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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)

# ANNOUNCEMENT OF ANNUAL RESULTS FOR THE YEAR ENDED 31 DECEMBER 2016

FINANCIAL HIGHLIGHT			
	For the ye	ar ended	
	31 Dece	ember	
	2016	2015	Change
	HK\$'000	HK\$'000	
Revenue	929,821	922,150	+0.8%
Gross profit	668,235	648,164	+3.1%
Profit attributable to the			
owners of the Company	252,002	229,052	+10.0%
	HK cents	HK cents	
Earnings per share			
Basic	42.79	39.77	+7.6%
Diluted	42.60	39.29	+8.4%

The board of Directors recommends the payment of final dividend of HK7.9 cents (2015: HK7.4 cents) per ordinary share for the year ended 31 December 2016.

<sup>\*</sup> For identification purposes only

#### **ANNUAL RESULTS**

The directors (the "**Directors**") of Lee's Pharmaceutical Holdings Limited (the "**Company**") are pleased to present the results of the Company and its subsidiaries (collectively, the "**Group**") for the financial year ended 31 December 2016 and the comparative figures as follows.

#### CONSOLIDATED STATEMENT OF PROFIT OR LOSS

For the year ended 31 December 2016

For the year ended 31 December 2016			
	Notes	2016 HK\$'000	2015 HK\$'000
Revenue	2	929,821	922,150
Cost of sales	_	(261,586)	(273,986)
Gross profit		668,235	648,164
Other income		72,137	12,194
Gain on deemed disposal of			21 925
interest in an associate Fair value changes of derivative		_	31,825
financial instruments		_	10,092
Impairment of intangible assets		(23,324)	(8,192)
Selling and distribution expenses		(204,225)	(256,465)
Administrative expenses		(146,511)	(112,310)
Research and development expenses		(67,886)	(38,883)
Dualit from anaustians		200 426	206 125
Profit from operations Finance costs		298,426 (3,803)	286,425 (3,040)
Share of results of associates		(12,019)	(29,450)
21.41.2 01 1.60.01.0 01 4000 01.4000			(25, 100)
Profit before taxation		282,604	253,935
Taxation	3	(50,198)	(40,938)
		222 407	212.007
Profit for the year		232,406	212,997
Attributable to:		252.002	220.052
Owners of the Company		252,002	229,052
Non-controlling interests		(19,596)	(16,055)
		232,406	212,997
		HK cents	HK cents
Earnings per share	<i>5</i>	42.70	20.77
Basic	5	42.79	39.77
Diluted	5	42.60	39.29

# CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the year ended 31 December 2016

	2016 HK\$'000	2015 HK\$'000
Profit for the year	232,406	212,997
Other comprehensive expense:		
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of		
financial statements of overseas subsidiaries	(49,054)	(56,386)
Fair value changes of available-for-sale		
financial assets	(11,817)	(4,218)
Other comprehensive expense for the year,		
net of tax	(60,871)	(60,604)
Total comprehensive income for the year	171,535	152,393
Total comprehensive income (expense) for		
the year attributable to:		
Owners of the Company	190,883	169,501
Non-controlling interests	(19,348)	(17,108)
	171,535	152,393

### CONSOLIDATED STATEMENT OF FINANCIAL POSITION

At 31 December 2016

At 31 December 2010			
	Notes	2016 HK\$'000	2015 HK\$'000
Non-current Assets			
Property, plant and equipment		437,092	355,940
Intangible assets		421,853	337,825
Lease premium for land		134,583	13,401
Goodwill		3,900	3,900
Interests in associates		46,820	58,671
Held-to-maturity financial assets		5,659	5,491
Available-for-sale financial assets		127,778	99,029
Prepayment for acquisition of a leasehold land			135,402
		1,177,685	1,009,659
Current Assets			
Lease premium for land		2,844	306
Inventories		134,910	169,878
Trade receivables	6	87,069	107,780
Other receivables, deposits and prepayments	Ü	106,223	108,821
Amount due from a related party			37,275
Advance to an associate		20,524	22,588
Tax recoverable		528	674
Pledged bank deposits		26,639	_
Time deposits		209,693	115,903
Cash and bank balances		295,282	278,244
		883,712	841,469
Current Liabilities			
Trade payables	7	42,301	37,621
Other payables	/	172,340	172,619
Obligations under license contract		490	505
Bank borrowings		133,578	66,769
Obligations under finance leases		467	303
Tax payables		9,199	4,139
		358,375	281,956
			<u> </u>
Net Current Assets		525,337	559,513
<b>Total Assets less Current Liabilities</b>		1,703,022	1,569,172

	2016 HK\$'000	2015 HK\$'000
Capital and Reserves		
Share capital	29,503	29,340
Reserves	1,572,223	1,438,098
<b>Equity Attributable to the Owners</b>		
of the Company	1,601,726	1,467,438
Non-controlling interests	32,990	49,390
Total Equity	1,634,716	1,516,828
Non-current Liabilities		
Deferred tax liabilities	25,290	18,281
Retirement benefit	42,015	33,195
Obligations under finance leases	1,001	868
	68,306	52,344
	1,703,022	1,569,172

### CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

For the year ended 31 December 2016

Attributable	to the Owner	s of the	Company
AUTIDIIIADIC	to the Owner	S OF THE	COMBANY

	-			Auributat	ne to the Owners of	the Company					
				Share-based		Investments				Attributable to	
	Share	Share	Merger	compensation		revaluation	Exchange	Retained		non-controlling	
	capital	premium	difference	reserve	Other reserves	reserve	reserve	profits	Sub-total	interests	Total
	HK\$'000	HK\$'000	HK\$'000	HK\$'000	HK\$'000	HK\$'000	HK\$'000	HK\$'000	HK\$'000	HK\$'000	HK\$'000
At 1 January 2016	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	_	_	_	3,901	_	-	_	_	3,901	_	3,901
Exercise of share options	163	3,229	-	(971)	-	-	-	-	2,421	-	2,421
Share of share-based compensation reserve of a subsidiary	-	-	-	23	-	-	-	-	23	17	40
Capital contribution from non-controlling interests				_				_	_	2,931	2,931
Share of reserve of associates	-	-	-	-	168	-	-	-	168	-	168
Profit (loss) for the year Other comprehensive (expense)	-	-	-	-	-	-	-	252,002	252,002	(19,596)	232,406
income for the year						(11,817)	(49,302)		(61,119)	248	(60,871)
Total comprehensive income											
(expense) for the year						(11,817)	(49,302)	252,002	190,883	(19,348)	171,535
2015 final dividend paid	-	-	_	-	_	-	_	(43,645)	(43,645)	_	(43,645)
2016 interim dividend paid								(19,463)	(19,463)		(19,463)
At 31 December 2016	29,503	721,154	9,200	11,671	59,512	(12,716)	(96,842)	880,244	1,601,726	32,990	1,634,716
At 1 January 2015	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		301,170	7,200	3,770	J/ <sub>3</sub> JTT	J,J1/ _	1,175	J10,T/1	3,770	01,520	3,770
Exercise of share options	259	22,547	_	(2,857)		_		_	19,949	_	19,949
Share of share-based compensation	23)	22,JT1		(2,037)					17,777		17,777
reserve of a subsidiary	-	-	_	23	-	_	-	-	23	18	41
Issue of shares pursuant to											
Placing Agreement	1,500	382,147	-	-	-	-	-	-	383,647	-	383,647
Issue of shares pursuant to Shareholders' Agreement	345	12,035	-	-	-	-	-	-	12,380	-	12,380
Capital contribution from non-controlling interests	_	_	_	_	_	_	_	_	_	1,954	1,954
Profit (loss) for the year	_			-	-	-		229,052	229,052	(16,055)	212,997
Other comprehensive expense											
for the year						(4,218)	(55,333)		(59,551)	(1,053)	(60,604)
Total comprehensive income											
(expense) for the year						(4,218)	(55,333)	229,052	169,501	(17,108)	152,393
2014 final dividend paid	_	_	_	_	_	_	_	(38,577)	(38,577)	_	(38,577)
2015 interim dividend paid								(17,596)	(17,596)		(17,596)
At 31 December 2015	29,340	717,925	9,200	8,718	59,344	(899)	(47,540)	691,350	1,467,438	49,390	1,516,828

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

For the year ended 31 December 2016

## 1. APPLICATION OF NEW AND AMENDMENTS TO HONG KONG FINANCIAL REPORTING STANDARDS

The accounting policies and method of computation used in these consolidated financial statements 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 year, the Group has applied, for the first time, the following amendments to Hong Kong Accounting Standards ("HKASs") and Hong Kong Financial Reporting Standards ("HKFRSs") issued by the Hong Kong Institute of Certified Public Accountants that are relevant for the preparation of the Group's consolidated financial statements:

Amendments to HKAS 1 Disclosure Initiative

Amendments to HKAS 16 and Clarification of Acceptable Methods of Depreciation and

HKAS 38 Amortisation

Amendments to HKAS 16 and Agriculture: Bearer Plants

HKAS 41

Amendments to HKAS 27 Equity Method in Separate Financial Statements

Amendments to HKFRS 10, Investment Entities: Applying the Consolidation Exception

HKFRS 12 and HKAS 28

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 year has had no material effect on the amounts reported in these consolidated financial statements and/or disclosures set out in these consolidated financial statements.

The Group has not early applied the following new and amendments to HKASs and HKFRSs that have been issued but are not yet effective:

HKFRS 9 Financial Instruments<sup>2</sup>

HKFRS 15 Revenue from Contracts with Customers<sup>2</sup>

HKFRS 16 Leases<sup>3</sup>

Amendments to HKAS 7 Disclosure Initiative<sup>1</sup>

Amendments to HKAS 12 Recognition of Deferred Tax Assets for Unrealised Losses<sup>1</sup>
Amendments to HKFRS 2 Classification and Measurement of Share-based Payment

Transactions<sup>2</sup>

Amendments to HKFRS 4 Applying HKFRS 9 Financial Instruments with HKFRS 4

Insurance Contracts<sup>2</sup>

Amendments to HKFRS 10 Sale or Contribution of Assets between an Investor and its

and HKAS 28 Associate or Joint Venture<sup>4</sup>

- Effective for annual periods beginning on or after 1 January 2017, with earlier application permitted
- Effective for annual periods beginning on or after 1 January 2018, with earlier application permitted
- Effective for annual periods beginning on or after 1 January 2019, with earlier application permitted
- <sup>4</sup> Effective for annual periods beginning on or after a date to be determined

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

#### 2. REVENUE AND SEGMENT INFORMATION

Revenue represents the net amounts received and receivable for goods sold by the Group to outside customers during the year.

Information reported to the Chairman of the Company, being the chief operating decision maker, for the purpose of resource allocation and assessment of segment performance focuses on the types of good delivered. No operating segments identified by the chief operating decision maker have been aggregated in arriving at the reportable segments of the Group.

Specifically, the Group's reportable and operating segments under HKFRS 8 are as follows:

Proprietary products – Manufacturing and sales of self-developed

pharmaceutical products

Licensed-in products – Trading of licensed-in pharmaceutical products

#### Segment revenue and results

The following is an analysis of the Group's revenue and results by reportable and operating segments:

	Proprietary products		Licen: prod	sed-in lucts	Consolidated		
	2016 HK\$'000	2015 HK\$'000	2016 HK\$'000	2015 HK\$'000	2016 HK\$'000	2015 HK\$'000	
Segment revenue	440,073	418,789	489,748	503,361	929,821	922,150	
Segment results Gain on deemed disposal of	207,574	185,379	118,253	70,316	325,827	255,695	
interest in an associate					_	31,825	
Interest income					1,651	3,832	
Unallocated expenses					(29,052)	(4,927)	
Profit from operations					298,426	286,425	
Finance costs					(3,803)	(3,040)	
Profit before share of results of associates					294,623	283,385	
Share of results of associates					(12,019)	(29,450)	
Profit before taxation					282,604	253,935	
Taxation					(50,198)	(40,938)	
					_	_	
Profit for the year					232,406	212,997	

Segment revenue reported above represents revenue generated from external customers. There were no inter-segment sales during the year (2015: nil).

The accounting policies of the operating segments are the same as the Group's accounting policies. Segment results represents the profit earned by each segment without allocation of central administration costs including directors' emoluments, gain on deemed disposal of interest in an associate, interest income, finance costs, share of results of associates, and income tax expense. This is the measure reported to the chief operating decision maker for the purposes of resource allocation and assessment of segment performance.

#### Segment assets and liabilities

The following is an analysis of the Group's assets and liabilities by reportable and operating segments:

	Proprietary products		Licensed-in products		Consolidated	
	2016	2015	2016	2015	2016	2015
	HK\$'000	HK\$'000	HK\$'000	HK\$'000	HK\$'000	HK\$'000
Segment assets	258,895	260,304	1,104,866	942,067	1,363,761	1,202,371
Unallocated assets					697,636	648,757
Total assets					2,061,397	1,851,128
Segment liabilities	85,420	87,839	264,757	190,846	350,177	278,685
Unallocated liabilities					76,504	55,615
Total liabilities					426,681	334,300

For the purposes of monitoring segment performance and allocating resources between segments:

- all assets are allocated to operating segments other than interests in associates, prepayment
  for acquisition of a leasehold land, part of lease premium for land, advance to an associate,
  amount due from a related party, tax recoverable, time deposits and cash and bank balances.
  Goodwill is allocated to segment of proprietary products. Assets used jointly by reportable
  segments are allocated on the basis of the revenues earned by individual reportable segment;
  and
- all liabilities are allocated to reportable segments other than tax payables, deferred tax liabilities, and retirement benefit. Liabilities for which reportable segments are jointly liable are allocated in proportion to segment assets.

Other segment information (included in the measure of segment profit or loss or regularly provided to the chief operating decision maker)

	<b>Proprietary</b>		Licen	sed-in		
	prod	lucts	prod	lucts	Consol	lidated
	2016	2015	2016	2015	2016	2015
	HK\$'000	HK\$'000	HK\$'000	HK\$'000	HK\$'000	HK\$'000
Depreciation of property,						
plant and equipment	26,289	30,205	6,761	3,164	33,050	33,369
Amortisation of intangible						
assets	-	_	12,678	10,814	12,678	10,814
Additions to non-current						
assets (Property, plant and						
equipment and intangible						
assets) during the year	52,331	81,480	217,339	152,950	269,670	234,430
Impairment of intangible						
assets	2,121	351	21,203	7,841	23,324	8,192

#### Geographical information

During the years ended 31 December 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 segmental information on revenue is presented. The Group's segment assets and liabilities for the year, analysed by geographical market, are as follows:

	The	PRC	C	Kong others	Total	
	2016	2015	2016	2015	2016	2015
	HK\$'000	HK\$'000	HK\$'000	HK\$'000	HK\$'000	HK\$'000
Segment assets	1,167,680	1,085,401	893,717	765,727	2,061,397	1,851,128
Segment liabilities	157,941	118,241	268,740	216,059	426,681	334,300

#### 3. TAXATION

	2016 HK\$'000	2015 HK\$'000
Current tax		
Hong Kong Profits Tax	18,538	25,300
PRC Enterprise Income Tax	23,318	12,161
	41,856	37,461
Under (over) provision in prior years		
Hong Kong Profits Tax	119	118
PRC Enterprise Income Tax	(62)	24
	57	142
Deferred tax		
Origination and reversal of		
temporary differences	8,285	3,335
	50,198	40,938

Hong Kong Profits Tax is calculated at 16.5% of the estimated assessable profit for both years.

Under the Law of the People's Republic of China on Enterprise Income Tax (the "EIT Law") and Implementation Regulation of the EIT Law, the tax rates of the PRC subsidiaries are 15% to 25% (2015: 15% to 25%).

Taxation arising in other jurisdictions is calculated at the rates prevailing in the relevant jurisdictions.

#### 4. DIVIDENDS

	2016 HK\$'000	2015 HK\$'000
Dividends for ordinary shareholders of the Company recognised as		
distribution during the year:		
2016 Interim – HK\$0.033 (2015: 2015 interim dividend	10.462	17.506
HK\$0.030) per share 2015 Final – HK\$0.074 (2015: 2014 final dividend HK\$0.066)	19,463	17,596
per share	43,645	38,577
	63,108	56,173

Subsequent to the end of the reporting period, final dividend in respect of the year ended 31 December 2016 of HK7.9 cents per share (2015: final dividend in respect of the year ended 31 December 2015 of HK7.4 cents per share), in an aggregate amount of HK\$46,614,000 (2015: HK\$43,423,000) has been proposed by the directors and is subject to approval by the shareholders at the forthcoming general meeting, and is not included as a dividend payable in the consolidated statement of financial position as at 31 December 2016.

#### 5. 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:

2016

2015

	HK\$'000	HK\$'000
Earnings:		
Net profit attributable to the owners of the Company for		
the purpose of basic and diluted earnings per share	252,002	229,052
	2016	2015
	Share(s)	Share(s)
	'000	'000
Number of shares:		
Weighted average number of ordinary shares		
for the purposes of basic earnings per share	588,923	575,986
Effect of dilutive potential ordinary shares:		
Options	2,688	7,026
Weighted average number of ordinary shares		
for the purposes of diluted earnings per share	591,611	583,012

#### 6. TRADE RECEIVABLES

	2016 HK\$'000	2015 HK\$'000
Trade receivables Less: Allowances for bad and doubtful debts	87,453 (384)	108,042 (262)
	87,069	107,780

The credit period on sales of goods is 30 – 120 days. The Group has recognised an allowance for doubtful debts of 100% against all receivables over 365 days because historical experience has been that receivables that are past due beyond 365 days are not recoverable. Allowances for doubtful debts are recognised against trade receivables over 180 days based on estimated irrecoverable amounts determined by reference to past default experience of the counterparty and an analysis of the counterparty's current financial position.

The following is an analysis of trade receivables by age, presented based on the invoice date, which approximates the respective revenue recognition dates, and net of allowance for bad and doubtful debts at the end of the reporting period:

	2016	2015
	HK\$'000	HK\$'000
0 – 30 days	47,314	50,767
31 – 120 days	38,368	50,236
121 – 180 days	1,073	5,839
181 – 365 days	225	934
Over 365 days and under 3 years	89	4
	87,069	107,780

The fair value of the Group's trade receivables at 31 December 2016 approximates to the corresponding carrying amount.

Trade receivables disclosed above include amounts which are past due at the end of the reporting period for which the Group has not recognised an allowance for bad and doubtful debts because there has not been a significant change in credit quality and the amounts are still considered recoverable. The Group does not hold any collateral or other credit enhancements over these balances nor does it have a legal right of offset against any amounts owed by the Group to the counterparty.

#### Aging of receivables that are past due but not impaired

	2016 HK\$'000	2015 HK\$'000
Overdue by:		
1 – 180 days	16,674	20,244
181 – 365 days		257
	16,876	20,501
Movement in allowance for bad and doubtful debts		
	2016	2015
	HK\$'000	HK\$'000
Balance at beginning of the year	262	564
Exchange rate adjustments	(21)	(17)
Provision for (written back of) allowance for		
bad and doubtful debts	143	(285)
Balance at the end of the year	384	262

In determining the recoverability of a trade receivable, the Group considers any change in the credit quality of the trade receivable from the date credit was initially granted up to the end of the reporting period. The concentration of credit risk is limited due to the customer base being large and unrelated.

#### Aging of receivables that are past due and impaired

	2016 HK\$'000	2015 HK\$'000
Overdue by:		
181 – 365 days	203	258
Over 365 days and under 3 years	181	4
	384	262

#### 7. TRADE PAYABLES

The fair value of the Group's trade payables at 31 December 2016 approximates to the corresponding carrying amount.

The following is an aging analysis of trade payables at 31 December 2015 and 2016.

	2016 HK\$'000	2015 HK\$'000
0 – 90 days	36,631	35,523
91 – 180 days	_	1
181 – 365 days	5,618	2,065
Over 365 days	52	32
	42,301	37,621

The average credit period on purchases of certain goods is 90 days. The Group has financial risk policies in place to ensure that all payables are paid within the credit timeframe.

#### MANAGEMENT DISCUSSION AND ANALYSIS

#### **Business review**

The pharmaceutical market environment has been surrounded by persistent challenges and emerging issues arising from unstable and unsettled Chinese economy, regulatory shakeups, drug cost containment measures and healthcare reform turbulences during the fiscal year. Nevertheless, against this backdrop, the Group has exercised cost discipline while continued to invest in future growth, explored and capitalised the potential of pipeline product collaboration opportunities to create values, and end up maintained profitability amid relatively stagnant revenue growth in 2016.

#### Revenue and profit

During the fiscal year, the Group recorded sales revenue of HK\$929,821,000, representing a turnaround performance of 0.8% improvement compared to the same period last year. Sales of licensed-in products was HK\$489,748,000 (2015: HK\$503,361,000) and accounted for 52.7% (2015: 54.6%) of the Group's revenue while sales of proprietary products was HK\$440,073,000 (2015: HK\$418,789,000) and contributed 47.3% (2015: 45.4%) of the Group's revenue.

The proprietary products maintained a steady revenue growth of 5.1% during the fiscal year. While both *Yallaferon*® and *Livaracine*® achieved modest revenue growth of 9.3% as compared to the same period last year, the revenue from the sale of *Slounase*® has fairly improved by 1.3%. In addition, the sale of *Eyprotor*® get off to good start since its relaunch in September 2016 which contributed HK\$3.6 million to the revenue of the Group during the fiscal year.

During the fiscal year, the Group has been able to identify and overcome numerous challenges stemmed from the licensed-in products such as the renewal of Import Drug License of Ferplex® in the first half of 2016. Upon the renewal thereof, sale of Ferplex® resumed normal and rapidly turned its negative trend into a positive 19.0% growth through 2016. In addition, the sale of Remodulin® in its third-year launch has recorded a decent overall growth of 67.2% as compared to the same period last year and contributed HK\$18.1 million to the revenue of the Group. Nevertheless, the aforesaid sales growths therefrom have been offsetting by the underperformance of Carnitene® and Zanidip® which led to an overall decline of, amid narrowed, 2.7% as compared to the same period last year.

Overall gross margin improved in the year under review and hit 71.9% in 2016 (2015: 70.3%), increased by 1.6 percentage points during the year. The Group continued the streamlining process on its sales and marketing efficiency and selling expenses to revenue ratio has further lowered to 22.0% (2015: 27.8%). The Group stay focused on its R&D path and continued to invest in its pipeline products development in cardiovascular, oncology and ophthalmology therapeutic areas. R&D expense during the year under review was HK\$67,886,000, increased by 74.6% from HK\$38,883,000 of the

prior year, and represented 7.3% (2015: 4.2%) to the corresponding yearly revenue. In the meantime, the Group has impaired certain licensing and R&D projects capitalised in the prior years with an aggregate carrying value of HK\$23,324,000 (2015: HK\$8,192,000) in 2016.

The Group continued to achieve savings from the stringent control on sales and marketing expenses. Furthermore, the Group received development grants, development milestone income, compensation for service provided in the registration area and upfront payment for the co-development of a combination product for the treatment of late stage cancers from the third parties and has been recognised as other income during the year under review. As a result, net profit attributable to the owners of the Company was HK\$252,002,000 (2015: HK\$229,052,000), which represented an increase of 10% over last year, and recorded an improved net profit margin of 27.1% (2015: 24.8%).

#### **Quality System, Production and Manufacturing Facilities**

The Group has completed its HK\$80 million investment in the solid dose production facility located on the sixth floor of the factory building in its manufacturing site in Nansha District, Guangzhou, and has successfully obtained the first pharmaceutical manufacturing license for tablet and capsule from the China Food and Drug Administration ("CFDA"). The capacity of this facility is estimated at up to 1 billion tablet/capsule units per year. The first registration batches have been in place in November 2016 and the Group is currently waiting for the stability test data thereof, along with preparatory work for obtaining Good Manufacturing Practice ("GMP") certification, for the submission on or around May 2017.

The Group has budgeted approximately HK\$80 million for the ophthalmic drugs production facility located on the fifth floor of the factory building in Guangzhou Nansha. The facility will be equipped with a state-of-the-art blow-fill-seal line and a multi-dose line and will adhere to the strictest quality standards. The construction has been commenced and is expected to be completed in mid-2017.

In the Hefei site, a new prefilled syringe facility for the upgrading of production capability and to meet all the needs for injection products has been completed during the fiscal year, and the next milestone therefor will be the manufacturing license application. Together with works in the Nansha site, those efforts significantly enhance the Group's manufacturing capability and enable it to move towards the target to become a fully integrated specialty pharma in China.

#### **Drug Development**

*Natulan*<sup>®</sup> registration study for the treatment of advanced Hodgkin's lymphoma in the PRC has been commenced and is expected to enrol 184 patients in total. The first patient has been successfully enrolled in December 2016.

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 the second quarter of 2017.

Phase IIb study of Anfibatide is in good progress. This is a phase IIb multi-centers, double-blinded, paralleled group, placebo controlled clinical study (clinicaltrial.gov registration No.: NCT02495012), led by the Peking University First Hospital. The study aims to evaluate the safety, efficacy, tolerability of Anfibatide in ST-segment elevation myocardial infarction (STEMI) patients who undergo PCI treatment after coronary angiography. 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 required have been enrolled.

In addition, Anfibatide has reached a milestone in its another 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.

During the fiscal year, the CFDA modified its regulations for conducting clinical trials in the PRC, in which the CFDA changed its regulations to allow Phase I or Phase II clinical trials with drug candidates manufactured abroad (including both the active pharmaceutical ingredient and the finished product). This rule change can significantly speed up drug development in China as the local drug development in China may now rely on drugs sourced outside of the country in early clinical trials. This change allowed the Group to accelerate the development activities in China for RGN-259 to treat ocular disorders prior to the completion of the Group's manufacturing capability in ophthalmic products.

The development of the two cardiovascular assets, namely Rostafuroxin and Istaroxime, under CVie Therapeutics Limited, a 56.26% owned subsidiary of the Group, has made significant progress therein during the year under review.

Phase IIb clinical study (Protocol No. CVTCV-001) in Taiwan for Rostafuroxin capsule 50ug, 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*<sup>®</sup>, 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. 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. Istaroxime possesses a dual mode of action, combining inotropic (myocyte contraction) and lusotropic (myocyte relaxation) effects. This is a Phase IIb, multi-center, randomised, double-blinded, parallel and placebo-controlled clinical study targeting a total of 120 patients in Italy (24 patients) and China (96 patients). Phase IIb clinical study in Italy was substantially completed. The Human Genetic Material Collection approval for the study in China has been obtained and the first patient has been successfully enrolled in December 2016. The study in China is expected to be completed by end of 2017. In addition, the Group has initiated a discovery and development collaboration in August 2016 with ScinoPharm Taiwan Limited to identify the new generation compound to Istaroxime for the treatment of acute and chronic heart failure in oral form.

Powder Pharmaceuticals Incorporated ("**PPI**"), an associated company of the Group which currently focusing on the development of two medical devices, namely  $Zingo^{\otimes}$  and Continuous Blood Glucose Monitoring System ("**CGM**"), has also made good progress on its product developments during the year under review.

In August 2016, PPI has successfully completed the first subject of its Clinical Study for CGM in Hong Kong. The clinical study is collaboration between The Chinese University of Hong Kong, EyeSense, and PPI. This clinical study will perform blood glucose clamp study with multiple CGM devices. The study of the first 10 subjects were completed during the year under review at Phase I Clinical Trial Centre of The Chinese University of Hong Kong and PPI is currently working on this study for 2 additional subjects before moving on to the next development step.

In March 2017, Zingo® has been granted by CFDA priority review for its clinical trial application. The clinical program will be commenced soon and is targeted to be approved by CFDA in 2018.

#### **International Partnerships**

In August 2016, the Group has made the first step towards combination therapy clinical trial in oncology area and entered a collaboration agreement with Beijing Shenogen Pharma Group Limited to jointly develop and commercialise a combination product which composed of the Group's licensed-in clinical compound, Pexa-Vec (formerly JX-594), for treatment of late stage cancers.

In September 2016, the Group has made a licensing agreement with a private company in the United States to license a novel therapeutic formulation for treatment of Diabetic Retinopathy ("**DR**") and other diseases of the eye. This is currently in the planning stage of Phase II clinical testing in patients with moderate stage DR in the United States. DR is the damage occurs to the retina due to diabetes and can lead to blindness if it is not treated. Recent studies suggested that 35% people with diabetes have DR globally and more than 20 million people in China are suffering from DR. The Group believes that the addition of this will definitely strengthen its pipeline on ophthalmology diseases area.

In December 2016, the Group has entered into a licensing agreement with TOT Biopharm Company Limited to license TAB014, the monoclonal antibody drug, exclusively within China, Hong Kong and Macau. TAB014 is a new antibody product that can be used to treat wet age-related macular degeneration (wAMD) and other eye diseases

#### Sales and marketing

The Group endure ongoing efforts in knowledge-based promotion and leverage on new media to support physician education and to disseminate scientific information for its products. During the fiscal year, the number of medical practitioners/physicians registered to the Group's fully sponsored China-Europe Echocardiography CME Project (中歐超聲心動圖繼續教育項目) has exceeded 14,000.

Along with the successful completion of transformation of its sales and marketing organisation to improve operation efficiency and extract more value, its efforts made so far have proven to be sustainable and have produced tangible results.

In addition, two new business units have been created to focus on sales and marketing of new and newer products as well as oncology products, respectively, during the year under review. The teams are currently working in full swing to the preparation works for the expected launch of *Mictonorm*® and *Sancuso*® in 2017.

#### **PROSPECTS**

Persistent changes and challenges is expected to follow suit in 2017.

In accordance to the announcement made by the State Council in its February 9, 2017 Circular on Several Opinions Concerning Further Reforms of the Policies Governing Drug Production, Circulation and Usage (the "Circular No. 13"), "Healthcare Affordability" is one of major themes in the coming healthcare reform to be launched in China. Hence, a more price-sensitive environment is expected to remain in this year. In addition, we have seen increasingly challenging operating conditions within the sector which are outside our control. Most of our continuing profits are generated in the PRC market and the value of these earnings during 2016 as expressed in HK Dollars has been eroded by the fall of Renminbi, with the depreciation trend may likely to be continued.

Amid the tough conditions ahead, the Group firmly believes that innovation is the engine that can drive strong and sustainable growth of its future. As another of the major themes in the Circular No. 13 is the determination of the government to accelerate approvals for new drugs and urges generics to pass the quality consistency tests. As a company always relies on new drug development as its engine for growth, the Group could become one of main beneficiaries of these regulatory changes. The favourable aura will help to reduce time to market for the Group's products, broadening the revenue base in the near future. In 2017 the Group expects to obtain five Investigational New Drug ("IND") approvals and two New Drug Application ("NDA") approvals. In addition, six IND submissions and two NDA submissions are planned for this year. Furthermore, six new clinical studies will be initiated, bringing the number of ongoing studies to twelve. The hectic pace of development activities is a reflection of our continual committed as well as our burgeoning confidence in the future.

With the full spectrum of manufacturing capability, comprehensive product pipeline and variety of partnerships, enhanced sales and marketing efficiency, strengthened regulatory expertise and healthy balance sheet, the Group is well positioned to capitalise the opportunities therefrom and to face the coming challenging year.

#### FINAL DIVIDEND

The Board of Directors recommended a final dividend of HK\$0.079 (2015: HK\$0.074) per share to shareholders registered in the Company's Register of Members as at the close of business on Friday, 26 May 2017.

#### ANNUAL GENERAL MEETING

The annual general meeting of the Company was scheduled to be held on Wednesday, 17 May 2017 ("AGM"). The notice of AGM will be issued to shareholders of the Company and published on the Company's website at www.leespharm.com and the designated website of the Stock Exchange at www.hkexnews.hk in due course.

#### **CLOSURE OF REGISTER OF MEMBERS**

#### (a) AGM

The register of members of the Company will be closed from Friday, 12 May 2017 to Wednesday, 17 May 2017 (both days inclusive), during which period no transfer of shares will be effected for determining the shareholders who are entitled to attend and vote at the AGM.

In order to qualify for the right to attend and vote at the AGM, all transfer documents accompanied by the relevant share certificates must be lodged with the share registrar of the Company in Hong Kong, Computershare Hong Kong Investor Services Limited at Shops 1712-1716, 17th Floor, Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong for registration not later than 4:30 p.m. on Thursday, 11 May 2017.

#### (b) Payment of the proposed final dividend

The register of members of the Company will be closed from Thursday, 25 May 2017 to Friday, 26 May 2017 (both days inclusive), during which period no transfer of shares will be effected for determining the shareholders who are entitled for the proposed final dividend for the year ended 31 December 2016.

In order to qualify for the proposed final dividend for the year ended 31 December 2016, all transfers documents accompanied by the relevant share certificates must be lodged with the share registrar of the Company in Hong Kong, Computershare Hong Kong Investor Services Limited at Shops 1712-1716, 17th Floor, Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong for registration not later than 4:30 p.m. on Wednesday, 24 May 2017.

Subject to shareholders' approval of the proposed final dividend of shares at the AGM, the final dividend is payable to shareholders whose names appear on the register of members of the Company at the close of business on Friday, 26 May 2017. The final dividend will be paid on Thursday, 15 June 2017.

#### 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 year ended 31 December 2016.

#### MODEL CODE FOR DIRECTORS' SECURITIES TRANSACTIONS

During the year ended 31 December 2016, the Company has adopted the Model Code for Securities Transactions by Directors of Listed Issuers ("Model Code") set out in Appendix 10 to the Rules Governing the Listing of Securities on the Stock Exchange ("Listing Rules"). The Company has made specific enquiries to all Directors, and the Company was not aware of any non-compliance with such Model Code and required standard of dealing throughout the year ended 31 December 2016.

#### CORPORATE GOVERNANCE PRACTICES

The Company has complied with the Code on Corporate Governance Practices (the "Code") as set out in Appendix 14 of the Listing Rules throughout the year ended 31 December 2016, with deviation from provision A.5 of the Code which stipulates that every listed company should establish a nomination committee. Detailed corporate governance practices and considered reasons for the deviation from provision A.5 of the Code will be stated in the annual report of the Company for the year ended 31 December 2016.

#### **REVIEW OF ANNUAL RESULTS**

The Group's annual results (including the audited consolidated financial statements) for the year ended 31 December 2016 including the accounting principles and practices adopted have been reviewed by the Audit Committee which consists of three independent non-executive Directors, namely, Dr. Chan Yau Ching, Bob, Mr. Lam Yat Cheong and Dr. Tsim Wah Keung, Karl.

# REVIEW OF PRELIMINARY ANNOUNCEMENT OF RESULTS BY INDEPENDENT AUDITOR

The figures in respect of this preliminary announcement of the Group's results for the year ended 31 December 2016 have been agreed by the Group's independent auditor, HLM CPA Limited, to the amounts set out in the Group's audited consolidated financial statements for the year. The work performed by HLM CPA Limited in this respect did not constitute an assurance engagement in accordance with Hong Kong Standards on Auditing, Hong Kong Standards on Review Engagements or Hong Kong Standards on Assurance Engagements issued by the Hong Kong Institute of Certified Public Accountants and consequently, no assurance has been expressed by HLM CPA Limited on this preliminary results announcement.

#### PUBLICATION OF FINANCIAL INFORMATION

The annual report of the Company for the year ended 31 December 2016 containing all the detailed information will be dispatched to the shareholders of the Company and published on the Company's website at www.leespharm.com and the designated website of the Stock Exchange at www.hkexnews.hk in due course.

By order of the Board

Lee's Pharmaceutical Holdings Limited

Lee Siu Fong

Chairman

Hong Kong, 23 March 2017

As at the date of this announcement, 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.