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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)

THIRD QUARTERLY RESULTS FOR THE NINE MONTHS ENDED 30 SEPTEMBER 2019

FINANCIAL HIGHLIGHT						
	Three months ended		Change	Nine months ended		Change
	30 September 2019	2018		30 September 2019	2018	
	HK\$'000	HK\$'000		HK\$'000	HK\$'000	
Revenue	306,334	299,202	+2.4%	913,868	866,925	+5.4%
Gross profit	198,584	194,456	+2.1%	600,911	572,689	+4.9%
Profit attributable to the owners of the Company	42,050	71,699	-41.4%	80,344	197,470	-59.3%
	HK cents	HK cents		HK cents	HK cents	
Earnings per share						
Basic	7.10	12.11	-41.4%	13.57	33.37	-59.3%
Diluted	7.10	12.06	-41.1%	13.55	33.15	-59.1%

* For identification purpose only

QUARTERLY FINANCIAL STATEMENTS

The directors (the “**Directors**”) of Lee’s Pharmaceutical Holdings Limited (the “**Company**”) present herewith the unaudited consolidated quarterly financial results (the “**Quarterly Results**”) of the Company and its subsidiaries (collectively, the “**Group**”) for the nine months ended 30 September 2019, together with the comparative figures for the corresponding period in 2018. The Quarterly Results are unaudited, but have been reviewed by the Company’s auditor, HLM CPA Limited (the “**Auditor**”) in accordance with Hong Kong Standard on Review Engagements 2410 “Review of Interim Financial Information Performed by the Independent Auditor of the Entity” issued by the Hong Kong Institute of Certified Public Accountants (the “**HKICPA**”). The audit committee of the Company has also reviewed with the management and the Auditor the Quarterly Results before recommending it to the board of Directors (the “**Board**”) for approval.

BUSINESS REVIEW

Renminbi plunged beyond 7 per US dollar has become a new normal as the escalating trade battle between China and the United States of America seems to be no end in sight, coupled with the persistent inflationary pressure in the operating environment in China have created challenging operating environments during the period under review. The revenue growth of the Group during the third quarter of this year was stagnant as the sale performance of individual products was mixed. Together with the escalating administrative costs as a reflection of the expanded business scale in Nansha site, the profitability of the Group during the quarter under review was affected as a result.

Taking into account the depreciation of Renminbi of 3.8% during the quarter under review, the Group’s reported revenue for the third quarter of this year was HK\$306,334,000 (three months ended 30 September 2018: HK\$299,202,000), which represented a quarter-on-quarter growth of 2.4%. Sales of Ferplex[®], Zanidip[®] and Yallaferon[®] for the third quarter of this year registered increase of 17.8%, 19.1% and 29.7%, respectively. Other newer products such as Rasilez[®], GaslonN[®] and Mictonorm[®] have also started making contribution to the growth during the third quarter of this year. But the overall growth was dragged down by the underperformance of Carnitene[®], Livaracine[®] and Slounase[®] sales. For the nine months ended 30 September 2019, the Group’s revenue reached HK\$913,868,000 (nine months ended 30 September 2018: HK\$866,925,000), increased by 5.4% over the same period last year.

Sales of licensed-in products accounted for 56.6% (nine months ended 30 September 2018: 53.6%) of the Group’s revenue while sales of proprietary products contributed 43.4% (nine months ended 30 September 2018: 46.4%) of the Group’s revenue.

The Group’s gross profit increased by HK\$28,222,000 or 4.9% during the first nine months of 2019. The Group’s gross profit for the third quarter of this year increased by HK\$4,128,000 or 2.1% over the same quarter last year. During the quarter under review, the Group’s overall gross profit margin held at 64.8%, slightly decreased by 0.2 percentage point as compare to 65.0% achieved in the same quarter last year. The Group’s gross profit margin for the nine months ended 30 September 2019 dropped to 65.8% from 66.1%, represented a decrease of 0.3 percentage point compared with same period last year.

The Group held its selling expenses to revenue ratio of 18.8% during the first nine months of this year, represented an increase of 1.2 percentage points compared with same period last year which mainly attributable to the addition preparation work done for the new products' pre-launch. The Group's efforts to restructure and rejuvenate its direct sales team remained intact during the quarter under review, and the revenue from direct sales has recorded a quarter-on-quarter growth of 36.5% during the third quarter of this year. On the other hand, the Group continued to uphold the developing of innovative drugs in order to broaden the Group's future growth opportunity. During the first nine months of 2019, the Group's investment in research and development ("**R&D**") expenses has increased 21.6% to HK\$116,457,000 from HK\$95,807,000 of the same period last year, which represented 12.7% of revenue during the period under review. Overall, the Group invested HK\$229,245,000 in R&D in the first nine months of 2019, including expensed and capitalised parts, which was equivalent to 25.1% of the Group's revenue. The Group's commitment to R&D has also brought the number one ranking in the "Most Innovative Small and Medium-sized Pharmaceutical Enterprises Award on the Asia Pacific Region 2019" by Clarivate Analytics, a digital health intelligence solution provider during the quarter under review. Administrative expenses has also increased due to the expanded business scale in Nansha site. Combined with the full impairment of the R&D costs amounted to HK\$108,564,000 by China Oncology Focus Limited ("**COFL**"), a 65% owned subsidiary of the Group, in relations to the Pexa-Vec global Phase III clinical trial for advanced liver cancer (the "**PHOCUS Study**") previously capitalised has been made during the second quarter of this year, net profit attributable to the owners of the Company for the first nine months of 2019 was HK\$80,344,000, decreased by 59.3% as compared to the same period last year.

The Group's solid dosage production facilities and ophthalmic drug production facilities in Nansha site are already fully operational with valid manufacturing licenses for various kinds of products. During the period under review, batch samples such as Apremilast tablets, Zotiraciclib (TG02) capsules, Gimitecan liquid capsules, Mictonorm[®] capsules and Epinastine tablets have been manufactured for GMP application and clinical trials. And the manufacturing of Tecarfarin tablet batch samples for GMP application and clinical trials is in progress. In addition, the transfer of Aliskiren manufacturing technology has been completed and batch samples have been manufactured and submitted for GMP application. In Hefei site, the upgrading of facilities for APIs such as Nadroparin calcium (那曲肝素鈣) has been completed during the period under review.

In order to restore revenue growth and improve profitability, the Group is actively introducing and developing new products in order to strengthen the overall product mix and to bring value in the short and medium term.

During the period under review and up to date, the Group's applications for Import Drug License ("**IDL**"), namely Trazodone[®], Prulifloxacin, INOMax[®] and Zingo[®], are under review by the Centre for Drug Evaluation (the "**CDE**").

The Group's applications for Abbreviated New Drug Application ("**ANDA**"), namely Sodium Phenylbutyrate Tablet, Sodium Phenylbutyrate Granule, Treprostinil, Fondaparinux, Nadroparin Calcium, Azilsartan and Bimatoprost (貝美前列素滴眼液), were also in good progress. Among these ANDA submissions, Sodium Phenylbutyrate Granule and Sodium Phenylbutyrate Tablet are under review by the CDE. For Treprostinil, the Group is actively communicating with the CDE for its acceptance for priority review. The bioequivalence studies of Fondaparinux have been completed and is pending for ANDA approval. And Nadroparin Calcium, Azilsartan and Bimatoprost are currently pending for the review by the CDE.

In addition, the Group is also actively introducing and developing other products such as Apremilast, Leuprorelin, and Natulan® which aim at optimising its product mix in the medium term.

Emerging from the failure of the PHOCUS Study of the Group's oncology R&D arm, COFL has conducted a pre-IND meeting with the CDE for the combination Phase Ib/II trial of ZKAB001 and Pexa-Vec to treat melanoma and has reached an agreement for the IND application with sufficient scientific basis.

In addition, COFL remained focused on its other ongoing clinical trial programs and continued its efforts to reach the destinations thereof, and ZKAB001 (PD-L1) monotherapy in recurrent and metastatic cervical cancer is currently the core development program of COFL. The trial for cervical cancer is led by Doctor Lingying Wu as the principal investigator. The trial consists of two phases, a traditional open labeled 3+3 dose escalation phase followed by an expansion phase. During the dose escalation phase, 3 doses, 5mg/kg, 10mg/kg, 15mg/kg, was tested with 14 days administration cycle in patients with recurrent and metastatic cervical cancer, and 5mg/kg was selected for the expansion phase.

So far the outcome of the clinical study of ZKAB001 (5mg/kg) for cervical cancer has been very encouraging. To date, 16 patients have been enrolled of whom 9 patients were examined, and 1 of whom had complete response (CR) and 4 of whom had partial response (PR), which indicated an implied Objective Response Rate (“**ORR**”) of 55.5% among the examined patients. With reference to a similar study of Pembrolizumab under Keynote-158 conducted by Merck and Co., Inc. in the United States in 2018, 98 patients were enrolled with an ORR of 12.2%, and in turn Pembrolizumab has successfully obtained approval for patients with recurrent and metastatic cervical cancer from the U.S. Food and Drug Administration using the results thereof. Therefore, COFL is currently expanding a registration enabling study and to enroll additional 50 patients and to involve 15 clinical trial centers in China. The patient enrollment is expected to be completed by the end of 2019 and the application to the National Medical Products Administration (“**NMPA**”) shall be made in 2020 if the results are positive which could lead to conditional approval of ZKAB001 for this indication.

To date, two other Phase I clinical trials for ZKAB001 in urothelial cancer and sarcoma have been completed. Based on the results thereof, a pivotal Phase III study of ZKAB001 in combination with chemotherapy for the first line treatment of urothelial cancer and a pivotal Phase III study of ZKAB001 monotherapy for maintenance stage of sarcoma after its first line treatment (to compare the event-free survival (EFS)) will be initiated early next year.

Following the completion of series A financing of the Group's ophthalmology R&D arm, China Ophthalmology Focus Limited (“**COPFL**”) is now working at full steam on the R&D of its pipeline products.

During the period under review and to date, COPFL has successfully completed a Phase II trial of Cyclosporine A (“**CsA**”) Ophthalmic Gel for the treatment of dry eye syndrome (the “**DES**”) in China (clinicaltrials.gov registration No.: NCT03676335), with the topline data show that the experimental drug has similar or a trend towards better efficacy than that of the marketed CsA Ophthalmic Emulsion. COPFL plans to meet with the CDE to discuss and agree upon a Phase III protocol of the CsA Ophthalmic Gel trial. The pivotal study is expected to initiate patient recruitment in early 2020.

In addition, the registration enabling Phase III study of the Group's in-house product, Adapalene and Clindamycin combination gel for acne, which is currently administered by COPFL and is led by Professor Gu Heng from the Hospital for Skin Diseases, Chinese Academy of Medical Sciences and involved 28 dermatology centers in China has successfully completed patient enrollment of 1,617 patients. Following the treatment of the last patient that is expected in early February 2020, the readout of the topline data will be made available and New Drug Application submission is expected during the first half of 2020.

With over 30 approved studies currently in progress, the Group is confident to establish a solid foundation for growth in the foreseeable future.

PROSPECT

Notwithstanding that the Group will continue to face different challenges towards the end of this year such as stagnant sales growth for certain products, downward pressure on profit margins and probable Renminbi depreciation, it is expected that more concrete progress could be reflected in the medium term given the Group's strong business fundamentals, and the Group remains cautiously optimistic in respect of its prospects.

Regarding the measure taken to improve the revenue growth, the Group has actively reforming and enhancing its sales distribution to improve efficiency and boost sales. Under the 2019 National Reimbursement Drug List published by National Healthcare Security Administration which will become effective from 1 January 2020, the Group's key products such as Carnitene[®], Znidip[®], Livaracine[®] and Slounase[®] will be remained therein and therefore will provide a stable revenue source for the Group in the short to medium term. Alongside the products recently launched such as Sancuso[®], Probiotics VSL#3[®], Episil[®] and Rasilez[®], these are expected to become additional growth drivers of the Group. In addition, the newly set up "Direct-to-Patient" business department may enable the Group to unlock the potential and create more value from selected products such as Ferplex[®] and Yallaferon[®] via new distribution channel. Moreover, the Group has a total of 14 IDL and ANDA pending for approval by the NMPA in the foreseeable future which may become new fuel for revenue growth in the medium to long term.

At the corporate level, the Group believes that having greater clarity in pharma business from biotech entrepreneurship by means of the proper employment of capital market platform could bring about additional value to the Group. With the completion of the Series A financing of COPFL, the Group's ophthalmology R&D arm, and together with good progress on its clinical trial programs made to date such as the completion of a Phase II clinical trial of CsA Ophthalmic Gel in China, COPFL has moved a big stride forward towards its spinning-off plan. In respect of COFL, the Group's oncology R&D arm, the attention has been shifting to its registration enabling expansional study of ZKAB001 for recurrent and metastatic cervical cancer in an aim to restore the overall value of COFL and to put its fund raising and spinning-off plans back on track after the disappointing clinical trial results in its PHOCUS Study.

The Group believes that the above corporate restructuring of ophthalmology and oncology R&D arms will diversify the risk and bring cost savings thereto. The Group will allow the savings to be invested in nearer term growth opportunities in other therapeutic areas, such as cardiovascular diseases, paediatrics, rare diseases and women health, and to put the Group back on the road to growth and enhance the shareholders' value.

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

CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS

For the three months and nine months ended 30 September 2019

		For the three months ended 30 September		For the nine months ended 30 September	
	<i>Notes</i>	2019 <i>HK\$'000</i> (unaudited)	2018 <i>HK\$'000</i> (unaudited)	2019 <i>HK\$'000</i> (unaudited)	2018 <i>HK\$'000</i> (unaudited)
Revenue	3	306,334	299,202	913,868	866,925
Cost of sales		(107,750)	(104,746)	(312,957)	(294,236)
Gross profit		198,584	194,456	600,911	572,689
Other income	4	10,882	11,305	41,334	32,022
Other gains and losses, net		(2,968)	9,841	(112,932)	18,831
Selling and distribution expenses		(63,593)	(50,518)	(171,656)	(152,685)
Administrative expenses		(60,331)	(43,843)	(165,029)	(123,416)
Reversal of (provision for) impairment loss on financial assets, net		94	417	(669)	122
Research and development expenses		(37,645)	(31,961)	(116,457)	(95,807)
Profit from operations		45,023	89,697	75,502	251,756
Finance costs		(1,801)	(1,437)	(4,492)	(3,387)
Share of results of associates		(3,024)	(3,507)	(8,180)	(11,392)
Profit before taxation		40,198	84,753	62,830	236,977
Taxation	5	(5,224)	(17,986)	(34,672)	(52,561)
Profit for the period		34,974	66,767	28,158	184,416
Attributable to:					
Owners of the Company		42,050	71,699	80,344	197,470
Non-controlling interests		(7,076)	(4,932)	(52,186)	(13,054)
		34,974	66,767	28,158	184,416
		<i>HK cents</i>	<i>HK cents</i>	<i>HK cents</i>	<i>HK cents</i>
Earnings per share:					
Basic	7	7.10	12.11	13.57	33.37
Diluted	7	7.10	12.06	13.55	33.15

CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the three months and nine months ended 30 September 2019

	For the three months ended 30 September		For the nine months ended 30 September	
	2019 <i>HK\$'000</i> (unaudited)	2018 <i>HK\$'000</i> (unaudited)	2019 <i>HK\$'000</i> (unaudited)	2018 <i>HK\$'000</i> (unaudited)
Profit for the period	34,974	66,767	28,158	184,416
Other comprehensive expense:				
Items that may be reclassified subsequently to profit or loss:				
Exchange differences on translation of financial statements of overseas subsidiaries	(44,740)	(54,188)	(37,284)	(78,563)
Share of associates' exchange reserve	-	(9)	-	(1,115)
Item that will not be reclassified subsequently to profit or loss:				
Fair value changes of financial assets at fair value through other comprehensive income	(61,324)	(29,265)	(99,995)	(25,768)
Other comprehensive expense for the period, net of tax	(106,064)	(83,462)	(137,279)	(105,446)
Total comprehensive (expense) income for the period	<u>(71,090)</u>	<u>(16,695)</u>	<u>(109,121)</u>	<u>78,970</u>
Total comprehensive (expense) income for the period attributable to:				
Owners of the Company	(57,437)	(7,865)	(48,529)	93,569
Non-controlling interests	(13,653)	(8,830)	(60,592)	(14,599)
	<u>(71,090)</u>	<u>(16,695)</u>	<u>(109,121)</u>	<u>78,970</u>

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

For the nine months ended 30 September 2019

	Attributable to the owners of the Company										Attributable to non- controlling interests	Total
	Share capital <i>HK\$'000</i>	Share premium <i>HK\$'000</i>	Merger difference <i>HK\$'000</i>	Share- based compensation reserve <i>HK\$'000</i>	Other reserves <i>HK\$'000</i>	Treasury shares <i>HK\$'000</i>	Investments revaluation reserve <i>HK\$'000</i>	Exchange reserve <i>HK\$'000</i>	Retained profits <i>HK\$'000</i>	Sub- total <i>HK\$'000</i>		
At 1 January 2019 (audited)	29,601	731,771	9,200	18,661	64,787	-	33,726	(80,236)	1,403,033	2,210,543	27,526	2,238,069
Employee share option benefits	-	-	-	4,049	-	-	-	-	-	4,049	-	4,049
Exercise of share options	14	1,828	-	(447)	-	-	-	-	-	1,395	-	1,395
Share of reserve of an associate	-	-	-	-	41	-	-	-	-	41	-	41
Share of options lapsed in an associate	-	-	-	-	(1)	-	-	-	1	-	-	-
Gain on deemed disposal of interests in subsidiaries	-	-	-	-	92,545	-	-	-	-	92,545	218,412	310,957
Capital contribution from non-controlling interests	-	-	-	-	-	-	-	-	-	-	2,192	2,192
Purchase of own shares	-	-	-	-	-	(8,655)	-	-	-	(8,655)	-	(8,655)
Profit (loss) for the period	-	-	-	-	-	-	-	-	80,344	80,344	(52,186)	28,158
Other comprehensive expense for the period												
– Exchange differences on translation of financial statements of overseas subsidiaries	-	-	-	-	-	-	-	(33,585)	-	(33,585)	(3,699)	(37,284)
– Fair value changes of financial assets at fair value through other comprehensive income	-	-	-	-	-	-	(95,288)	-	-	(95,288)	(4,707)	(99,995)
Total comprehensive (expense) income for the period	-	-	-	-	-	-	(95,288)	(33,585)	80,344	(48,529)	(60,592)	(109,121)
2018 final dividend paid	-	-	-	-	-	-	-	-	(49,754)	(49,754)	-	(49,754)
2019 interim dividend paid	-	-	-	-	-	-	-	-	(10,662)	(10,662)	-	(10,662)
At 30 September 2019 (unaudited)	<u>29,615</u>	<u>733,599</u>	<u>9,200</u>	<u>22,263</u>	<u>157,372</u>	<u>(8,655)</u>	<u>(61,562)</u>	<u>(113,821)</u>	<u>1,422,962</u>	<u>2,190,973</u>	<u>187,538</u>	<u>2,378,511</u>

Attributable to the owners of the Company

	Share capital HK\$'000	Share premium HK\$'000	Merger difference HK\$'000	Share-based compensation reserve HK\$'000	Other reserves HK\$'000	Treasury shares HK\$'000	Investments revaluation reserve HK\$'000	Exchange reserve HK\$'000	Retained profits HK\$'000	Sub-total HK\$'000	Attributable to non-controlling interests HK\$'000	Total HK\$'000
At 1 January 2018 (audited)	29,547	724,868	9,200	15,368	41,407	-	(30,421)	(31,809)	1,046,186	1,804,346	(7,414)	1,796,932
Employee share option benefits	-	-	-	3,700	-	-	-	-	-	3,700	-	3,700
Exercise of share options	54	6,903	-	(1,582)	-	-	-	-	-	5,375	-	5,375
Share of share-based compensation reserve of a subsidiary	-	-	-	17	-	-	-	-	-	17	13	30
Share of reserve of an associate	-	-	-	-	42	-	-	-	-	42	-	42
Share of options lapsed in an associate	-	-	-	-	(3)	-	-	-	3	-	-	-
Gain on partial disposal of interests in a subsidiary	-	-	-	-	24,185	-	-	-	-	24,185	(4,024)	20,161
Capital contribution from non-controlling interests	-	-	-	-	-	-	-	-	-	-	1,954	1,954
Profit (loss) for the period	-	-	-	-	-	-	-	-	197,470	197,470	(13,054)	184,416
Other comprehensive (expense) income for the period												
- Exchange differences on translation of financial statements of overseas subsidiaries	-	-	-	-	-	-	-	(78,649)	-	(78,649)	86	(78,563)
- Share of associates' exchange reserve	-	-	-	-	(1,115)	-	-	-	-	(1,115)	-	(1,115)
- Fair value changes of financial assets at fair value through other comprehensive income	-	-	-	-	-	-	(24,137)	-	-	(24,137)	(1,631)	(25,768)
Total comprehensive (expense) income for the period	-	-	-	-	(1,115)	-	(24,137)	(78,649)	197,470	93,569	(14,599)	78,970
2017 final dividend paid	-	-	-	-	-	-	-	-	(41,439)	(41,439)	-	(41,439)
2018 interim dividend paid	-	-	-	-	-	-	-	-	(20,129)	(20,129)	-	(20,129)
At 30 September 2018 (unaudited)	29,601	731,771	9,200	17,503	64,516	-	(54,558)	(110,458)	1,182,091	1,869,666	(24,070)	1,845,596

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

For the nine months ended 30 September 2019

1. BASIS OF PREPARATION

The unaudited condensed consolidated financial statements have been prepared in accordance with Hong Kong Accounting Standards (“**HKASs**”) issued by the Hong Kong Institute of Certified Public Accountants (the “**HKICPA**”) as well as with the applicable disclosure requirements of Appendix 16 to the Rules Governing the Listing of Securities (the “**Listing Rules**”) on The Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”).

2. PRINCIPAL ACCOUNTING POLICIES

The unaudited condensed consolidated financial statements have been prepared on the historical cost basis except for certain financial instruments that are measured at fair values as appropriate.

The unaudited condensed consolidated financial statements do not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Group’s annual financial statements for the year ended 31 December 2018.

The accounting policies and methods of computation used in preparing the unaudited condensed consolidated financial statements for the nine months ended 30 September 2019 are consistent with those used in the Group’s annual financial statements for the year ended 31 December 2018 except as described below.

In the current period, the Group has applied, for the first time, the following new and amendments to HKASs and Hong Kong Financial Reporting Standards (“**HKFRSs**”) issued by the HKICPA that are relevant for the preparation of the Group’s unaudited condensed consolidated financial statements:

HKFRS 16	Leases
HK (IFRIC) – Int 23	Uncertainty over Income Tax Treatments
Amendments to HKAS 19	Plan Amendments, Curtailment or Settlement
Amendments to HKAS 28	Long-term Interests in Associates and Joint Ventures
Amendments to HKFRS 9	Prepayment Features with Negative Compensation
Amendments to HKFRSs	Annual Improvement to HKFRSs 2015 – 2017 Cycle

Except as described below, the application of the other new and amendments to HKASs and HKFRSs in the current period has had no material effect on the amounts reported in these unaudited condensed consolidated financial statements and/or disclosures set out in these unaudited condensed consolidated financial statements.

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

HKFRS 17	Insurance Contracts ³
Amendments to HKAS 1 And HKAS 8	Definition of Material ¹
Amendments to HKFRS 3	Definition of a Business ²
Amendments to HKFRS 10 and HKAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture ⁴

¹ Effective for annual periods beginning on or after 1 January 2020, with earlier application permitted

² Effective for business combinations and asset acquisitions for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after 1 January 2020, with earlier application permitted

³ Effective for annual periods beginning on or after 1 January 2021, with earlier application permitted

⁴ Effective for annual periods beginning on or after a date to be determined

The Group has already commenced an assessment of the impact of these new and 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 positions.

Impacts and changes in accounting policies of application on HKFRS 16 “Leases”

The Group has applied HKFRS 16 for the first time in the current period. HKFRS 16 introduces a comprehensive model for the identification of lease arrangements and accounting treatments for both lessors and lessees which superseded HKAS 17 “Leases” and the related interpretations.

Under HKFRS 16, distinctions of operating leases and finance leases are removed for lessee accounting and is replaced by a model where a right-of-use asset and a corresponding liability have to be recognised for all leases by lessees, except for short-term leases and leases of low value assets.

The right-of-use asset is initially measured at cost and subsequently measured at cost (subject to certain exceptions) less accumulated depreciation and impairment losses, adjusted for any remeasurement of the lease liability. The lease liability is initially measured at the present value of the lease payments that are not paid at that date. Subsequently, the lease liability is adjusted for interest and lease payments, as well as the impact of lease modification, amongst others.

Other than certain requirements which are also applicable to lessor, HKFRS 16 substantially carries forward the lessor accounting requirements in HKAS 17 and continues to require a lessor to classify a lease either as an operating lease or a finance lease.

The Group has elected the practical expedient to apply HKFRS 16 to contracts that were previously identified as lease applying HKAS 17 and HK(IFRIC) – Int 4 “Determining whether an Arrangement contains a Lease” and not apply this standard to contracts that were not previously identified as containing a lease applying HKAS 17 and HK(IFRIC) – Int 4. Therefore, the Group will not reassess whether the contracts are, or contain a lease which already existed prior to the date of initial application, i.e. 1 January 2019. Furthermore, the Group has opted the modified retrospective approach for the application of HKFRS 16 as lessee and will recognise the cumulative effect of initial application to opening retained profits without restating comparative information.

Based on the allowed practical expedients under HKFRS 16, the Group has elected not to apply the requirements of HKFRS 16 in respect of recognition of lease liability and right-of-use assets to leases for which the lease term ends within twelve months of the date of initial application.

The summary of net impacts of HKFRS 16 on the condensed consolidated statement of profit or loss of the Group for the nine months ended 30 September 2019 are set out as below. Line items that were not affected by the changes have not been included.

	As per HKFRS 16 HK\$'000 (unaudited)	As per HKAS 17 HK\$'000 (unaudited)	Impact due to change HK\$'000 (unaudited)
Cost of sales	<u>312,957</u>	<u>312,964</u>	<u>(7)</u>
Administrative expenses	<u>165,029</u>	<u>165,188</u>	<u>(159)</u>
Research and development expenses	<u>116,457</u>	<u>116,479</u>	<u>(22)</u>
Finance costs	<u>4,492</u>	<u>4,289</u>	<u>203</u>
Profit for the period	<u>28,158</u>	<u>28,173</u>	<u>(15)</u>
Profit (loss) for the period attributable to:			
Owners of the Company	<u>80,344</u>	<u>80,310</u>	<u>34</u>
Non-controlling interests	<u>(52,186)</u>	<u>(52,137)</u>	<u>(49)</u>
	<u>28,158</u>	<u>28,173</u>	<u>(15)</u>
	<i>HK cents</i>	<i>HK cents</i>	<i>HK cents</i>
Earnings per share			
Basic	<u>13.57</u>	<u>13.56</u>	<u>0.01</u>
Diluted	<u>13.55</u>	<u>13.55</u>	<u>–</u>

3. REVENUE

The principal activities of the Group are the development of, manufacturing of and sales and marketing of pharmaceutical products. During the period, revenue represents the net amount received and receivable for goods sold by the Group to outside customers and are recognised at point in time as follows:

Business segments

	For the three months ended 30 September		For the nine months ended 30 September	
	2019 HK\$'000 (unaudited)	2018 HK\$'000 (unaudited)	2019 HK\$'000 (unaudited)	2018 HK\$'000 (unaudited)
Proprietary products	125,957	135,062	396,965	402,066
Licensed-in products	180,377	164,140	516,903	464,859
	<u>306,334</u>	<u>299,202</u>	<u>913,868</u>	<u>866,925</u>

Geographical segments

During the nine months ended 30 September 2019 and 2018, 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 is presented.

4. OTHER INCOME

	For the three months ended 30 September		For the nine months ended 30 September	
	2019 HK\$'000 (unaudited)	2018 HK\$'000 (unaudited)	2019 HK\$'000 (unaudited)	2018 HK\$'000 (unaudited)
Interest income on:				
Bank deposits	2,898	1,243	6,118	4,944
Guaranteed investments measured at amortised cost	–	–	–	112
Loan receivables	232	828	718	828
Advance to associates	386	350	1,141	813
	<u>3,516</u>	<u>2,421</u>	<u>7,977</u>	<u>6,697</u>
Total interest income	3,516	2,421	7,977	6,697
Development grants	1,090	1,065	8,123	6,575
Incentives from vendor	–	–	2,116	–
Research and development service income	5,888	6,744	22,123	16,945
Sundry income	388	1,075	995	1,805
	<u>10,882</u>	<u>11,305</u>	<u>41,334</u>	<u>32,022</u>

5. TAXATION

	For the three months ended 30 September		For the nine months ended 30 September	
	2019 <i>HK\$'000</i> (unaudited)	2018 <i>HK\$'000</i> (unaudited)	2019 <i>HK\$'000</i> (unaudited)	2018 <i>HK\$'000</i> (unaudited)
Current tax				
Hong Kong Profits Tax	3,046	16,300	18,857	21,883
PRC Enterprise Income Tax	(743)	5,258	5,387	24,487
	2,303	21,558	24,244	46,370
Under (over) provision in prior years				
PRC Enterprise Income Tax	46	3	(3,048)	(287)
Deferred tax				
Origination and reversal of temporary differences	2,875	(3,575)	13,476	6,478
	5,224	17,986	34,672	52,561

Hong Kong Profits Tax is calculated at 16.5% of the estimated assessable profits for the three and nine months ended 30 September 2018. On 21 March 2018, the Hong Kong Legislative Council passed The Inland Revenue (Amendment) (No. 7) Bill 2017 (the “**Bill**”) which introduces the two-tiered profits tax rates regime. The Bill was signed into law on 28 March 2018 and was gazetted on the following day. Under the two-tiered profits tax rates regime, the first HK\$2 million of assessable profits of qualifying corporations will be taxed at 8.25%, and assessable profits above HK\$2 million will be taxed at 16.5%. The assessable profits of corporations not qualifying for the two-tiered profits tax rates regime will continue to be taxed at a flat rate of 16.5%. The two-tiered profits tax rates regime is applicable to the Group for the three months and nine months ended 30 September 2019. Accordingly, the Hong Kong Profits Tax for the three months and nine months ended 30 September 2019 is calculated at 8.25% on the first HK\$2 million of the estimated assessable profits and at 16.5% on the estimated assessable profits above HK\$2 million.

Tax arising in the PRC is calculated at the tax rates prevailing in the PRC. Taxation arising in other jurisdictions is calculated at the tax rate prevailing in the relevant jurisdictions.

6. DIVIDENDS

An interim dividend for the six months ended 30 June 2019 of HK\$0.018 (for the six months ended 30 June 2018: HK\$0.034) per share, totalling approximately HK\$10,662,000 (for the six months ended 30 June 2018: approximately HK\$20,129,000) was declared on 29 August 2019 and paid on 30 September 2019.

The Board does not recommend the payment of other interim dividend for the nine months ended 30 September 2019 (nine months ended 30 September 2018: nil).

7. EARNINGS PER SHARE

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

	For the three months ended 30 September		For the nine months ended 30 September	
	2019	2018	2019	2018
	HK\$'000	HK\$'000	HK\$'000	HK\$'000
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
<i>Earnings:</i>				
Net profit attributable to the owners of the Company for the purpose of basic and diluted earnings per share	42,050	71,699	80,344	197,470
	592,309	592,029	592,242	591,777
	121	2,333	516	3,956
	592,430	594,362	592,758	595,733

	For the three months ended 30 September		For the nine months ended 30 September	
	2019	2018	2019	2018
	Share(s)'000	Share(s)'000	Share(s)'000	Share(s)'000
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
<i>Number of shares:</i>				
Weighted average number of ordinary shares for the purpose of basic earnings per share	592,309	592,029	592,242	591,777
Effect of dilutive potential ordinary shares:				
Options	121	2,333	516	3,956
Weighted average number of ordinary shares for the purpose of diluted earnings per share	592,430	594,362	592,758	595,733

8. RELATED PARTY TRANSACTIONS

During the reporting 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) Transactions with associates

	For the nine months ended 30 September	
	2019 HK\$'000 (unaudited)	2018 HK\$'000 (unaudited)
Interest income	1,141	813
Service income	–	9,960
Purchase of goods	–	57
Sales of goods	–	1,483
	<u>1,141</u>	<u>12,313</u>

(b) Compensation of key management personnel

The remuneration of directors and other members of key management during the period were as follows:

	For the nine months ended 30 September	
	2019 HK\$'000 (unaudited)	2018 HK\$'000 (unaudited)
Short-term employee benefits	14,627	13,515
Share-based payments	2,224	1,803
Retirement and other post-employment benefits	12,030	9,791
– Defined contribution plan	30	41
– Retirement benefits	12,000	9,750
	<u>28,881</u>	<u>25,109</u>

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

During the nine months ended 30 September 2019, there is approximately HK\$3,144,000 (nine months ended 30 September 2018: approximately HK\$250,000) was donated to Kanya Lee Scholarship. Dr. Li Xiaoyi, director of the Company, is also a member of key management of Kanya Lee Scholarship and Kanya Lee Scholarship is considered as a related party to the Group.

(d) **Transaction with Lee’s Techno-Net Limited (“Techno-Net”)**

In April 2019, the Company, through its wholly-owned subsidiary Lee’s Pharmaceutical (HK) Limited, acquired the entire equity interest in Dreamboat Ventures Limited from Techno-Net at total consideration of HK\$2,400,000. Ms. Lee Siu Fong and Ms. Leelalertsuphakun Wanee, directors of the Company, are the common directors of Techno-Net and Techno-Net is considered as a related party to the Group.

9. CAPITAL COMMITMENTS

	At 30 September 2019 <i>HK\$’000</i> (unaudited)	At 31 December 2018 <i>HK\$’000</i> (audited)
Capital commitments contracted for in respect of:		
Investment in financial assets at fair value through other comprehensive income and financial assets at fair value through profit or loss	33,012	27,780
Intangible assets – license fee and development cost	75,740	77,629
Property, plant and equipment	112,291	114,233
	221,043	219,642

PURCHASE, SALE OR REDEMPTION OF LISTED SECURITIES

During the nine months ended 30 September 2019, the Company repurchased its own shares on the Stock Exchange as follows:

Month/Year	Number of shares repurchased	Highest price paid per share HK\$	Lowest price paid per share HK\$	Aggregate price paid (including expenses) HK\$
September 2019	<u>1,931,000</u>	4.58	4.18	<u>8,655,084</u>

The above repurchased shares were cancelled after the end of the reporting period.

Saved as disclosed above, there were no other purchase, sale or redemption of the Company's listed securities by the Company or any of its subsidiaries during the nine months ended 30 September 2019.

DIVIDEND

The Board does not recommend payment of dividend for the nine months ended 30 September 2019 (nine months ended 30 September 2018: nil)

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

Hong Kong, 28 November 2019

As at the date of this announcement, Ms. Lee Siu Fong (Chairman), Ms. Leelertsuphakun Wanee and Dr. Li Xiaoyi are executive Directors; Mr. Simon Miles Ball 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.