

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



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 2021

FINANCIAL HIGHLIGHT						
	Three months ended			Nine months ended		
	30 September		Change	30 September		Change
	2021	2020		2021	2020	
	HK\$'000	HK\$'000		HK\$'000	HK\$'000	
Revenue	368,335	337,326	+9.2%	952,387	894,042	+6.5%
Gross profit	248,250	210,050	+18.2%	634,796	575,669	+10.3%
Profit attributable to the owners of the Company	13,843	25,024	-44.7%	2,169,043	122,006	+1,677.8%
	HK cents	HK cents		HK cents	HK cents	
Earnings per share						
Basic	2.35	4.25	-44.7%	368.52	20.75	+1,676.0%
Diluted	2.35	4.25	-44.7%	368.34	20.74	+1,676.0%

* For identification purpose only

QUARTERLY FINANCIAL STATEMENTS

The directors (the “**Directors**”) of Lee’s Pharmaceutical Holdings Limited (the “**Company**”) present herewith the unaudited consolidated quarterly financial results (the “**Quarterly Results**”) of the Company and its subsidiaries (collectively, the “**Group**”) for the three months and nine months ended 30 September 2021, together with the comparative figures for the corresponding period in 2020. 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

Revenue and Profit

First nine months of 2021 revenue of the Group totalled HK\$952,387,000 (First nine months of 2020: HK\$894,042,000), an increase of 6.5% compared to the same period last year. Third-quarter 2021 revenue of the Group totalled HK\$368,335,000 (Third-quarter 2020: HK\$337,326,000), an increase of 9.2% compared to the prior-year quarter and a sequential increase of 22.4% over second-quarter 2021. First nine months of 2021 sales growth was primarily driven by the sales of Yallaferon[®], Ferplex[®], Carnitene[®], Slounase[®] and Treprostinil Injection which grew by 70.7%, 33.7%, 16.7%, 7.2% and 125.0%, respectively, and fully compensated for the loss of revenue from Zanidip[®] after the termination of its distribution right in China and the sales decline of Livaracine[®] attributable to its re-listing process in hospitals after the obtaining of drug registration approval as Nadroparin Calcium for Injection.

Sales of licensed-in products in the first nine months of 2021 accounted for 58.5% (First nine months of 2020: 58.6%) of the Group’s revenue while sales of proprietary and generic products in the first nine months of 2021 contributed 41.5% (First nine months of 2020: 41.4%) of the Group’s revenue.

First nine months of 2021 gross profit of the Group was HK\$634,796,000 (First nine months of 2020: HK\$575,669,000), an increase of 10.3% compared to the same period last year. Third-quarter 2021 gross profit of the Group was HK\$248,250,000 (Third-quarter 2020: HK\$210,050,000), an increase of 18.2% compared to the prior-year quarter. Third-quarter 2021 gross profit margin of the Group was 67.4%, increased by 5.1 percentage point as compared to 62.3% achieved during the prior-year quarter. The Group’s gross profit margin was 66.7% in the first nine months of 2021, improved by 2.3 percentage points as to 64.4% achieved in the same period last year. The increased gross profit margin was mainly driven by the improved material purchase costs on certain proprietary products during the quarter under review.

The Group's research and development (“**R&D**”) expenses during the period under review represented new drugs development in major therapeutic areas such as cardiovascular, woman health, paediatrics, rare diseases, dermatology and obstetrics, as well as in the area of oncology under a separate R&D arm within the Group.

Mainland China's healthcare system has undergone a series of major reforms to its regulatory and reimbursement policies in the first nine months of 2021, and one major market access reform is the volume-based procurement (“**VBP**”) program which exerts downward pressure on drug prices. Under the National 14th Five-Year Plan for Medical Security released on 29 September 2021, it is expected that the VBP program will continue and may cover more drugs by the end of 2022. In addition, an annual price adjustment mechanism may be established for medical services on provincial level by June 2022. Furthermore, drug and consumable VBP program may be conducted at least once a year on provincial level. Therefore, following the results of the fifth round of VBP in June 2021, the Group recognised a one-time loss of approximately HK\$190.1 million attributable to the full impairment made in respect of the licensing fee and development cost previously capitalised for a total of 14 drug development programs after the optimisation of its R&D portfolio; and recognised a one-time loss of approximately HK\$40.2 million attributable to the full impairment for the licensing fee and development cost previously capitalised for a launched oral antihypertensive product, namely Rasilez[®], due to the concern about its future market and revenue potential in view of the lowered prices of competing antihypertensive products after the completion of the latest round of VBP program.

Saved for the above, the Group has made continuous investment into R&D activities during the period under review. An aggregate of HK\$345,218,000 has been spent in the first nine months of 2021 (First nine months of 2020: HK\$268,605,000), represented 36.2% to the corresponding revenue for the period (First nine months of 2020: 30.0%). Among which HK\$180,448,000 (First nine months of 2020: HK\$143,073,000) has been recognised as expenses and HK\$164,770,000 (First nine months of 2020: HK\$125,532,000) has been capitalised as intangible assets. In addition, license fees for licensed-in products of HK\$100,446,000 has been recognised as intangible assets during the first nine months of 2021 (First nine months of 2020: HK\$34,938,000).

Strengthening the existing and exploring new distribution channels and preparing for the roll-out of new and upcoming products is the major theme at the time, and adequate resources have been deployed thereto during the period under review. Overall, the selling expenses to revenue ratio during the first nine months of 2021 increased to 27.2%, compared to 21.3% same period last year. As an example of such efforts, the Group has achieved a speedy take-over of the Bredinin[™] sales since July 2021 and realised the revenue of approximately HK\$16.4 million in the third-quarter 2021.

Together with a one-time gain of approximately HK\$2.3 billion attributable to the derecognition of investment in Zhaoke Ophthalmology Limited (“**ZKO**”, stock code: 6622.HK) as an associate of the Company immediately after the separate listing of ZKO on 29 April 2021, net profit attributable to owners of the Company in the first nine months of 2021 was HK\$2,169,043,000, increased by approximately 16.8 times over the first nine months of 2020.

Manufacturing Facilities and Production Capability

During first nine months of 2021, the Group achieved good progress in production capacity expansions and manufacturing facility upgrades of Yallaferon[®] and Livaracine[®] as well as the technology transfer of certain new products in the form of oral lyophilised powder and liposome in Hefei site. In Nansha site, the GMP production lines of Tecarfarin tablet and Nokxaban tablet have been completed and the making of clinical samples have been done. The equipment installation and commission for the manufacturing of inhaled pharmaceutical aerosols has been completed and the making of clinical samples has also been done. The equipment installation and commission for the productions of oral cytotoxic drugs and continuous glucose monitor were completed, and both facilities are ready for making clinical samples and/or registration batch.

Drug Development

To date, the Group has over 40 projects from early- to late-stage development.

The applications made in the prior year for Import Drug License (“**IDL**”), such as Natulan[®], INOmax[®], Zingo[®] and Teglutik[®], and for Abbreviated New Drug Application (“**ANDA**”), namely Azilsartan and Apremilast tablet (阿普米司特片), are under review by the Centre for Drug Evaluation (the “**CDE**”). The New Drug Application (“**NDA**”) for Adasuve[®] made in the prior year has been officially accepted by the China’s National Medical Products Administration (“**NMPA**”).

During the first nine months of 2021 and up to date, measurable progress has been made in various clinical programs.

Major Therapeutic Areas

Cetraxal[®] Plus

On 4 January 2021, the Group recruited its first patient dosed with Cetraxal[®] Plus an ear drops product licensed from Laboratorios Salvat S.A. targeting acute otitis externa (AOE), and acute otitis media with tympanostomy tubes (AOMT) in a Phase III clinical trial in China. In October 2021, the Group has completed the required enrolment of 600 subjects.

In addition, Cetraxal[®] Plus has successfully launched in Hong Kong market on 4 October 2021.

Intrarosa[®]

On 5 January 2021, the Group has been granted the clinical trial approval from the China's NMPA to initiate a Phase III, multicenter, randomised, double blinded, parallel group clinical trial of Intrarosa[®], a product licensed from Endoceutics, Inc., in the treatment of vulvovaginal atrophy ("VVA"). The approval from the Human Genetic Resources Administration of China ("HGRAC") for this pivotal Phase III study has been obtained in July 2021, and the first patient has been enrolled on 13 September 2021. Intrarosa[®] is the only U.S. Food and Drug Administration ("FDA") and European Medicines Agency ("EMA") approved, locally administered, daily non-estrogen steroid for the treatment of VVA due to menopause. Intrarosa[®]'s product information does not have any boxed (safety) warnings, contrary to all other FDA approved drugs for the treatment of VVA, which have boxed warnings. Intrarosa[®] contains prasterone, also known as dehydroepiandrosterone (DHEA). Prasterone is an inactive endogenous steroid, which is converted locally into androgens and estrogens to help restore the vaginal tissue as indicated by improvements in the percentage of superficial and parabasal cells, and pH.

Lutrate[®]

On 27 January 2021, the NDA of Lutrate[®] Depot (leuprolide acetate for depot suspension) 3.75 mg 1-month administration ("Lutrate[®]") for the palliative treatment of advanced prostate cancer has been accepted for review by NMPA. Lutrate[®] contains the active ingredient leuprolide acetate which belongs to a group of drugs called luteinising hormone-releasing hormone ("LHRH") agonists that reduce testosterone – the major androgen. Treatment with LHRH agonists is the predominant form of androgen deprivation therapy and has become the standard of care for metastatic prostatic cancer.

Staccato[®] fentanyl

Staccato[®] fentanyl for inhalation system is a combination drug-device delivery product designed for rapid, systemic delivery of aerosolised fentanyl via the lung. The product integrates the latest technology with a unique drug delivery technology, ensuring efficacy while deterring abuse and preventing overdose. This Phase I/IIa trial includes a randomised, double blinded, placebo control self-crossover study in stage I and an open non-blinded pharmacokinetics study in stage II of fentanyl aerosol inhalation in Chinese patients with cancer outbreak pain. The product is designed basing on Staccato[®] technology and drug fentanyl licensed in from Alexza Pharmaceuticals ("Alexza") and further developed by the Group by adding artificial intelligence cloud control system. The approval from the HGRAC for this Phase I/IIa clinical trial has been obtained in August 2021, and the first patient has been enrolled on 20 October 2021.

The initiation of this Phase I/IIa trial is based on the results from an earlier Phase I clinical trial approved by the FDA and conducted by Alexza, in which the delivered aerosol of fentanyl showed promising efficacy and safety profile in normal patients. This current clinical trial in China aims to evaluate the safety, tolerability, pharmacokinetics, and dose-effect response of fentanyl aerosol in Chinese patients with cancer outbreak pain. The study will be conducted in 11 trial centers. 60 patients in stage I and 36 patients in stage II will be enrolled therefor.

GCC-4401C

On 1 March 2021, the Group has been granted the approval of the Investigational New Drug (“IND”) application of GCC-4401C from the NMPA to conduct clinical trials investigating GCC-4401C as a potential treatment for cirrhotic patients with non-tumoral portal vein thrombosis (PVT). GCC-4401C is a novel direct oral anticoagulant with structural similarity to rivaroxaban. It directly inhibits the activity of factor Xa, an important validated target in the blood coagulation pathway, to prevent thrombosis.

Anfibatide

On 3 June 2021, the principal findings of the completed Phase I clinical trial (clinicaltrials.gov registration number: NCT01588132) which evaluated the anti-thrombotic efficacy and safety of Anfibatide in vitro, ex vivo with human blood, and after injection and infusion in healthy human subjects was published in Scientific Reports in an article titled “In vitro assessment and Phase I randomized clinical trial of Anfibatide a snake venom derived anti-thrombotic agent targeting human platelet GPIIb/IIIa”. Anfibatide is a new molecular entity discovered and developed by the Group. It is a first-in-class platelet GPIIb/IIIa receptor antagonist that has fast onset, potent, and reversible antithrombotic effect among healthy subjects without impairing coagulation or prolonging bleeding time. The data published suggesting that Anfibatide may be a potentially safe and effective agent for anti-thrombotic therapy targeting platelet GPIIb/IIIa which deserves further investigation. Full version of this article can be found at www.nature.com/articles/s41598-021-91165-8.

During the period under review and up to date, the Group obtained 2 ANDA approvals from NMPA.

Fondaparinux Sodium Injection

On 2 February 2021, Fondaparinux Sodium Injection (0.5 ml: 2.5 mg), a drug indicated to prevent deep vein thrombosis (DVT; a blood clot, usually in the leg), which can lead to pulmonary embolism (PE; a blood clot in the lung), in people who are having hip surgery, hip or knee replacement, or abdominal surgery, obtained approval for manufacturing and marketing from the NMPA. Fondaparinux sodium is a synthetic and specific inhibitor of coagulation activated factor X (factor Xa) with high bioavailability, fast acting and longer half-life. It has no effect on factor IIa, and has low bleeding adverse event. It inhibits only

free factor Xa but not factor Xa bound to the prothrombinase. Use of fondaparinux does not require monitoring of PT (prothrombin time) and aPTT (activated partial thromboplastin time). The short chain length of fondaparinux sodium results in devoid of immunogenicity. It does not interact with platelet and does not induce thrombocytopenia. It has no hepatotoxicity and has less allergic reactions.

Sodium Phenylbutyrate Granules

On 13 May 2021, the Drug Registration Certificate for Sodium Phenylbutyrate Granules (specification: 150g/bottle, containing 0.94g Sodium Phenylbutyrate for every 1g) developed and manufactured by Zhaoke Pharmaceutical (Guangzhou) Company Limited (“**Zhaoke Guangzhou**”), a wholly-owned subsidiary of the Company, has been obtained from the NMPA. Sodium Phenylbutyrate is used as an adjuvant treatment for long-term treatment on urea cycle disorders patients resulting from carbamoyl phosphate synthetase deficiency, ornithine transcarbamylase deficiency or argininosuccinate synthetase deficiency. It is applicable to new-born babies (born less than 28 days) with profound biotinidase deficiency and to patients with a history of late onset hyperammonemia brain dysfunction (partial biotinidase deficiency, born for more than one month). The Sodium Phenylbutyrate Granules developed and manufactured by Zhaoke Guangzhou is the first generic version in China. As there is no original Sodium Phenylbutyrate available for sale in China, the Group’s Sodium Phenylbutyrate Granules would address the unmet medical needs in China.

Oncology Pipeline Highlights

China Oncology Focus Limited (“**COF**”), a 65% owned subsidiary of the Group, is the Group’s R&D arm around oncology. To date, there are 10 oncology assets, including 5 innovative and 5 generics, in development for the treatment of a range of cancers.

Socazolimab in recurrent or metastatic cervical cancer

On 5 February 2021, the breakthrough therapy designation (“**BTD**”) has been granted by the NMPA to COF for its Socazolimab (anti-PD-L1 monoclonal antibody, formerly known as ZKAB001) to treat recurrent and metastatic cervical cancer. Socazolimab is a fully human anti PD-L1 monoclonal antibody targeting tumor PD-L1 protein. It can release the “brake” causing by the tumor cell to the immune system. On 26 October 2021, the NDA for Socazolimab in recurrent or metastatic cervical cancer has been successfully submitted and accepted by the CDE. The priority review and conditional approval applications have also been submitted simultaneously with the NDA.

Socazolimab in osteosarcoma

During the period under review and up to date, the registration enabling Phase III clinical trial using Socazolimab in osteosarcoma is in good progress. To date, 126 patients have been enrolled.

Socazolimab combined with chemotherapy in small-cell lung cancer

On 1 March 2021, COF has been granted the clinical trial application approval from the NMPA to conduct a Phase III, multicenter, randomised, double blinded, parallel-group clinical trial of Socazolimab combined with chemotherapy in the first-line treatment of extensive-stage small-cell lung cancer (“**ES-SCLC**”). The approval is based on the results from an earlier Phase Ib trial in which Socazolimab combined with carboplatin and etoposide showed promising efficacy and safety profile in patients with extensive-stage small-cell lung cancer. This clinical trial is led by Prof. Shun Lu (陸舜) from Shanghai Chest Hospital (上海市胸科醫院). The first patient has been enrolled on 15 July 2021 and 100 patients have been enrolled to date.

Socazolimab combined with Pexa-Vec in metastatic melanoma

On 21 October 2021, COF has enrolled the first patient in China in a Phase Ib/II clinical study of Pexa-Vec (Vaccinia GM CSF/Thymidine Kinase-Deactivated Virus) combined with Socazolimab in metastatic melanoma.

The study is led by Prof. Jun Guo (郭軍) from Beijing University Cancer Hospital (北京大學腫瘤醫院) and is divided into two Phases: Phase Ib and Phase II. The safety and Phase II recommended dose of the combination therapy in patients with local progression of failed first-line treatment or metastatic melanoma will be evaluated in Phase Ib and maximal 12 patients will be enrolled in this stage. The recruitment for this Phase Ib study is expected to be completed in June 2022.

Objective response rate (ORR) and progression-free survival (PFS) of Socazolimab combined with Pexa-Vec or Socazolimab monotherapy in patients with local progression or metastatic melanoma will be evaluated in Phase II, and a total of 45 patients will be enrolled in that phase.

Business Partnership

The in-licensing approach is the Group’s preferred mode of business development strategy. Nevertheless, the Group has remained selective in entering new in-licensing deals. Only 1 licensing deal has been entered into during the period under review. On 15 June 2021, the Group had successfully entered into a license agreement with Asahi Kasei Pharma Corporation, a Japan-based company, pursuant to which the Group is awarded the exclusive license to commercialise Bredinin™ (generic name: mizoribine) for the indication of suppression of rejection reaction in renal transplantation in Mainland China. Bredinin™ was first launch in China in 1999 and has already established a decent market presence within the patient population. In addition, supplemental new drug application (sNDA) for the additional indications such as lupus nephritis (LN) and nephrotic syndrome (NS) were submitted to NMPA in June 2020.

Corporate Development

On 29 April 2021, the Group's investment in ZKO has been successfully listed on the Main Board of The Stock Exchange of Hong Kong Limited ("HKEx") at HK\$16.80 per ZKO share and raised approximately HK\$1,932.3 million. Upon the listing of ZKO, ZKO ceased to be an associate of the Company since the Group will not exercise significant influence over the operations thereof and is accounted for as financial assets at fair value through other comprehensive income for financial reporting purposes. The Group has recorded a one-time gain of approximately HK\$2.3 billion in the Company's consolidated statement of profit or loss on this derecognition of investment in ZKO as an associate of the Company in the second quarter of 2021.

PROSPECTS

China's pharmaceutical market has been constantly growing with abundant opportunities in recent years. Nevertheless, despite the remarkable prosperity of the market, the Group remains of the view that the tough environment will be persisted and foresees that pressure on drug prices will be one of the key challenges to industry players as the more drugs will be covered by the VBP program in the near future.

To cope with the new normal, efficiency must be emphasised at every step of the value chain: from R&D process, manufacturing, and sales, and to make sure that the Group is financially stable with strong governance and good sources of liquidity, so that the Group can create value for the shareholders over the long run.

The completion of the spin-off and listing of the ophthalmology arm in April 2021 was a testament to the Group's determination in unlocking value of its R&D strength for the shareholders. To date, the Group has prudently allocated resources to develop its business in other major therapeutic areas, especially cardiovascular, rare disease, and oncology. And the Group will endeavour to continue its efforts to seek opportunities to optimise its R&D project portfolio.

Group Commercial Operations Centre established since 2020 has strengthened and transformed the Group's salesforce and has recently passed the test in taking over the distributorship role of Bredinin™ in July 2021. The Group feel more confident of the efficiency of its salesforce than ever in launching new products in the upcoming future.

Besides, positive catalysts such as the containment of COVID-19 spreads in China and the rebound in economic activities within the region, the newly approved products to be launched, may drive the Group to overcome the challenges.

Towards the end of 2021, the increasing vaccination rate in every country represents some light at the end of the COVID-19 tunnel. The Group will continue to adopt prudent business and financial strategies to strengthen its foundation. The Group firmly believes that all these works to be done will eventually drive growth therefor and will eventually create more value for all stakeholders.

CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS

For the three months and nine months ended 30 September 2021

	Notes	For the three months ended 30 September		For the nine months ended 30 September	
		2021 HK\$'000 (unaudited)	2020 HK\$'000 (unaudited)	2021 HK\$'000 (unaudited)	2020 HK\$'000 (unaudited)
Revenue	3	368,335	337,326	952,387	894,042
Cost of sales		<u>(120,085)</u>	<u>(127,276)</u>	<u>(317,591)</u>	<u>(318,373)</u>
Gross profit		248,250	210,050	634,796	575,669
Other income	4	19,690	14,454	84,628	78,082
Other gains and losses, net		(2,310)	(2,410)	2,090,956	(7,799)
Selling and distribution expenses		(94,745)	(68,247)	(258,863)	(190,383)
Administrative expenses		(92,077)	(65,993)	(216,278)	(177,126)
Net reversal of (provision for) expected credit losses on financial assets		598	318	179	(269)
Research and development expenses		<u>(67,549)</u>	<u>(67,913)</u>	<u>(180,448)</u>	<u>(143,073)</u>
Profit from operations		11,857	20,259	2,154,970	135,101
Finance costs		(1,752)	(1,547)	(4,275)	(5,092)
Share of results of associates		<u>(62)</u>	<u>(1,964)</u>	<u>(3,373)</u>	<u>(8,003)</u>
Profit before taxation		10,043	16,748	2,147,322	122,006
Taxation	5	<u>1,041</u>	<u>(12,999)</u>	<u>(2,336)</u>	<u>(42,316)</u>
Profit for the period		<u>11,084</u>	<u>3,749</u>	<u>2,144,986</u>	<u>79,690</u>
Attributable to:					
Owners of the Company		13,843	25,024	2,169,043	122,006
Non-controlling interests		<u>(2,759)</u>	<u>(21,275)</u>	<u>(24,057)</u>	<u>(42,316)</u>
		<u>11,084</u>	<u>3,749</u>	<u>2,144,986</u>	<u>79,690</u>
		<i>HK cents</i>	<i>HK cents</i>	<i>HK cents</i>	<i>HK cents</i>
Earnings per share:					
Basic	7	<u>2.35</u>	<u>4.25</u>	<u>368.52</u>	<u>20.75</u>
Diluted	7	<u>2.35</u>	<u>4.25</u>	<u>368.34</u>	<u>20.74</u>

CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the three months and nine months ended 30 September 2021

	For the three months ended		For the nine months ended	
	30 September		30 September	
	2021	2020	2021	2020
	<i>HK\$'000</i>	<i>HK\$'000</i>	<i>HK\$'000</i>	<i>HK\$'000</i>
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Profit for the period	11,084	3,749	2,144,986	79,690
Other comprehensive income (expense):				
Items that may be reclassified subsequently to profit or loss:				
– Exchange differences on translation of financial statements of overseas subsidiaries	9,531	69,171	21,563	45,234
– Share of other comprehensive income of associates	–	220	46	134
– Reclassification of exchange reserve upon disposal of an overseas subsidiary	–	–	–	(19)
Item that will not be reclassified subsequently to profit or loss:				
– Fair value changes of financial assets at fair value through other comprehensive income	<u>(602,504)</u>	<u>(37,165)</u>	<u>(1,384,331)</u>	<u>(252,973)</u>
Other comprehensive (expense) income for the period, net of tax	<u>(592,973)</u>	<u>32,226</u>	<u>(1,362,722)</u>	<u>(207,624)</u>
Total comprehensive (expense) income for the period	<u>(581,889)</u>	<u>35,975</u>	<u>782,264</u>	<u>(127,934)</u>
Total comprehensive (expense) income for the period attributable to:				
Owners of the Company	(578,825)	53,748	810,978	(77,526)
Non-controlling interests	<u>(3,064)</u>	<u>(17,773)</u>	<u>(28,714)</u>	<u>(50,408)</u>
	<u>(581,889)</u>	<u>35,975</u>	<u>782,264</u>	<u>(127,934)</u>

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

For the nine months ended 30 September 2021

	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>	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 2021 (audited)	29,406	714,813	9,200	40,847	65,228	(254,155)	(14,843)	1,559,299	2,149,795	(34,417)	2,115,378
Employee share option benefits	-	-	-	13,464	-	-	-	-	13,464	-	13,464
Exercise of share options	36	5,278	-	(1,771)	-	-	-	-	3,543	-	3,543
Share of reserve of an associate	-	-	-	-	28	-	-	-	28	-	28
Profit (loss) for the period	-	-	-	-	-	-	-	2,169,043	2,169,043	(24,057)	2,144,986
Other comprehensive income (expense) for the period											
– Exchange differences on translation of financial statements of overseas subsidiaries	-	-	-	-	-	-	21,453	-	21,453	110	21,563
– Share of other comprehensive income of associates	-	-	-	-	46	-	-	-	46	-	46
– Fair value changes of financial assets at fair value through other comprehensive income	-	-	-	-	-	(1,379,564)	-	-	(1,379,564)	(4,767)	(1,384,331)
Total comprehensive income (expense) for the period	-	-	-	-	46	(1,379,564)	21,453	2,169,043	810,978	(28,714)	782,264
2020 final dividend paid	-	-	-	-	-	-	-	(18,254)	(18,254)	-	(18,254)
At 30 September 2021 (unaudited)	<u>29,442</u>	<u>720,091</u>	<u>9,200</u>	<u>52,540</u>	<u>65,302</u>	<u>(1,633,719)</u>	<u>6,610</u>	<u>3,710,088</u>	<u>2,959,554</u>	<u>(63,131)</u>	<u>2,896,423</u>

	Attributable to the owners of the Company								Attributable to non-controlling interests	Total	
	Share capital	Share premium	Merger difference	Share-based compensation reserve	Other reserves	Investments revaluation reserve	Exchange reserve	Retained profits			Sub-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 2020 (audited)	29,396	714,146	9,200	23,675	157,404	(8,386)	(97,707)	1,468,172	2,295,900	181,538	2,477,438
Employee share option benefits	-	-	-	11,514	-	-	-	-	11,514	-	11,514
Exercise of share options	10	667	-	(231)	-	-	-	-	446	-	446
Share options lapsed	-	-	-	(39)	-	-	-	39	-	-	-
Share of reserve of an associate	-	-	-	-	42	-	-	-	42	-	42
Capital contribution from non-controlling interests	-	-	-	-	-	-	-	-	-	31,226	31,226
Acquisition of a subsidiary	-	-	-	-	-	-	-	-	-	(2,250)	(2,250)
Disposal of a subsidiary	-	-	-	-	-	-	-	-	-	(1,891)	(1,891)
Profit (loss) for the period	-	-	-	-	-	-	-	122,006	122,006	(42,316)	79,690
Other comprehensive income (expense) for the period											
- Exchange differences on translation of financial statements of overseas subsidiaries	-	-	-	-	-	-	41,942	-	41,942	3,292	45,234
- Share of other comprehensive expense of associates	-	-	-	-	134	-	-	-	134	-	134
- Reclassification of exchange reserve upon disposal of an overseas subsidiary	-	-	-	-	-	-	(19)	-	(19)	-	(19)
- Fair value changes of financial assets at fair value through other comprehensive income	-	-	-	-	-	(241,589)	-	-	(241,589)	(11,384)	(252,973)
Total comprehensive income (expense) for the period	-	-	-	-	134	(241,589)	41,923	122,006	(77,526)	(50,408)	(127,934)
2019 final dividend paid	-	-	-	-	-	-	-	(22,349)	(22,349)	-	(22,349)
2020 interim dividend paid	-	-	-	-	-	-	-	(15,879)	(15,879)	-	(15,879)
At 30 September 2020 (unaudited)	29,406	714,813	9,200	34,919	157,580	(249,975)	(55,784)	1,551,989	2,192,148	158,215	2,350,363

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

For the nine months ended 30 September 2021

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 on The Stock Exchange of Hong Kong Limited.

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 2020.

The accounting policies and methods of computation used in preparing the unaudited condensed consolidated financial statements for the three months and nine months ended 30 September 2021 are consistent with those used in the Group’s annual financial statements for the year ended 31 December 2020 except as described below.

In the current reporting period, the Group has applied, for the first time, the following 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:

Amendments to HKFRS 9, HKAS 39, HKFRS 7, HKFRS 4 and HKFRS 16	Interest Rate Benchmark Reform – Phase 2
Amendments to HKFRS 16	COVID-19-Related Rent Concessions

The application of these amendments to HKASs and HKFRSs 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:

Accounting Guideline 5 (Revised)	Merger Accounting for Common Control Combination ²
HKFRS 17	Insurance Contracts and the related Amendments ³
Amendments to HKAS 1	Classification of Liabilities as Current and Non-current or related amendments to Hong Kong Interpretation 5 (2020) ³
Amendments to HKAS 1	Disclosure of Accounting Policies ³
Amendments to HKAS 8	Definition of Accounting Estimates ³
Amendments to HKAS 12	Deferred Tax related to Assets and Liabilities arising from a Single Transaction ³
Amendments to HKAS 16	Property, Plant and Equipment – Proceeds before Intended Use ²
Amendments to HKAS 37	Onerous Contracts – Cost of Fulfilling a Contract ²
Amendments to HKFRS 3	Reference to the Conceptual Framework ²
Amendments to HKFRS 10 and HKAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture ⁴
Amendments to HKFRS 16	COVID-19-Related Rent Concessions beyond 30 June 2021 ¹
Amendments to HKFRSs	Annual Improvements to HKFRSs 2018–2020 ²

¹ Effective for annual periods beginning on or after 1 April 2021, earlier application is permitted

² Effective for annual periods beginning on or after 1 January 2022, earlier application is permitted

³ Effective for annual periods beginning on or after 1 January 2023, earlier application is permitted

⁴ Effective 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.

3. REVENUE

The principal activities of the Group are the developing, manufacturing 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	
	2021 HK\$'000 (unaudited)	2020 HK\$'000 (unaudited)	2021 HK\$'000 (unaudited)	2020 HK\$'000 (unaudited)
Proprietary and generic products	145,766	152,533	395,401	370,215
Licensed-in products	222,569	184,793	556,986	523,827
	368,335	337,326	952,387	894,042

Geographical segments

During the three months and nine months ended 30 September 2021 and 2020, 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	
	2021 HK\$'000 (unaudited)	2020 HK\$'000 (unaudited)	2021 HK\$'000 (unaudited)	2020 HK\$'000 (unaudited)
Interest income on:				
Bank deposits	535	959	1,927	5,725
Financial assets at fair value through profit or loss	–	–	83	–
Advance to associates	868	700	2,447	1,616
Total interest income	1,403	1,659	4,457	7,341
Compensation income	–	–	–	41,208
Development and government grants	2,443	6,355	13,058	18,003
Incentives from vendor	–	2,860	–	2,860
Rental and utilities income	3,801	321	8,721	934
Research and development service income	8,205	2,587	53,209	4,892
Sundry income	3,838	672	5,183	2,844
	19,690	14,454	84,628	78,082

The Group received the development grants from local government as recognition of the Group's performance and development of high-technology pharmaceutical products.

5. TAXATION

	For the three months ended 30 September		For the nine months ended 30 September	
	2021 HK\$'000 (unaudited)	2020 HK\$'000 (unaudited)	2021 HK\$'000 (unaudited)	2020 HK\$'000 (unaudited)
Current tax				
Hong Kong Profits Tax	(7,120)	8,019	8,082	30,845
PRC Enterprise Income Tax	1,993	–	1,993	–
	(5,127)	8,019	10,075	30,845
Under (over) provision in prior years				
Hong Kong Profits Tax	171	–	171	–
PRC Enterprise Income Tax	(1)	–	(531)	(228)
	170	–	(360)	(228)
Deferred tax				
Origination and reversal of temporary differences	3,916	4,980	(7,379)	11,699
	(1,041)	12,999	2,336	42,316

Hong Kong Profits Tax for the three months and nine months ended 30 September 2021 is calculated at 8.25% (three months and nine months ended 30 September 2020: 8.25%) on the first HK\$2 million of the estimated assessable profits and at 16.5% (three months and nine months ended 30 September 2020: 16.5%) on the estimated assessable profits above HK\$2 million according to the two-tiered profits tax rates regime.

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 2021 of HK\$0.030 per share, totalling approximately HK\$17,665,000 (six months ended 30 June 2020: HK\$0.027 per share, totalling approximately HK\$15,879,000) was declared on 26 August 2021 and is subsequently paid on 6 October 2021.

The board of directors does not recommend the payment of other interim dividend for the nine months ended 30 September 2021 (nine months ended 30 September 2020: 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	
	2021 HK\$'000 (unaudited)	2020 HK\$'000 (unaudited)	2021 HK\$'000 (unaudited)	2020 HK\$'000 (unaudited)
<i>Earnings:</i>				
Net profit attributable to the owners of the Company for the purpose of basic and diluted earnings per share	13,843	25,024	2,169,043	122,006
	For the three months ended 30 September 2021 Share(s)'000 (unaudited)	2020 Share(s)'000 (unaudited)	For the nine months ended 30 September 2021 Share(s)'000 (unaudited)	2020 Share(s)'000 (unaudited)
<i>Number of shares:</i>				
Weighted average number of ordinary shares for the purpose of basic earnings per share	588,835	588,125	588,586	588,119
Effect of dilutive potential ordinary shares:				
Options	195	351	282	4
Weighted average number of ordinary shares for the purpose of diluted earnings per share	589,030	588,476	588,868	588,123

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	
	2021 HK\$'000 (unaudited)	2020 HK\$'000 (unaudited)
Interest income	2,447	1,616
Rental and utilities income	4,231	934
Research and development service income	21,798	–
Purchase of consumable	2,850	632
	<u>2,447</u>	<u>1,616</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	
	2021 HK\$'000 (unaudited)	2020 HK\$'000 (unaudited)
Short-term employee benefits	39,292	17,829
Share-based payments	8,343	7,504
Retirement and other post-employment benefits	18,012	19,713
– Defined contribution plan	12	27
– Retirement benefits	18,000	19,686
	<u>65,647</u>	<u>45,046</u>

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

During the nine months ended 30 September 2021, there is approximately HK\$1,250,000 (nine months ended 30 September 2020: approximately HK\$1,275,000) was donated to Kanya Lee Scholarship. Ms. Leelalertsuphakun Wanee and Ms. Lee Siu Fong, directors of the Company, are also members of key management of Kanya Lee Scholarship and Kanya Lee Scholarship is considered as a related party to the Group.

(d) Issue of subsidiary's shares to Perfect Concept Holdings Limited (“PCH”)

During the nine months ended 30 September 2020, China Oncology Focus Limited, on a pro rata basis, issued 18,620 shares to PCH. Ms. Leelalertsuphakun Wanee, Ms. Lee Siu Fong and Dr. Li Xiaoyi were both the directors of the Company and the substantial shareholders of PCH and PCH was considered as a related party to the Group. Total consideration received for the issue of shares thereto was US\$4,003,300 (equivalent to approximately HK\$31,226,000). No such event has occurred during the nine months ended 30 September 2021.

(e) **Interest expenses for shareholder loans from PCH**

During the nine months ended 30 September 2020, included in finance costs there was interest expenses for loans from PCH amounting to HK\$147,000. Loans from PCH were fully settled in year 2020 and no interest expenses was incurred during the nine months ended 30 September 2021.

9. CAPITAL COMMITMENTS

	At 30 September 2021 HK\$'000 (unaudited)	At 31 December 2020 HK\$'000 (audited)
Capital commitments contracted for in respect of:		
– Financial assets at fair value through other comprehensive income	40,931	10,750
– Intangible assets – license fee and development cost	114,123	88,458
– Property, plant and equipment	87,039	91,212
	242,093	190,420

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 nine months ended 30 September 2021.

DIVIDEND

The Board does not recommend payment of dividend for the nine months ended 30 September 2021 (nine months ended 30 September 2020: Nil).

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

Hong Kong, 25 November 2021

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