiring investment property must determine whether:

- (a) the property meets the definition of investment property in terms of HKAS 40; and
- (b) the transaction meets the definition of a business combination under HKFRS 3.

The directors do not anticipate that the application of the amendments included in the *Annual Improvements to HKFRS 2011 – 2013 Cycle* will have a material effect on the Group's unaudited condensed consolidated financial statements.

HKFRS 9 Financial Instruments

HKFRS 9 issued in 2009 introduced new requirements for the classification and measurements of financial assets. HKFRS 9 was amended in 2010 to include requirements for the classification and measurement of financial liabilities and for derecognition, and further amended in 2013 to include the new requirements for hedge accounting.

Key requirements of HKFRS 9 are described below:

- All recognised financial assets that are within the 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. All other debt investments and equity investments are measured at their fair values at the end of subsequent accounting 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.



- With regard to the measurement of financial liabilities designated as at fair value through profit or loss, HKFRS 9 requires that 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 of financial liabilities attributable to changes in the financial liabilities' credit risk are not subsequently reclassified to profit or loss. Under HKAS 39, the entire amount of the change in fair value of the financial liability designated as fair value through profit or loss was presented in profit or loss.

The new general hedge accounting requirements retain the three types of hedge accounting. However, greater flexibility has been introduced to the types of transactions eligible for hedge accounting, specifically broadening the types of instruments that qualify for hedging instruments and the types of risk components of non-financial items that are eligible for hedge accounting. In addition, the effectiveness test has been overhauled and replaced with the principle of an "economic relationship". Retrospective assessment of hedge effectiveness is also no longer required. Enhanced disclosure requirements about an entity's risk management activities have also been introduced.

The directors anticipate that the adoption of HKFRS 9 in the future will not have a significant impact on the amounts reported in respect of the Group's financial assets and financial liabilities.

Amendments to HKAS 19 Defined Benefit Plan: Employee Contributions

The amendments to HKAS 19 clarify how an entity should account for contribution made by employees or third parties to defined benefits plans, based on whether those contributions are dependent on the number of years of service provided by the employee.

For contributions that are independent of the number of years of service, the entity may either recognise the contributions as a reduction in the service cost in the period in which the related service is rendered, or to attribute them to the employees' periods of service using the projected unit credit method; whereas for contributions that are dependent on the number of years of service, the entity is required to attribute them to the employees' periods of service.

The directors do not anticipate that the application of these amendments to HKAS 19 will have a significant impact on the Group's unaudited condensed 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 directors do not anticipate that the application of these amendments to HKAS 32 will have a significant impact on the Group’s unaudited condensed consolidated financial statements as the Group does not have any financial assets and financial liabilities that qualify for offset.

Amendments to HKAS 36 Recoverable Amount Disclosures for Non-Financial Assets

The amendments to HKAS 36 remove the requirement to disclose the recoverable amount of a cash-generating unit (CGU) to which goodwill or other intangible assets with indefinite useful lives had been allocated when there has been no impairment or reversal of impairment of the related CGU. Furthermore, the amendments introduce additional disclosure requirements regarding the fair value hierarchy, key assumptions and valuation techniques used when the recoverable amount of an asset or CGU was determined based on its fair value less costs of disposal.

The directors do not anticipate that the application of these amendments to HKAS 36 will have a significant impact on the Group’s unaudited condensed consolidated financial statements.

Amendments to HKAS 39 Novation of Derivatives and Continuation of Hedge Accounting

The amendments to HKAS 39 provide relief from the requirement to discontinue hedge accounting when a derivative hedging instrument is novated under certain circumstances. The amendments also clarify that any change to the fair value of the derivative hedging instrument arising from the novation should be included in the assessment of hedge effectiveness.

The directors do not anticipate that the application of these amendments to HKAS 39 will have any effect on the Group’s unaudited condensed consolidated financial statements as the Group does not have any derivatives that are subject to novation.



HK (IFRIC) – Int 21 Levies

HK (IFRIC) – Int 21 *Levies* addresses the issue of when to recognise a liability to pay a levy. The Interpretation defines a levy, and specifies that the obligating event that gives rise to the liability is the activity that triggers the payment of the levy, as identified by legislation. The Interpretation provides guidance on how different levy arrangements should be accounted for, in particular, it clarifies that neither economic compulsion nor the going concern basis of financial statements preparation implies that an entity has a present obligation to pay a levy that will be triggered by operating in a future period.

The directors anticipate that the application of HK (IFRIC) – Int 21 will have no effect on the Group's unaudited condensed consolidated financial statements as the Group does not have any levy arrangements.

HKFRS 14 Regulatory Deferral Accounts

HKFRS 14 addresses the issues of financial reporting requirements for rate-regulated assets and liabilities (which are termed “regulatory deferral account balances”) that arises when an entity is subject to rate regulation.

The directors anticipate that the application of HKFRS 14 will have no material impact on the Group's unaudited condensed 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	
	2014	2013
	<i>HK\$'000</i>	<i>HK\$'000</i>
Proprietary products	80,273	62,495
Licensed-in products	125,941	85,952
	206,214	148,447

Geographical segments

During the period ended 31 March 2014 and 2013, 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	
	2014 HK\$'000	2013 HK\$'000
Current tax		
Hong Kong Profits Tax	6,320	3,963
PRC Enterprise Income Tax	2,710	1,343
Under (over) provision in prior years	978	(139)
	10,008	5,167
Deferred tax		
Origination and reversal of temporary differences	(319)	509
	9,689	5,676

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 shareholders of the Company is based on the following data:–

	For the three months ended 31 March	
	2014 HK\$'000	2013 HK\$'000
<i>Earnings:</i>		
Net profit attributable to the shareholders of the Company for the purpose of basic earnings per share	42,100	32,310
Effect of dilutive potential ordinary shares:		
Adjustment in relation to contingent share agreement	(403)	–
Net profit attributable to the shareholders of the Company for the purpose of diluted earnings per share	41,697	32,310
	2014 Share(s)	2013 Share(s)
<i>Number of shares:</i>		
Weighted average number of ordinary shares for the purpose of basic earnings per share	540,499,048	521,371,104
Effect of dilutive potential ordinary shares:		
Options	9,864,584	11,747,018
Contingent share arrangement	4,995,724	20,162,391
Weighted average number of ordinary shares for the purpose of diluted earnings per share	555,359,356	553,280,513

5. Related party transactions

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

(a) Purchase from Sigma-Tau Group

Name of related party	Note	Nature of transaction	For the three months ended 31 March	
			2014 HK\$'000	2013 HK\$'000
Sigma-Tau Group	(1)	Purchase of pharmaceutical product	3,791	20,281
Simga-Tau Group	(1)	Purchase of experimental products for use in R&D	803	1,768
			4,594	22,049

Note:

- Sigma-Tau Industrie Farmaceutiche Riunite S.p.A. is a shareholder of the Company which is also a member of Sigma-Tau Group.

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

During the three months ended 31 March 2014, the Group received HK\$121,000 (31 March 2013: HK\$116,000) 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	
	2014	2013
	<i>HK\$'000</i>	<i>HK\$'000</i>
Short-term employee benefits	3,996	4,312
Share-based payments	295	198
Retirement and other post-employment benefits	3,348	2,723
	7,639	7,233

6. Capital commitments

	31 March 2014	31 December 2013
	<i>HK\$'000</i>	<i>HK\$'000</i>
Capital commitments in respect of:		
Intangible assets – license fee and development cost	12,238	15,049
Property, plant and equipment	13,377	15,308
Construction contract	18,560	28,096
	44,175	58,453

7. Events after the end of the interim period

On 2 May 2014, the Group signed a Deed of Guarantee for providing guarantee in amount of HK\$6,000,000 to Bank in respect of the Facility given by Bank to Powder Pharmaceutical Incorporated. Further detail of this transaction is set out in the announcement of the Company dated 2 May 2014.