



李氏大藥廠

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 Report 2020



\* 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 2020, together with the comparative figures for the corresponding period in 2019. 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

After hard-fought battles since the beginning of the year, China has basically managed to contain the COVID-19 epidemic and has gradually resumed business activities within the region during the third quarter of this year. Taking into account the depreciation of Renminbi of 2.8% during the period under review, the Group's reported revenue for the third quarter of this year was HK\$337,326,000 (three months ended 30 September 2019: HK\$306,334,000), which represented a quarter-on-quarter growth of 10.1% and mainly contributed by the sales growth of Yallaferon® and Livaracine® of 30.6% and 13.5%, respectively, during the quarter under review. For the nine months ended 30 September 2020, the Group's revenue reached HK\$894,042,000 (nine months ended 30 September 2019: HK\$913,868,000) and the decrease has tapered to 2.2% over the same period last year.

Sales of licensed-in products accounted for 58.6% (nine months ended 30 September 2019: 56.6%) of the Group's revenue while sales of proprietary and generic products contributed 41.4% (nine months ended 30 September 2019: 43.4%) of the Group's revenue.

The Group's gross profit for the third quarter of this year was HK\$210,050,000, increased by HK\$11,466,000 or 5.8%. For the nine months ended 30 September 2020, the Group's gross profit was HK\$575,669,000 (nine months ended 30 September 2019: HK\$600,911,000) and the decrease has narrowed to 4.2% over the same period last year. The Group's gross profit margin for the third quarter of this year was 62.3%, decreased by 2.5 percentage points as compared to 64.8% achieved during the same quarter last year. The Group's gross profit margin for the nine months ended 30 September 2020 was 64.4%, decreased by 1.4 percentage points as compared to the same period last year.

In order to staying ahead in an increasingly competitive environment, the Group continued to allocate adequate resources to its sales and marketing function during the period under review, and special focus has been placed on strengthening existing and exploring new distribution channels as well as on the preparation for the roll-out of new and upcoming products. Selling and distribution expenses to revenue ratio during the period under review has increased to 21.3% (nine months ended 30 September 2019: 18.8%). The Group's research and development ("**R&D**") activities for new drugs have been resumed gradually since the second quarter of this year amid the fight against the COVID-19 outbreak. During the first nine months of 2020, HK\$268,605,000 (for the nine months ended 30 September 2019: HK\$229,245,000) was spent in R&D activities, representing 30.0% (for the nine months ended 30 September 2019: 25.1%) to the corresponding revenue during the period under review. Among which HK\$143,073,000 (for the nine months ended 30 September 2019: HK\$116,457,000) has been recognised as expenses and HK\$125,532,000 (for the nine months ended 30 September 2019: HK\$112,788,000) has been capitalised as intangible assets. Administrative expenses has increased by 7.3% during the period under review due to the ongoing business expansion in Nansha site as well as the increase in staff costs. Taking into account the effect of the one-off compensation income of HK\$41.2 million from the early termination of a product license in the second quarter of this year and the absence of considerable intangible assets impairment as compared to the non-recurring loss of approximately HK\$108.6 million incurred by the Group's 65%-owned oncology R&D arm during the second quarter of last year, net profit attributable to the owners of the Company for the nine months of 2020 was HK\$122,006,000, increased by 51.9% over the same period last year.

During the quarter under review and up to date, the Group continue to achieve good progress in production capacity expansions and manufacturing facility upgrades of Yallaferon® and Livaracine® in Hefei site. In Nansha site, the manufacturing of Tecarfarin tablet and Nokxaban tablet for GMP applications and clinical trials are actively moving forward in good progress. The equipment installation and commission for the production of oral cytotoxic drugs has been completed, and the facility is ready for making clinical samples and registration batch. The facility for continuous glucose monitor is ongoing and full commission is expected by end of this year.

Following the successful production of clinical sample of Staccato® fentanyl early this year, the Investigational New Drug (“**IND**”) application of Staccato® fentanyl for inhalation for the treatment of cancer breakthrough pain has been approved by the China’s National Medical Products Administration (“**NMPA**”) on 2 November 2020. Staccato® fentanyl for inhalation system is a combination drug device delivery product designed for rapid, systemic delivery of aerosolised fentanyl via the lung. Staccato® fentanyl integrates the latest technology with a unique drug delivery technology, ensuring efficacy while deterring abuse and preventing overdose. The Phase I/IIa clinical trial of Staccato® fentanyl is expected to commence in early 2021.

The Group’s R&D pipeline includes over 40 projects from early- to late-stage development in cardiovascular, woman health, paediatrics, rare diseases, oncology, dermatology, obstetrics and urology. The Group’s commitment to R&D persisted and measurable progress has been made during the period and up to date. The Group has also involved in the business in ophthalmology through its investment in Zhaoke Ophthalmology Limited (“**ZKO**”), the then subsidiary of the Group during the period under review, which has subsequently become an associated company of the Group on 2 October 2020.

Following the Import Drug License (“**IDL**”) of Unidrox® (Prulifloxacin tablet) obtained from the NMPA in the second quarter of this year, it is expected that one additional IDL will be obtained therefrom before the end of this year. On 10 November 2020, Trazodone (Trittico®) for the treatment of patients suffered from depression has been successfully passed the technical review by the Centre for Drug Evaluation (the “**CDE**”) and the IDL application has been escalated to the NMPA for the final approval. To date, four other applications for the IDLs made by the Group are under review by the CDE, including Natulan®, INOmax®, Zingo® and Teglutik®.

The Group’s applications for Abbreviated New Drug Application (“**ANDA**”) were also in good progress during the period under review and up to date.

On 18 March 2020, the manufacturing and marketing of Treprostinil Injection, a drug indicated for the treatment of pulmonary arterial hypertension and developed by Zhaoke Pharmaceutical (Hefei) Company Limited (“**ZKHF**”), a wholly owned subsidiary of the Company, was approved by NMPA which made ZKHF’s Treprostinil the first generic available in China.

On 24 July 2020, the conclusion of Livaracine® being bioequivalent to the original import drug of nadroparin calcium for injection (brand name: Fraxiparine) has been accepted and has been successfully obtained drug registration approval from the NMPA. This is a validation and confirmation of Livaracine®’s quality, safety and efficacy profile and is expected to significantly expand the current indications thereof.

Among other ANDA submissions, Fondaparinux Calcium and Sodium Phenylbutyrate Granule have been successfully passed the manufacturing audit conducted by NMPA. The final approvals thereof are expected before the end of 2020. Supplement data for Sodium Phenylbutyrate Tablet has been requested by the CDE and will be submitted soon. In addition, Bimatoprost, an ophthalmic product which belongs to ZKO, being the Group’s ophthalmology R&D arm, is currently under review by the CDE.

Following the completion of the registration enabling Phase III study of Adapalene-Clindamycin Combination Gel ("**ACCG**") in China in June 2020 for the treatment of moderate acne vulgaris, New Drug Application ("**NDA**") submission has been made in November 2020 and marketing approval is expected to be received in 2021.

The Group has completed the pivotal Phase III trial of an investigational inhaled antipsychotic product, namely Staccato<sup>®</sup> loxapine for inhalation system (Adasuve<sup>®</sup>), in treating acute agitation in patients with schizophrenia or bipolar disorder (manic or mixed episodes) as defined by The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM5) criteria in China on 24 August 2020. The study was conducted in 14 trial sites and total 150 patients were enrolled therefor. The first patient was enrolled on 29 April 2020 and the last patient was enrolled on 11 July 2020. The analysis of unblinded topline data has been completed and the positive results thereof showed that this study has met its primary endpoint, a rapid onset of action was demonstrated by a statistically significant decrease ( $p < 0.05$ ) from baseline in the Positive and Negative Syndrome Scale Excited Component (also known as PEC) score at 2 hours post dose. NDA is expected to be submitted by the end of 2020.

In the area of oncology, China Oncology Focus Limited ("**COFL**") has accelerated the development process of ZKAB001, an anti-PD-L1 monoclonal antibody, in several area.

In recurrent and metastatic cervical cancer which could become a new hope to the patients in need, COFL has submitted the application of breakthrough therapeutic drugs designation on 10 July 2020 to NMPA under the revised Drug Registration Regulation ("**Revised DRR**") which has come into effect from 1 July 2020. The Revised DRR expanded priority review to breakthrough therapeutic drugs, which are used for the prevention and treatment of diseases that seriously affect the quality of life or seriously life threatening, for which there are no effective prevention or treatment methods or, compared with existing measures of treatment, there is sufficient evidence to show that they have obvious clinical advantages.

Phase Ib+III clinical trial of ZKAB001 in front line treatment of small cell lung cancer administered by COFL has started patient enrolment in April 2020. The Phase Ib trial has nearly reached its enrolment target and no serious adverse event has been observed with positive efficacy signal. The registration enabling trial is planned to start in 2021 and enrol over 350 patients across 30 different sites in China.

Following the completion of a Phase I clinical trial for ZKAB001 in osteosarcoma patients, a pivotal Phase III study of ZKAB001 monotherapy for maintenance stage of sarcoma after its first line treatment has been initiated subsequent to the period under review and has the first patient dosed on 21 August 2020. This pivotal Phase III clinical trial is titled "Study of ZKAB001 for Maintenance Therapy in Patients With High-grade Osteosarcoma After Adjuvant Chemotherapy" and is being conducted at 34 trial sites in China and expected to enrol 362 patients in total, including placebo cohort. The patients will receive ZKAB001 treatment every three weeks for 16 cycles or for one year, whichever comes first. 1-year disease-free survival of the patients will be the primary endpoint of this clinical trial.

Another pivotal Phase Ib+III study of ZKAB001 in combination with chemotherapy for the first line treatment of urothelial cancer has been initiated. So far, several patients have been dosed and all sites will be activated before the end of 2020. In addition, a neoadjuvant study for esophageal cancer has been started. This Phase Ib study will involve 6 centers with an enrolment of 30 patients. For oncolytic virus Pexa-Vec development, IND approval for combination of Pexa-Vec with PD-L1 for treatment of late stage melanoma has been obtained. First patient dosing is expected in early 2021. Other studies for solid tumours such as ovarian cancer, glioblastoma, cholangiocarcinoma and pancreatic cancer for other oncology products such as Zotiraciclib (TG02) and Gimatecan.

In the area of ophthalmology, ZKO has agreed the Phase III protocol of the Cyclosporine A Ophthalmic Gel trial with CDE for the treatment of dry eye in China. The application of ethical clearance is currently in progress and the pivotal Phase III study is expected to initiate patient recruitment before the end of November 2020.

Subsequent to the end of period under review, the newly licensed NVK-002 by Zhaoke (Hong Kong) Ophthalmology Pharmaceutical Limited ("**ZKOHK**"), a wholly owned subsidiary of ZKO, from Nevakar Inc. ("**Nevakar**"), a U.S.-based biopharmaceutical company developing multiple innovative medications in the ophthalmic and hospital injectable areas, has also made good progress in its Phase III Childhood Atropine for Myopia Progression ("**CHAMP**") study, an U.S. Food and Drug Administration ("**FDA**") approved drug trial, carried out by Nevakar in the U.S. and Europe. NVK-002 is a preservative-free, novel topical eye treatment for slowing the progression of myopia in children and the first patient has completed three year enrollment in the Phase III CHAMP study on 12 November 2020.

With a view to achieve steady and sustainable sales growth, the Group has kept hiring talented sales executives to strengthen its sales force. Subsequent to the end of the period under review, the Group Commercial Operations Centre ("**GCOC**") has been officially established on 22 October 2020 in order to enhance the efficiency and effectiveness of the Group's commercial operations in China. The Group believes that the GCOC will further enhance the Group's ability to respond to rapidly changing pharmaceutical market environment and business needs, to unleash the full potential of the launched products, and to enhance the readiness for new and upcoming products launch.

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. During the period under review and up to date, the Group has entered into three in-licensing deals with foreign business partners which involve four new ophthalmic products to enrich the pipeline of the ophthalmology R&D arm under ZKO.

On 25 June 2020, ZKOHK and PanOptica, Inc. ("**PAN**"), a U.S.-based ophthalmology-focused pharmaceutical company developing a topical eye drop for the treatment of sight-threatening eye diseases caused by abnormal or leaky blood vessels, entered into a binding letter of intent for exclusive rights to develop, manufacture and commercialise PAN-90806 in China, Hong Kong, Macau, South Korea and other countries of Southeast Asia. Both ZKOHK and PAN plan to collaborate in the world-wide development of PAN-90806 in wet age-related macular degeneration ("**wAMD**"), and also potentially in other neovascular eye diseases, like diabetic retinopathy.



PAN-90806 is a once-daily topically applied small molecule VEGF receptor 2 tyrosine kinase inhibitor and blocks angiogenesis and vascular leakage. A specially designed patented formulation allows PAN-90806 to reach the back of the eye via the choriocapillaris circulation for its therapeutic effects while reducing its effective concentration in the front of the eye to avoid potential off-target adverse effects. At least two clinical trials have been conducted in the U.S. and both showed signs of therapeutic efficacies of PAN-90806 as indicated by improvement in visual acuity and reduction in retinal thickness. A bridging Phase II trial is being planned in China to confirm and extend these results. ZKOHK believes that PAN-90806 represents a potential game changer in the management of wAMD. VEGF inhibition has been demonstrated to be efficacious in the treatment of wAMD in multiple clinical trials. An eye drop formulation will provide a non-invasive, more convenient and easier to adhere alternative to combat this debilitating disease either alone or in combination with other IVT therapies to reduce their frequency of administration. VEGF inhibition is the cornerstone of treatment, and alternatives to life-long IVT injections are a significant unmet need in optimising safety, convenience, patient access, and ultimately clinical outcomes for patients with these devastating conditions. Both PAN and ZKOHK intend to complete the transaction by the end of 2020.

On 24 July 2020, following the binding letter of intent signed in May 2020, ZKOHK, and IACTA Pharmaceuticals, Inc. ("**IACTA**"), a U.S.-based ophthalmology focused pharmaceutical company developing drugs with novel mechanisms of action that treat diseases in areas of significant unmet medical need, entered into a license agreement for exclusive rights to develop, manufacture and commercialise IC-265 and IC-270 in China and other countries of Southeast Asia (the "**Territory**"). IC-265, currently in the Phase II development in U.S. for the treatment of dry eye, is a proprietary, highly selective and potent Syk kinase inhibitor with broad anti-inflammatory and anti-allergic effects. Since Syk is the critical starting point in the activation of the inflammatory or immune cascade in the eye, the Syk kinase inhibitor is able to block multiple downstream signalling pathways leading to different ophthalmic ailments, including dry eye. IC-270 is a fixed dose combination of IC-265 and an anti-histamine agent for the treatment of inflammatory ophthalmic diseases including allergic conjunctivitis. ZKOHK believes that this unique combination will simultaneously address multiple key inflammatory symptoms in the eye in a fashion unattainable by current therapies. ZKOHK will be spearheading its clinical development activities (and those of IC-

265) required for regulatory approval in the Territory. Both IACTA and ZKOHK plan to collaborate in the world-wide development of IC-265 and IC-270 by creating a joint development committee to oversee and steer the development of these two assets.

On 19 October 2020, ZKOHK and Nevakar entered into an exclusive licensing agreement for the development, manufacture and commercialisation of NVK-002 in China, Hong Kong, Macau, Taiwan, South Korea and other countries of Southeast Asia. The CHAMP study follows ground-breaking studies conducted in Asia that concluded that low doses of atropine could be used to slow the progression of myopia in children. CHAMP is a 576 subject, randomised, placebo-controlled, double-masked study evaluating the effects of NVK-002 on myopia progression in children. The study duration is three years, after which enrolled patients are re-randomised for a fourth year of follow-up. With this milestone, the trial remains on-track for a three-year data readout in 2022. If approved, NVK-002 could be the first pharmaceutical treatment for slowing myopia progression and preserving vision in children.

Following the possible spin-off of ZKO, the Group has made an inter-group licensing deal subsequent to the end of the period under review. On 2 October 2020, a license agreement (the "**ACCG License Agreement**") has been entered into between the Group and ZKO which involve the grant of the commercialisation right of ACCG in China for the treatment of moderate acne vulgaris by ZKO to the Group. Pursuant to the ACCG License Agreement, ZKO agreed to grant exclusive license rights to the Group in relation to the ACCG in China, Hong Kong, Macau and Taiwan, and in consideration of which, the Group agreed to pay the upfront payment (inclusive of tax) of US\$10,000,000 which has been settled by way of the repurchase of ZKO shares in cash), the milestone payment (inclusive of tax) of US\$5,000,000 and a sales commission to ZKO in accordance with the terms of the ACCG License Agreement. Following the completion of the ACCG License Agreement, ZKO and its subsidiaries were no longer indirect non-wholly-owned subsidiaries and become associated companies of the Group, and the financial results of ZKO and its subsidiaries will not be consolidated in the consolidated financial statements of the Group thereafter. Details of the ACCG License Agreement have been disclosed in the Company's announcement dated 4 October 2020.

On 9 October 2020, ZKO was successful in a financing event which provided adequate resources to uphold the commitment of ZKO to drug innovation and development in various ophthalmic indications and to help pave its path towards possible spin-off and a separate listing in the future. In this Series B financing, ZKO managed to attract new and previous investors which are among the most recognised and respected players in the biotech industry, and raised US\$145,000,000 (approximately HK\$1,131,000,000 equivalent). Right before the completion of the Series B preferred shares subscription agreement (the "**Series B Completion**"), the Group owned 48.539% of the interest in ZKO. Immediately after the Series B Completion, the Group's indirect interest in ZKO was reduced to 33.575% (on an enlarged basis by taking into account the issuance of the preferred shares on an as if converted basis). Details of the Series B financing have been disclosed in the Company's announcement dated 11 October 2020. All conditions to the Series B preferred shares subscription agreement have been fulfilled and the aggregate consideration of US\$145,000,000 has been fully settled by the investors on 17 November 2020.

## PROSPECTS

While the Group remains of the view that the tough environment will be persisted throughout this year, with the coronavirus has been largely under control in China and the economy has gradually re-opened within the region, the Group was delighted that an improving performance in the third quarter of this year has been achieved.

In addition, the enhancement and reform in the pharmaceutical industry in China continues to move forward during the period under review, starting from the new national reimbursement drug list with effect from the beginning of this year, the intensified and expanded Group Purchasing Organisation (GPO) programme following the increasing number of bioequivalence qualified generic drug being approved, as well as the recent China's Biosecurity Law and China Patent Law which have been passed on 17 October 2020 and will take effect in 2021. Being a research-based biopharmaceutical group, it is believed that the Group will be eventually benefit from these new laws and regulations in the long run.

The imminent approval of three new products that brings the total new approval to six for the year will provide catalysts for future growth. These new products will also broaden the revenue base and become new growth driver. The revamping and restructuring of the sales and marketing organisation will increase the market competitiveness of existing products and improve product life-cycle management. The enhanced effectiveness and efficiency of the commercial operation will bring alignment to the market environment and make it more agile and responsive to competition.

The Group will continue to stay focus on its new drug development, sales organisation reform and expansion, and cost containment in order to differentiate itself from others pharmaceutical companies. Besides, the Group has made a big step forward in the path towards possible spin-off and a separate listing of ZKO in the future after the completion of the Series B fundraising of ZKO with strong support from new and previous investors thereof, which are among the most recognised and respected players in the biotech industry.

On 20 November 2020, the Company has received the approval of the PN15 application from The Stock Exchange of Hong Kong Limited that it may proceed with the possible spin-off and separate listing of ZKO which marks a significant step in the process thereof. Biotech IPO hub in Hong Kong is taking its shape and has already become the second-largest biotech IPO market in the world and the largest in Asia as of today. The Group believes that the spin-off and separate listing of R&D arms, such as ophthalmology and oncology projects, into standalone companies will in turn drive the market to recognise the value of its robust R&D pipelines.

Beyond the present headwinds, the Group remains cautiously optimistic about the medium-term future.

# Condensed Consolidated Statement of Profit or Loss

For the three months and nine months ended 30 September 2020

|   | Notes | For the three months<br>ended 30 September |                                 | For the nine months<br>ended 30 September |                                 |
|---|-------|--|---------------------------------|---|---------------------------------|
|   |       | 2020<br>HK\$'000<br>(unaudited)            | 2019<br>HK\$'000<br>(unaudited) | 2020<br>HK\$'000<br>(unaudited)           | 2019<br>HK\$'000<br>(unaudited) |
| Revenue   | 3     | 337,326                                    | 306,334                         | 894,042                                   | 913,868                         |
| Cost of sales   |       | (127,276)                                  | (107,750)                       | (318,373)                                 | (312,957)                       |
| Gross profit  |       | 210,050                                    | 198,584                         | 575,669                                   | 600,911                         |
| Other income  | 4     | 14,454                                     | 10,882                          | 78,082                                    | 41,334                          |
| Other gains and losses, net   |       | (2,410)                                    | (2,968)                         | (7,799)                                   | (112,932)                       |
| Selling and distribution<br>expenses                                      |       | (68,247)                                   | (63,593)                        | (190,383)                                 | (171,656)                       |
| Administrative expenses   |       | (65,993)                                   | (60,331)                        | (177,126)                                 | (165,029)                       |
| Net reversal of (provision<br>for) impairment loss on<br>financial assets |       | 318  | 94                              | (269)                                     | (669)                           |
| Research and development<br>expenses                                      |       | (67,913)                                   | (37,645)                        | (143,073)                                 | (116,457)                       |
| Profit from operations  |       | 20,259                                     | 45,023                          | 135,101                                   | 75,502                          |
| Finance costs   |       | (1,547)                                    | (1,801)                         | (5,092)                                   | (4,492)                         |
| Share of results of associates  |       | (1,964)                                    | (3,024)                         | (8,003)                                   | (8,180)                         |
| Profit before taxation  |       | 16,748                                     | 40,198                          | 122,006                                   | 62,830                          |
| Taxation  | 5     | (12,999)                                   | (5,224)                         | (42,316)                                  | (34,672)                        |
| Profit for the period   |       | 3,749                                      | 34,974                          | 79,690                                    | 28,158                          |
| Attributable to:  |       |  |                                 |   |                                 |
| Owners of the Company   |       | 25,024                                     | 42,050                          | 122,006                                   | 80,344                          |
| Non-controlling interests   |       | (21,275)                                   | (7,076)                         | (42,316)                                  | (52,186)                        |
|   |       | 3,749                                      | 34,974                          | 79,690                                    | 28,158                          |
|   |       | HK cents                                   | HK cents                        | HK cents                                  | HK cents                        |
| Earnings per share:   |       |  |                                 |   |                                 |
| Basic   | 7     | 4.25                                       | 7.10                            | 20.75                                     | 13.57                           |
| Diluted   | 7     | 4.25                                       | 7.10                            | 20.74                                     | 13.55                           |

# Condensed Consolidated Statement of Profit or Loss and Other Comprehensive Income

For the three months and nine months ended 30 September 2020

|   | For the three months<br>ended 30 September |                                 | For the nine months<br>ended 30 September |                                 |
|---|--|---------------------------------|---|---------------------------------|
|   | 2020<br>HK\$'000<br>(unaudited)            | 2019<br>HK\$'000<br>(unaudited) | 2020<br>HK\$'000<br>(unaudited)           | 2019<br>HK\$'000<br>(unaudited) |
| Profit for the period   | 3,749                                      | 34,974                          | 79,690                                    | 28,158                          |
| Other comprehensive income (expense):   |  |                                 |   |                                 |
| Items that may be reclassified subsequently to profit or loss:                            |  |                                 |   |                                 |
| – Exchange differences on translation of financial statements of overseas subsidiaries    | 69,171                                     | (44,740)                        | 45,234                                    | (37,284)                        |
| – Share of other comprehensive income of associates                                       | 220  | –                               | 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 | (37,165)                                   | (61,324)                        | (252,973)                                 | (99,995)                        |
| Other comprehensive income (expense) for the period, net of tax                           | 32,226                                     | (106,064)                       | (207,624)                                 | (137,279)                       |
| Total comprehensive income (expense) for the period                                       | 35,975                                     | (71,090)                        | (127,934)                                 | (109,121)                       |
| Total comprehensive income (expense) for the period attributable to:                      |  |                                 |   |                                 |
| Owners of the Company   | 53,748                                     | (57,437)                        | (77,526)                                  | (48,529)                        |
| Non-controlling interests   | (17,773)                                   | (13,653)                        | (50,408)                                  | (60,592)                        |
|   | 35,975                                     | (71,090)                        | (127,934)                                 | (109,121)                       |

# Condensed Consolidated Statement of Changes in Equity

For the nine months ended 30 September 2020

|   | Attributable to the owners of the Company |               |                   |                          |                |                 |                                 |                  |                  |           | Attributable to non-controlling interests | Total     |
|---|---|---------------|-------------------|--------------------------|----------------|-----------------|---------------------------------|------------------|------------------|-----------|---|-----------|
|   | Share capital                             | Share premium | Merger difference | Share-based compensation |                | Treasury shares | Investments revaluation reserve | Exchange reserve | Retained profits | Sub-total |   |           |
|   |   |               |                   | reserve                  | Other reserves |                 |                                 |                  |                  |           |   |           |
|   | HK\$'000                                  | 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 income of associates                                       | -   | -             | -                 | -                        | 134            | -               | -                               | -                | -                | 134       | -   | 134       |
| - Redclassification 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 |

Attributable to the owners of the Company

|   | Share-based compensation |               |                   |                                  |                |                 |                                 |                  |                  | Attributable to non-controlling interests |   | Total     |
|---|--------------------------|---------------|-------------------|----------------------------------|----------------|-----------------|---------------------------------|------------------|------------------|---|---|-----------|
|   | Share capital            | Share premium | Merger difference | Share-based compensation reserve | Other reserves | Treasury shares | Investments revaluation reserve | Exchange reserve | Retained profits | Sub-total                                 | Attributable to non-controlling interests |           |
|   | HK\$'000                 | 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 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)  | 29,615                   | 733,599       | 9,200             | 22,263                           | 157,372        | (8,655)         | (61,562)                        | (113,821)        | 1,422,962        | 2,190,973                                 | 187,538                                   | 2,378,511 |



# Notes to the Unaudited Condensed Consolidated Financial Statements

For the nine months ended 30 September 2020

## 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 2019.

The accounting policies and methods of computation used in preparing the unaudited condensed consolidated financial statements for the nine months ended 30 September 2020 are consistent with those used in the Group’s annual financial statements for the year ended 31 December 2019 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:

|  |                                |
|--|--------------------------------|
| Amendments to HKAS 1 and HKAS 8            | Definition of Material         |
| Amendments to HKFRS 3                      | Definition of a Business       |
| Amendments to HKFRS 9, HKAS 39 and HKFRS 7 | Interest Rate Benchmark Reform |

The application of these new and 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:

|   |  |
|---|--|
| HKFRS 17  | Insurance Contracts <sup>4</sup>   |
| HK Int – 5 (2020)   | Presentation of Financial Statements – Classification by the Borrower of a Term Loan that Contains a Repayment on Demand Clause <sup>4</sup> |
| Amendments to HKAS 1  | Classification of Liabilities as Current and Non-current <sup>4</sup>  |
| Amendments to HKFRS 9, HKAS 39, HKFRS 7, HKFRS 4 and HKFRS 16 | Interest Rate Benchmark Reform – Phase 2 <sup>2</sup>  |
| Amendments to HKFRS 10 and HKAS 28                            | Sale or Contribution of Assets between an Investor and its Associate or Joint Venture <sup>5</sup>   |
| Amendments to HKFRS 16  | COVID-19-Related Rent Concessions <sup>1</sup>   |
| Amendments to HKFRSs  | Annual Improvements to HKFRSs 2018–2020 <sup>3</sup>   |

<sup>1</sup> Effective for annual periods beginning on or after 1 June 2020, earlier application is permitted

<sup>2</sup> Effective for annual periods beginning on or after 1 January 2021, earlier application is permitted

<sup>3</sup> Effective for annual periods beginning on or after 1 January 2022, earlier application is permitted

<sup>4</sup> Effective for annual periods beginning on or after 1 January 2023, earlier application is permitted

<sup>5</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 positions.

### 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 |                                 |
|----------------------------------|---|---------------------------------|--|---------------------------------|
|                                  | 2020<br>HK\$'000<br>(unaudited)         | 2019<br>HK\$'000<br>(unaudited) | 2020<br>HK\$'000<br>(unaudited)        | 2019<br>HK\$'000<br>(unaudited) |
| Proprietary and generic products | 152,533                                 | 125,958                         | 370,215                                | 396,965                         |
| Licensed-in products             | 184,793                                 | 180,376                         | 523,827                                | 516,903                         |
|                                  | <b>337,326</b>                          | 306,334                         | <b>894,042</b>                         | 913,868                         |

#### *Geographical segments*

During the three and nine months ended 30 September 2020 and 2019, 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<br>ended 30 September |                                 | For the nine months<br>ended 30 September |                                 |
|---|--|---------------------------------|---|---------------------------------|
|   | 2020<br>HK\$'000<br>(unaudited)            | 2019<br>HK\$'000<br>(unaudited) | 2020<br>HK\$'000<br>(unaudited)           | 2019<br>HK\$'000<br>(unaudited) |
| Interest income on:                           |  |                                 |   |                                 |
| Bank deposits                                 | 959  | 2,898                           | 5,725                                     | 6,118                           |
| Loan receivables                              | –  | 232                             | –   | 718                             |
| Advance to associates                         | 700  | 386                             | 1,616                                     | 1,141                           |
| Total interest income                         | 1,659                                      | 3,516                           | 7,341                                     | 7,977                           |
| Compensation income                           | –  | –                               | 41,208                                    | –                               |
| Development and government<br>grants          | 6,355                                      | 1,090                           | 18,003                                    | 8,123                           |
| Incentives from vendor                        | 2,860                                      | –                               | 2,860                                     | 2,116                           |
| Rental and utilities income<br>from associate | 321  | –                               | 934                                       | –                               |
| Research and development<br>service income    | 2,587                                      | 5,888                           | 4,892                                     | 22,123                          |
| Sundry income                                 | 672  | 388                             | 2,844                                     | 995                             |
|   | 14,454                                     | 10,882                          | 78,082                                    | 41,334                          |

## 5. TAXATION

|  | For the three months<br>ended 30 September |                                 | For the nine months<br>ended 30 September |                                 |
|--|--|---------------------------------|---|---------------------------------|
|  | 2020<br>HK\$'000<br>(unaudited)            | 2019<br>HK\$'000<br>(unaudited) | 2020<br>HK\$'000<br>(unaudited)           | 2019<br>HK\$'000<br>(unaudited) |
| Current tax  |  |                                 |   |                                 |
| Hong Kong Profits Tax                                | 8,019                                      | 3,046                           | 30,845                                    | 18,857                          |
| PRC Enterprise Income Tax                            | –  | (743)                           | –   | 5,387                           |
|  | 8,019                                      | 2,303                           | 30,845                                    | 24,244                          |
| Under (over) provision in prior<br>years             |  |                                 |   |                                 |
| PRC Enterprise Income Tax                            | –  | 46                              | (228)                                     | (3,048)                         |
| Deferred tax   |  |                                 |   |                                 |
| Origination and reversal of<br>temporary differences | 4,980                                      | 2,875                           | 11,699                                    | 13,476                          |
|  | 12,999                                     | 5,224                           | 42,316                                    | 34,672                          |

Hong Kong Profits Tax for the three and nine months ended 30 September 2020 is calculated at 8.25% (three and nine months ended 30 September 2019: 8.25%) on the first HK\$2 million of the estimated assessable profits and at 16.5% (three and nine months ended 30 September 2019: 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 2020 of HK\$0.027 per share, totalling approximately HK\$15,879,000 (six months ended 30 June 2019: HK\$0.018 per share, totalling approximately HK\$10,662,000) was declared on 27 August 2020 and paid on 30 September 2020.

The board of directors does not recommend the payment of other interim dividend for the nine months ended 30 September 2020 (nine months ended 30 September 2019: 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<br>ended 30 September |                                 | For the nine months<br>ended 30 September |                                 |
|--|--|---------------------------------|---|---------------------------------|
|  | 2020<br>HK\$'000<br>(unaudited)            | 2019<br>HK\$'000<br>(unaudited) | 2020<br>HK\$'000<br>(unaudited)           | 2019<br>HK\$'000<br>(unaudited) |
| <i>Earnings:</i>   |  |                                 |   |                                 |
| Net profit attributable to the owners of the Company for the purpose of basic and diluted earnings per share | <b>25,024</b>                              | 42,050                          | <b>122,006</b>                            | 80,344                          |

|  | For the three months<br>ended 30 September |   | For the nine months<br>ended 30 September |   |
|--|--|---|---|---|
|  | 2020<br>Share(s)<br>'000<br>(unaudited)    | 2019<br>Share(s)<br>'000<br>(unaudited) | 2020<br>Share(s)<br>'000<br>(unaudited)   | 2019<br>Share(s)<br>'000<br>(unaudited) |
| <i>Number of shares:</i>   |  |   |   |   |
| Weighted average number of ordinary shares for the purpose of basic earnings per share   | 588,125                                    | 592,309                                 | 588,119                                   | 592,242                                 |
| Effect of dilutive potential ordinary shares:  |  |   |   |   |
| Options  | 351  | 121                                     | 4   | 516                                     |
| Weighted average number of ordinary shares for the purpose of diluted earnings per share | 588,476                                    | 592,430                                 | 588,123                                   | 592,758                                 |

## 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<br>ended 30 September |                                 |
|-----------------------------|---|---------------------------------|
|                             | 2020<br>HK\$'000<br>(unaudited)           | 2019<br>HK\$'000<br>(unaudited) |
| Interest income             | 1,616                                     | 1,141                           |
| Rental and utilities income | 934                                       | –                               |

**(b) Compensation of key management personnel**

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

|   | <b>For the nine months<br/>ended 30 September</b> |             |
|---|---|-------------|
|   | <b>2020</b>                                       | 2019        |
|   | <b>HK\$'000</b>                                   | HK\$'000    |
|   | <b>(unaudited)</b>                                | (unaudited) |
| Short-term employee benefits                  | <b>17,829</b>                                     | 14,627      |
| Share-based payments                          | <b>7,504</b>                                      | 2,224       |
| Retirement and other post-employment benefits | <b>19,713</b>                                     | 12,030      |
| – Defined contribution plan                   | <b>27</b>   | 30          |
| – Retirement benefits                         | <b>19,686</b>                                     | 12,000      |
|   | <b>45,046</b>                                     | 28,881      |

**(c) Donation to Lee's Pharmaceutical – Kanya Lee Scholarship Limited ("Kanya Lee Scholarship")**

During the nine months ended 30 September 2020, there is approximately HK\$1,275,000 (nine months ended 30 September 2019: approximately HK\$3,144,000) 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) Issue of subsidiary's shares to Perfect Concept Holdings Limited ("PCH")**

During the period under review, China Oncology Focus Limited, an indirect non-wholly-owned subsidiary, on a pro rata basis, issued 18,620 shares to PCH. Ms. Leelalertsuphakun Wanee, Ms. Lee Siu Fong and Dr. Li Xiaoyi are both the directors of the Company and the substantial shareholders of PCH and PCH is considered as a related party to the Group. Total consideration received for the issue of shares is US\$4,003,300 (equivalent to approximately HK\$31,226,000).

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

During the period under review, included in finance costs there was interest expenses for loans from PCH amounting to approximately HK\$147,000 (nine months ended 30 September 2019: approximately HK\$296,000).

## 9. CAPITAL COMMITMENTS

|   | At<br>30 September<br>2020<br>HK\$'000<br>(unaudited) | At<br>31 December<br>2019<br>HK\$'000<br>(audited) |
|---|---|--|
| Capital commitments contracted for in respect of:                                 |   |  |
| – Investment in financial assets at fair value through other comprehensive income | 21,985  | 29,892   |
| – Intangible assets – license fee and development cost                            | 142,156   | 103,455  |
| – Property, plant and equipment   | 110,543   | 100,452  |
|   | <b>274,684</b>  | <b>233,799</b>                                     |

## 10. EVENTS AFTER THE REPORTING PERIOD

Subsequent to the end of the reporting period, on 2 October 2020, a license agreement (the “**ACCG License Agreement**”) has been entered into between the Group and Zhaoke Ophthalmology Limited (“**ZKO**”, formerly known as China Ophthalmology Focus Limited) which involve the grant of the commercialisation right of ACCG in China for the treatment of moderate acne vulgaris by ZKO to the Group. Pursuant to the ACCG License Agreement, ZKO agreed to grant an exclusive license rights to the Group in relation to the ACCG in China, Hong Kong, Macau and Taiwan, and in consideration of which, the Group agreed to pay the upfront payment (inclusive of tax) of US\$10,000,000 which has been settled by way of the repurchase of ZKO shares in cash), the milestone payment (inclusive of tax) of US\$5,000,000 and a sales commission to ZKO in accordance with the terms of the ACCG License Agreement. Following the completion of the ACCG License Agreement, ZKO and its subsidiaries were no longer indirect non-wholly-owned subsidiaries and become associated companies to the Group. Details of the ACCG License Agreement have been disclosed in the Company’s announcement dated 4 October 2020.

## **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 2020.

## **DIVIDEND**

The Board does not recommend payment of dividend for the nine months ended 30 September 2020 (nine months ended 30 September 2019: nil).

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

Hong Kong, 26 November 2020

*As at the date of this report, Ms. Lee Siu Fong (Chairman), Ms. Leelalertsuphakun 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.*