LEE'S PHARM.
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)
(於開曼群島註冊成立之有限公司)
(Stock Code 股份代號:950)

李我同心 再次騰飛
A TRANSCENDING LEAP

第三季度業績報告

Third Quarterly Report 2021

* For identification purpose only
僅供識別

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.

季度財務報表

李氏大藥廠控股有限公司(「**本公司**」)董事(「**董事**」)謹此呈報本公司及其附屬公司(統稱「**本集團**」)截至二零二一年九月三十日止三個月及九個月之未經審核綜合季度財務業績(「**季度業績**」)連同二零二零年同期之比較數字。季度業績未經審核,惟獲本公司核數師恒健會計師行有限公司(「**核數師**」)按照香港會計師公會頒佈之《香港審閱工作準則》第2410號「實體的獨立核數師對中期財務資料的審閱」進行審閱。本公司審核委員會於向董事會推薦季度業績以供批准前,亦已與管理層及核數師審閱季度業績。

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.

業務回顧

收益及溢利

於二零二一年首九個月，本集團錄得總收益952,387,000港元(二零二零年首九個月：894,042,000港元)，較去年同期增長6.5%。本集團二零二一年第三季度的總收益為368,335,000港元(二零二零年第三季度：337,326,000港元)，較去年同一季度增長9.2%，亦較二零二一年第二季度增長22.4%。二零二一年首九個月的銷售額增長主要受《尤靖安》®、《菲普利》®、《可益能》®、《速樂涓》®及曲前列尼爾注射液的銷售額分別增長70.7%、33.7%、16.7%、7.2%及125.0%帶動，充份抵銷了《再寧平》®中國特許授權終止後喪失的收益及因《立邁青》®於取得作為那屈肝素鈣注射液的藥品批准文號後需重新安排在醫院上市而產生的銷售額跌幅。

二零二一年首九個月引進產品的銷售額佔本集團收益的58.5%(二零二零年首九個月：58.6%)，而二零二一年首九個月專利及仿製產品的銷售額則佔本集團收益的41.5%(二零二零年首九個月：41.4%)。

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.

於二零二一年首九個月，本集團錄得毛利634,796,000港元(二零二零年首九個月：575,669,000港元)，較去年同期增長10.3%。本集團二零二一年第三季度的毛利為248,250,000港元(二零二零年第三季度：210,050,000港元)，較去年同一季度增長18.2%。本集團二零二一年第三季度的毛利率為67.4%，較去年同一季度的62.3%上升5.1個百分點。本集團二零二一年首九個月的毛利率為66.7%，較去年同期的64.4%上升2.3個百分點，主要源於回顧季度內若干專利產品的材料採購成本改善。

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.

於回顧期內，本集團的研究及開發(「**研發**」)費用來自心血管、女性健康、兒科、罕見病、皮膚科及產科等各種主要治療領域的新藥開發，以及獨立的腫瘤科研發分支。

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.

中國內地醫療制度的監管及保障政策於二零二一年首九個月進行多項重大改革，其中一項主要市場准入改革為藥品集中採購(「**藥品集採**」)計劃，對藥品價格構成壓力。根據於二零二一年九月二十九日頒佈的《「十四五」全民醫療保障規劃》，藥品集採計劃預計將會延續，更可能於二零二二年底或之前覆蓋更多藥物。此外，省級醫療服務價格年度調整機制可能於二零二二年六月或之前出台。再者，省級藥品及耗材集採計劃可能至少每年進行一次。因此，在二零二一年六月的第五批藥品集採完成後，本集團優化研發組合後就合共14項藥物開發項目已資本化的專利費及開發成本全數減值確認一次性虧損約190,100,000港元；且在最新一輪藥品集採計劃完成後，已推出的口服抗高血壓藥《銳思力》®在其他抗高血壓競爭產品價格下滑的情況下，未來市場及收益潛力存疑，故本集團亦就其已資本化的專利費及開發成本全數減值確認一次性虧損約40,200,000港元。

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).

除上文所述者外，本集團於回顧期內繼續投資於研發活動，二零二一年首九個月總開支為345,218,000港元(二零二零年首九個月：268,605,000港元)，佔相應期間收益的36.2%(二零二零年首九個月：30.0%)，當中180,448,000港元(二零二零年首九個月：143,073,000港元)已確認為費用，而164,770,000港元(二零二零年首九個月：125,532,000港元)已資本化作為無形資產。此外，於二零二一年首九個月，100,446,000港元(二零二零年首九個月：34,938,000港元)的引進產品專利費亦已確認為無形資產。

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.

回顧期內的重點為強化現有分銷管道，同時探索新分銷管道，以及為新產品及即將面世的產品上市作準備，且已投放足夠資源。整體而言，與去年同期的21.3%比較，二零二一年首九個月銷售費用對收益的比率上升至27.2%。有關努力的例子包括本集團自二零二一年七月起迅速接手布累迪寧的銷售工作，更於二零二一年第三季度實現收益約16,400,000港元。

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.

加上緊隨兆科眼科有限公司(「**兆科眼科**」，股份代號：6622.HK)於二零二一年四月二十九日分拆上市後，終止將本公司於兆科眼科的投資確認為聯營公司時的一次性收益約2,300,000,000港元，二零二一年首九個月的本公司擁有人應佔純利為2,169,043,000港元，較二零二零年首九個月增加約16.8倍。

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.

生產設施及生產能力

於二零二一年首九個月，本集團合肥基地的《尤靖安》®及《立邁青》®產能提升及生產設施升級以及若干口服凍乾粉及脂質體新產品的技術轉移進度良好。南沙基地生產特卡法林藥片及諾克沙班藥片已完成GMP生產線建設並已生產臨床試驗用藥。生產氣溶膠吸入劑的設施亦已完成安裝及調試，並已生產臨床試驗用藥，而生產口服細胞毒性藥物及進行連續血糖監測的設備則已完成安裝及調試，兩者均已準備好生產臨床試驗用藥及／或註冊批次。

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.

藥物開發

截至目前為止，本集團有超過40個分別處於早期至後期開發階段的項目。

於上一年度，本集團的進口藥品註冊證申請(即Natulan®、INOmax®、Zingo®及Teglutik®)及簡化新藥上市申請(「**簡化新藥申請**」)(即阿齊沙坦及阿普米司特片)正由藥品審評中心(「**藥審中心**」)評審。而上一年度的Adasuve®新藥上市申請(「**新藥申請**」)已獲中國國家藥品監督管理局(「**國家藥監局**」)正式受理。

於二零二一年首九個月及截至目前為止，多項臨床計劃取得實質進展。

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.

主要治療領域

Cetraxal® Plus

於二零二一年一月四日，本集團於中國招募首名病人在三期臨床試驗中使用Cetraxal® Plus。Cetraxal® Plus為Laboratorios Salvat S.A.特許授權的滴耳液產品，治療急性外耳道炎及伴有鼓膜置管的急性中耳炎。於二零二一年十月，本集團已完成入組所需的600名受試者。

此外，Cetraxal® Plus已成功於二零二一年十月四日在香港市場推出。

Intrarosa®

於二零二一年一月五日，本集團已獲中國國家藥監局批授開展Intrarosa®的多中心、隨機、雙盲、並行組別的三期臨床試驗的臨床試驗批准。Intrarosa®為Endoceutics, Inc.特許授權的產品，用於治療外陰陰道萎縮(「**VVA**」)。此關鍵的三期研究已於二零二一年七月取得中國人類遺傳資源管理辦公室(「**遺傳辦**」)批准，故首名患者已於二零二一年九月十三日入組。Intrarosa®是全球唯一獲美國食品藥品監督管理局(「**FDA**」)及歐洲藥品管理局(「**EMA**」)批准的供日常局部使用的不含雌激素類固醇，適用於治療因更年期而出現的VVA。Intrarosa®的產品資料並無任何包裝(安全)警告，有別於其他獲FDA認證用於治療VVA的藥物，全部均印有包裝警告。Intrarosa®含有普拉睪酮(又名脫氫表雄酮(DHEA))。普拉睪酮為一種非活性內源性類固醇，會內部轉化為雄激素及雌激素，幫助修復陰道纖維組織，從表層和副基底細胞的百分比以及酸鹼值改善可見一斑。

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.

Lutrate®

於二零二一年一月二十七日，Lutrate® Depot(醋酸亮丙瑞林長效懸浮液)3.75毫克1個月輸注(「**Lutrate®**」)的新藥申請已獲國家藥監局受理，該藥物乃用於晚期前列腺癌的紓緩治療。Lutrate®含有活性成份醋酸亮丙瑞林，屬於一組名為促黃體激素釋放激素(「**LHRH**」)促進劑的藥物，可減少主要雄激素睪酮。以LHRH促進劑進行治療為雄激素去除療法的主要方式，現已成為轉移性前列腺癌的護理標準。

Staccato®芬太尼

Staccato®芬太尼吸入製劑是一種複合型吸入式給藥裝置，其設計是透過肺部迅速及規律地吸入霧化芬太尼。此項產品結合具有獨特給藥技術的最新科技，於確保藥效的同時防止濫用及過量用藥。此項針對中國爆發性癌痛患者的霧化芬太尼吸入製劑一／二a期試驗包括第一階段的隨機、雙盲、安慰劑對照及自身交叉研究以及第二階段的開放性不遮盲藥物代謝動力學研究。該項產品的設計以從Alexza Pharmaceuticals(「**Alexza**」)引進的Staccato®技術與芬太尼藥物為基礎，再由本集團加入人工智能雲端控制系統加以改良。此項一／二a期臨床試驗已於二零二一年八月取得遺傳辦批文，首名患者已於二零二一年十月二十日入組。

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.

此項一／二a期試驗的開展建基於Alexza早前已獲FDA審批的第一期臨床試驗結果，當中顯示一般患者吸入霧化芬太尼的藥效及安全程度理想。目前在中國進行的臨床試驗旨在評估霧化芬太尼在中國爆發性癌痛患者間的安全性、耐受性、藥物代謝動力學表現及劑量反應。該項研究將於11個試驗中心進行，第一階段及第二階段將分別招募60名及36名患者。

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.

GCC-4401C

於二零二一年三月一日，本集團獲國家藥監局批准GCC-4401C的新藥臨床試驗申請(「**臨床試驗申請**」)，以對GCC-4401C作為可能治療非腫瘤性門靜脈血栓(PVT)的肝硬化患者進行臨床試驗。GCC-4401C為一種與利伐沙班結構類似的新型直接口服抗凝血劑。凝血因數Xa為血液凝固路徑中的重要靶點，GCC-4401C直接抑制凝血Xa因子的活動，以防止血栓形成。

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 GPIbα". Anfibatide is a new molecular entity discovered and developed by the Group. It is a first-in-class platelet GPIbα 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 GPIbα 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.

安菲博肽

評估安菲博肽在體外、人體血液離體以及在健康人體受試者體內注射和輸液後的抗血栓功效及安全性的一期臨床試驗(clinicaltrials.gov註冊編號：NCT01588132)已經完成，其主要研究結果已於二零二一年六月三日在《科學報告》上發表，文章標題為《靶向人血小板GPIbα的蛇毒源抗血栓劑安菲博肽的體外評估及一期隨機臨床試驗*》(In vitro assessment and Phase I randomized clinical trial of Anfibatide a snake venom derived anti-thrombotic agent targeting human platelet GPIbα)。安菲博肽為本集團發現和開發的新分子實體，是首創血小板GPIbα受體對抗劑，在健康受試者中具有快速起效、有效及可逆的抗血栓作用，不會損害凝血功能或延長出血時間。在期刊中發表的資料顯示，安菲博肽可能是一種靶向血小板GPIbα的安全和有效的抗血栓治療劑，並且值得進一步研究。該文章的完整版本可以在www.nature.com/articles/s41598-021-91165-8找到。

於回顧期內及截至目前為止，本集團已取得國家藥監局發出2項簡化新藥申請批准。

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.

磺達肝癸鈉注射液

於二零二一年二月二日，磺達肝癸鈉注射液(0.5毫升：2.5毫克)已獲國家藥監局的生產及上市批文。該藥物適用於預防正進行髖關節手術、髖關節或膝關節置換或下腹手術的人士出現可導致肺栓塞(PE；肺部血凝塊)的深靜脈血栓(DVT；一般見於腿部的血凝塊)。磺達肝癸鈉乃人工合成的活化凝血X因子(Xa因子)選擇性抑制劑，具有生物利用度高、起效快、半衰期長等優點。磺達肝癸鈉對IIa因子無作用，出血的不良反應少，僅抑制游離的Xa因子而不抑制與凝血酶原酶結合的Xa因子，不需監測PT(凝血酶原時間)及aPTT(活化部分凝血酶時間)。磺達肝癸鈉分子鏈短，不能誘導抗體反應，與血小板並無相互作用，不會引起血小板減少症，且對肝臟無毒害作用，過敏反應發生少。

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.

苯丁酸鈉顆粒

於二零二一年五月十三日，由本公司全資附屬公司兆科藥業(廣州)有限公司(「**兆科廣州**」)開發並生產的苯丁酸鈉顆粒(規格：150克／瓶，每1克含苯丁酸鈉0.94克)取得國家藥監局的藥品註冊證書。苯丁酸鈉作為輔助治療藥物，用於氨基甲醯磷酸合成酶缺乏症、鳥氨酸氨甲醯基轉移酶缺乏症或精氨基琥珀酸合成酶缺乏症引起的尿素循環異常患者的長期治療，適用於新生兒期(出生28天內)出現完全酶缺乏症的患者，亦適用於有高血氨性腦病病史的遲發型(部分酶缺乏症，發生於出生一個月後)患者。兆科廣州開發並生產的苯丁酸鈉顆粒為國內首仿藥物。目前中國沒有原研苯丁酸鈉銷售，本集團的苯丁酸鈉顆粒正好填補國內醫療需求的空白。

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.

腫瘤管道重點

本集團擁有65%權益的附屬公司中國腫瘤醫療有限公司(「**COF**」)為本集團在腫瘤科方面的研發分支。截至目前為止，10項腫瘤產品正在開發，包括5項創新及5項仿製藥，用於治療多種癌症。

使用Socazolimab的復發或轉移性宮頸癌治療

於二零二一年二月五日，COF用於治療復發性或轉移性宮頸癌的抗PD-L1單克隆抗體Socazolimab(前稱ZKAB001)獲得國家藥監局突破性療法認定。Socazolimab為針對腫瘤PD-L1蛋白的完全人類抗PD-L1單克隆抗體，可以釋放由腫瘤細胞引起的免疫系統「剎車」。於二零二一年十月二十六日，使用Socazolimab治療復發性或轉移性宮頸癌的新藥申請已成功向藥審中心提交，並獲藥審中心受理審評。優先審評及有條件批准的申請亦已隨同新藥申請一併提交。

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.

使用Socazolimab的骨肉瘤治療

於回顧期內及截至目前為止，使用Socazolimab的骨肉瘤維持治療可望達成註冊的三期臨床試驗進度良好。迄今已招募126名患者。

使用Socazolimab結合化療治療小細胞肺癌

於二零二一年三月一日，COF獲國家藥監局批准臨床試驗申請，以對結合化療一線治療擴散期小細胞肺癌(「**ES-SCLC**」)的Socazolimab進行多中心、隨機、雙盲、並行組別的三期臨床試驗。該批准的依據為先前第一b期試驗的結果，當中結合卡鉑和依托泊苷的Socazolimab在擴散期小細胞肺癌患者中表現出良好的療效及安全性。此臨床試驗將由上海市胸科醫院陸舜教授牽頭，首名患者已於二零二一年七月十五日入組，迄今已有100名患者入組。

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.

使用Socazolimab結合Pexa-Vec治療轉移性黑色素瘤

於二零二一年十月二十一日，COF就使用Pexa-Vec（表達粒細胞－巨噬細胞集落刺激因子／滅活胸苷激酶的牛痘病毒）結合Socazolimab治療轉移性黑色素瘤的第一b／二期臨床研究於中國入組首名患者。

該研究由北京大學腫瘤醫院的郭軍教授牽頭，分為第一b期及第二期兩期。第一b期將評估一線治療無效造成局部擴散及轉移性黑色素瘤的患者使用結合療程的安全性及第二期建議劑量，將入組最多12名患者。第一b期研究的招募工作預計將於二零二二年六月完成。

第二期將評估使用Socazolimab結合Pexa-Vec或Socazolimab單藥療法治療局部擴散或轉移性黑色素瘤患者的客觀緩解率及無惡化生存期，將入組合共45名患者。

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.

業務夥伴

特許經營策略為本集團業務發展策略的首選模式。然而，本集團在訂立新的特許經營交易時，仍然堅持精挑細選。本集團於回顧期內僅訂立一項特許經營交易。於二零二一年六月十五日，本集團成功與日本公司旭化成製藥株式会社訂立授權協議。據此，本集團獲得布累迪寧(通用名稱：咪唑立賓)商業化的獨家授權，在中國大陸用於抑制腎臟移植的排斥反應。布累迪寧於一九九九年首次在中國面市，已在患者群體中建立良好的市場地位。此外，狼瘡性腎炎(LN)及腎病綜合症(NS)追加適應症的補充新藥申請已於二零二零年六月提交國家藥監局。

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.

企業發展

於二零二一年四月二十九日，本集團於兆科眼科的投資成功於香港聯合交易所有限公司(「**聯交所**」)主板上市，發售價為每股兆科眼科股份16.80港元，集資額約為1,932,300,000港元。於兆科眼科上市後，由於本集團不能再對兆科眼科的運作行使重大影響力，故兆科眼科不再為本公司的聯營公司，就財務報告而言入賬列作按公平值透過其他全面收益列賬的財務資產。於二零二一年第二季終止將本公司於兆科眼科的投資確認為聯營公司時，本集團於本公司的綜合損益表內錄得一次性收益約2,300,000,000港元。

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.

展望

中國醫藥市場近年不斷發展，商機處處。然而，儘管市場欣欣向榮，惟本集團依然相信，藥品集採計劃預計將覆蓋更多藥物，藥物價格壓力將繼續為業界帶來挑戰，可見未來的環境仍將荊棘滿途。

為適應新常態，價值鏈中的每一個環節(包括研發過程、生產以至銷售等)均強調效率。本集團亦須保持穩健財政、良好管治及充裕流動資源，方能長遠為股東創造價值。

眼科分支於二零二一年四月完成分拆上市，印證本集團為股東釋放研發實力價值的決心。本集團正在審慎地投放資源開拓其他主要治療領域的業務，尤其是心血管、罕見病及腫瘤科。此外，本集團亦將繼續努力探索優化研發項目組合的機會。

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 saleforce than ever in launching new products in the upcoming future.

自二零二零年起成立的集團營銷中心成功鞏固並改革本集團的銷售團隊，近期更通過試煉，於二零二一年七月接手布累迪寧的銷售工作，增強了本集團對於其銷售團隊日後有效推出新產品的信心。

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.

此外，中國有效遏止COVID-19蔓延、區內經濟復甦及新產品獲批上市等種種正面因素，亦可望協助本集團克服挑戰。

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.

步向二零二一年底，各國疫苗接種率節節上升，為征服COVID-19帶來曙光。本集團將繼續採用審慎的業務及財務策略鞏固基礎。本集團深信，上述各項任務將可成就增長，最終為所有持份者創造更高價值。

CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS

簡明綜合損益表

For the three months and nine months ended 30 September 2021

截至二零二一年九月三十日止三個月及九個月

		Notes 附註	For the three months ended 30 September 截至九月三十日止三個月		For the nine months ended 30 September 截至九月三十日止九個月	
			2021 二零二一年	2020 二零二零年	**2021 二零二一年**	2020 二零二零年
			HK$'000 千港元	HK$'000 千港元	**HK$'000 千港元**	HK$'000 千港元
			(unaudited) (未經審核)	(unaudited) (未經審核)	**(unaudited) (未經審核)**	(unaudited) (未經審核)
Revenue	收益	3	**368,335**	337,326	**952,387**	894,042
Cost of sales	銷售成本		**(120,085)**	(127,276)	**(317,591)**	(318,373)
Gross profit	毛利		**248,250**	210,050	**634,796**	575,669
Other income	其他收益	4	**19,690**	14,454	**84,628**	78,082
Other gains and losses, net	其他收益及虧損淨額		**(2,310)**	(2,410)	**2,090,956**	(7,799)
Selling and distribution expenses	銷售及分銷費用		**(94,745)**	(68,247)	**(258,863)**	(190,383)
Administrative expenses	行政費用		**(92,077)**	(65,993)	**(216,278)**	(177,126)
Net reversal of (provision for) expected credit losses on financial assets	財務資產預期信貸虧損撥回(撥備)淨額		**598**	318	**179**	(269)
Research and development expenses	研究及開發費用		**(67,549)**	(67,913)	**(180,448)**	(143,073)
Profit from operations	經營溢利		**11,857**	20,259	**2,154,970**	135,101
Finance costs	財務成本		**(1,752)**	(1,547)	**(4,275)**	(5,092)
Share of results of associates	分佔聯營公司業績		**(62)**	(1,964)	**(3,373)**	(8,003)
Profit before taxation	除稅前溢利		**10,043**	16,748	**2,147,322**	122,006
Taxation	稅項	5	**1,041**	(12,999)	**(2,336)**	(42,316)
Profit for the period	本期間溢利		**11,084**	3,749	**2,144,986**	79,690
Attributable to:	下列人士應佔：					
Owners of the Company	本公司擁有人		**13,843**	25,024	**2,169,043**	122,006
Non-controlling interests	非控股權益		**(2,759)**	(21,275)	**(24,057)**	(42,316)
			11,084	3,749	**2,144,986**	79,690
			HK cents 港仙	HK cents 港仙	**HK cents 港仙**	HK cents 港仙
Earnings per share:	每股盈利：					
Basic	基本	7	**2.35**	4.25	**368.52**	20.75
Diluted	攤薄	7	**2.35**	4.25	**368.34**	20.74

CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

簡明綜合損益及其他全面收益表

For the three months and nine months ended 30 September 2021

截至二零二一年九月三十日止三個月及九個月

		For the three months ended 30 September 截至九月三十日止三個月		For the nine months ended 30 September 截至九月三十日止九個月	
		2021 二零二一年 HK$'000 千港元 (unaudited) (未經審核)	2020 二零二零年 HK$'000 千港元 (unaudited) (未經審核)	**2021 二零二一年 HK$'000 千港元 (unaudited) (未經審核)**	2020 二零二零年 HK$'000 千港元 (unaudited) (未經審核)
Profit for the period	本期間溢利	**11,084**	3,749	**2,144,986**	79,690
Other comprehensive income (expense):	其他全面收益(開支)：				
Items that may be reclassified subsequently to profit or loss:	其後可能重新分類至損益之項目：				
– Exchange differences on translation of financial statements of overseas subsidiaries	–海外附屬公司財務報表換算之匯兑差額	**9,531**	69,171	**21,563**	45,234
– Share of other comprehensive income of associates	–分佔聯營公司之其他全面收益	**–**	220	**46**	134
– Reclassification of exchange reserve upon disposal of an overseas subsidiary	–於出售一間海外附屬公司時將匯兑儲備重新分類	**–**	–	**–**	(19)
Item that will not be reclassified subsequently to profit or loss:	其後不會重新分類至損益之項目：				
– Fair value changes of financial assets at fair value through other comprehensive income	–按公平值透過其他全面收益列賬之財務資產之公平值變動	**(602,504)**	(37,165)	**(1,384,331)**	(252,973)
Other comprehensive (expense) income for the period, net of tax	本期間其他全面(開支)收益，扣除稅項	**(592,973)**	32,226	**(1,362,722)**	(207,624)
Total comprehensive (expense) income for the period	本期間全面(開支)收益總額	**(581,889)**	35,975	**782,264**	(127,934)
Total comprehensive (expense) income for the period attributable to:	下列人士應佔本期間全面(開支)收益總額：				
Owners of the Company	本公司擁有人	**(578,825)**	53,748	**810,978**	(77,526)
Non-controlling interests	非控股權益	**(3,064)**	(17,773)	**(28,714)**	(50,408)
		(581,889)	35,975	**782,264**	(127,934)

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

簡明綜合權益變動表

For the nine months ended 30 September 2021

截至二零二一年九月三十日止九個月

		Attributable to the owners of the Company 本公司擁有人應佔									Attributable to non-controlling interests 非控股權益應佔 HK$'000 千港元	Total 總計 HK$'000 千港元
		Share capital 股本 HK$'000 千港元	Share premium 股份溢價 HK$'000 千港元	Merger difference 合併差額 HK$'000 千港元	Share-based compensation reserve 以股份支付之酬金儲備 HK$'000 千港元	Other reserves 其他儲備 HK$'000 千港元	Investments revaluation reserve 投資重估儲備 HK$'000 千港元	Exchange reserve 匯兌儲備 HK$'000 千港元	Retained profits 保留溢利 HK$'000 千港元	Sub-total 小計 HK$'000 千港元		
At 1 January 2021 (audited)	於二零二一年一月一日(經審核)	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	僱員購股權福利	-	-	-	13,464	-	-	-	-	13,464	-	13,464
Exercise of share options	行使購股權	36	5,278	-	(1,771)	-	-	-	-	3,543	-	3,543
Share of reserve of an associate	分佔一間聯營公司儲備	-	-	-	-	28	-	-	-	28	-	28
Profit (loss) for the period	本期間溢利(虧損)	-	-	-	-	-	-	-	2,169,043	2,169,043	(24,057)	2,144,986
Other comprehensive income (expense) for the period	本期間其他全面收益(開支)											
– Exchange differences on translation of financial statements of overseas subsidiaries	–海外附屬公司財務報表換算之匯兑差額	-	-	-	-	-	-	21,453	-	21,453	110	21,563
– Share of other comprehensive income of associates	–分佔聯營公司之其他全面收益	-	-	-	-	46	-	-	-	46	-	46
– Fair value changes of financial assets at fair value through other comprehensive income	–按公平值透過其他全面收益列賬之財務資產之公平值變動	-	-	-	-	-	(1,379,564)	-	-	(1,379,564)	(4,767)	(1,384,331)
Total comprehensive income (expense) for the period	本期間全面收益(開支)總額	-	-	-	-	46	(1,379,564)	21,453	2,169,043	810,978	(28,714)	782,264
2020 final dividend paid	已付二零二零年末期股息	-	-	-	-	-	-	-	(18,254)	(18,254)	-	(18,254)
At 30 September 2021 (unaudited)	於二零二一年九月三十日(未經審核)	29,442	720,091	9,200	52,540	65,302	(1,633,719)	6,610	3,710,088	2,959,554	(63,131)	2,896,423

		Attributable to the owners of the Company 本公司擁有人應佔										
		Share capital 股本 HK$'000 千港元	Share premium 股份溢價 HK$'000 千港元	Merger difference 合併差額 HK$'000 千港元	Share-based compensation reserve 以股份支付之酬金儲備 HK$'000 千港元	Other reserves 其他儲備 HK$'000 千港元	Investments revaluation reserve 投資重估儲備 HK$'000 千港元	Exchange reserve 匯兌儲備 HK$'000 千港元	Retained profits 保留溢利 HK$'000 千港元	Sub-total 小計 HK$'000 千港元	Attributable to non-controlling interests 非控股權益應佔 HK$'000 千港元	Total 總計 HK$'000 千港元
At 1 January 2020 (audited)	於二零二零年一月一日（經審核）	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	僱員購股權福利	–	–	–	11,514	–	–	–	–	11,514	–	11,514
Exercise of share options	行使購股權	10	667	–	(231)	–	–	–	–	446	–	446
Share options lapsed	已失效購股權	–	–	–	(39)	–	–	–	39	–	–	–
Share of reserve of an associate	分佔一間聯營公司儲備	–	–	–	–	42	–	–	–	42	–	42
Capital contribution from non-controlling interests	非控股權益出資	–	–	–	–	–	–	–	–	–	31,226	31,226
Acquisition of a subsidiary	收購一間附屬公司	–	–	–	–	–	–	–	–	–	(2,250)	(2,250)
Disposal of a subsidiary	出售一間附屬公司	–	–	–	–	–	–	–	–	–	(1,891)	(1,891)
Profit (loss) for the period	本期間溢利(虧損)	–	–	–	–	–	–	–	122,006	122,006	(42,316)	79,690
Other comprehensive income (expense) for the period	本期間其他全面收益(開支)											
– Exchange differences on translation of financial statements of overseas subsidiaries	–海外附屬公司財務報表換算之匯兌差額	–	–	–	–	–	–	41,942	–	41,942	3,292	45,234
– Share of other comprehensive expense of associates	–分佔聯營公司之其他全面開支	–	–	–	–	134	–	–	–	134	–	134
– Reclassification of exchange reserve upon disposal of an overseas subsidiary	–於出售一間海外附屬公司時將匯兌儲備重新分類	–	–	–	–	–	–	(19)	–	(19)	–	(19)
– Fair value changes of financial assets at fair value through other comprehensive income	–按公平值透過其他全面收益列賬之財務資產之公平值變動	–	–	–	–	–	(241,589)	–	–	(241,589)	(11,384)	(252,973)
Total comprehensive income (expense) for the period	本期間全面收益（開支）總額	–	–	–	–	134	(241,589)	41,923	122,006	(77,526)	(50,408)	(127,934)
2019 final dividend paid	已付二零一九年末期股息	–	–	–	–	–	–	–	(22,349)	(22,349)	–	(22,349)
2020 interim dividend paid	已付二零二零年中期股息	–	–	–	–	–	–	–	(15,879)	(15,879)	–	(15,879)
At 30 September 2020 (unaudited)	於二零二零年九月三十日（未經審核）	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

未經審核簡明綜合財務報表附註

截至二零二一年九月三十日止九個月

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.

1. 編製基準

未經審核簡明綜合財務報表乃按照香港會計師公會頒佈之香港會計準則及香港聯合交易所有限公司證券上市規則附錄十六之適用披露規定編製。

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.

2. 主要會計政策

未經審核簡明綜合財務報表乃按歷史成本基準編製，惟若干財務工具按公平值計量(視適當情況而定)除外。

未經審核簡明綜合財務報表不包括須於全年財務報表提供之所有資料及披露事項，並應與本集團截至二零二零年十二月三十一日止年度之全年財務報表一併閱讀。

編製截至二零二一年九月三十日止三個月及九個月之未經審核簡明綜合財務報表所用之會計政策及計算方法與本集團截至二零二零年十二月三十一日止年度之全年財務報表所用者一致，惟下述者除外。

2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

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.

2. 主要會計政策(續)

於本報告期間內，本集團首次應用香港會計師公會所頒佈就編製本集團未經審核簡明綜合財務報表而言相關之下列香港會計準則及香港財務報告準則之修訂：

香港財務報告準則第9號、香港會計準則第39號、香港財務報告準則第7號、香港財務報告準則第4號及香港財務報告準則第16號之修訂	利率基準改革－第2階段
香港財務報告準則第16號之修訂	COVID-19相關租金優惠

應用該等香港會計準則及香港財務報告準則之修訂對本未經審核簡明綜合財務報表所呈報之金額及／或本未經審核簡明綜合財務報表所載之披露事項並無重大影響。

2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

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]

2. 主要會計政策(續)

本集團並無提早採用下列已頒佈但尚未生效之新增香港會計準則及香港財務報告準則以及香港會計準則及香港財務報告準則之修訂：

會計指引第5號（修訂）	共同控制下業務合併之合併會計處理[2]
香港財務報告準則第17號	保險合約及相關修訂[3]
香港會計準則第1號之修訂	流動及非流動負債之分類或香港詮釋第5號（二零二零年）之相關修訂[3]
香港會計準則第1號之修訂	會計政策披露[3]
香港會計準則第8號之修訂	會計估計定義[3]
香港會計準則第12號之修訂	與一項單一交易產生之資產及負債有關之遞延稅項[3]
香港會計準則第16號之修訂	物業、廠房及設備－作擬定用途前之所得款項[2]
香港會計準則第37號之修訂	虧損合約－履行合約之成本[2]
香港財務報告準則第3號之修訂	對概念框架之提述[2]
香港財務報告準則第10號及香港會計準則第28號之修訂	投資者與其聯營公司或合營企業之間之資產出售或注資[4]
香港財務報告準則第16號之修訂	於二零二一年六月三十日後之COVID-19相關租金優惠[1]
香港財務報告準則之修訂	香港財務報告準則二零一八年至二零二零年之年度改進[2]

2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

[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.

2. 主要會計政策(續)

[1] 於二零二一年四月一日或之後開始之年度期間生效，可提早應用
[2] 於二零二二年一月一日或之後開始之年度期間生效，可提早應用
[3] 於二零二三年一月一日或之後開始之年度期間生效，可提早應用
[4] 生效日期待定

本集團已開始評估該等新增香港會計準則及香港財務報告準則以及香港會計準則及香港財務報告準則之修訂之影響，但尚無法說明該等新增香港會計準則及香港財務報告準則以及香港會計準則及香港財務報告準則之修訂會否對本集團之經營業績及財務狀況造成重大影響。

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:

3. 收益

本集團之主要業務為開發、製造、銷售及推廣藥品。期內，收益指本集團向外部客戶出售貨品之已收及應收款項淨額，並按時間點確認如下：

Business segments

業務分部

		For the three months ended 30 September 截至九月三十日止三個月		For the nine months ended 30 September 截至九月三十日止九個月	
		2021 二零二一年	2020 二零二零年	**2021 二零二一年**	2020 二零二零年
		HK$'000 千港元	HK$'000 千港元	**HK$'000 千港元**	HK$'000 千港元
		(unaudited) (未經審核)	(unaudited) (未經審核)	**(unaudited) (未經審核)**	(unaudited) (未經審核)
Proprietary and generic products	專利及仿製產品	**145,766**	152,533	**395,401**	370,215
Licensed-in products	引進產品	**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.

地區分部

於截至二零二一年及二零二零年九月三十日止三個月及九個月，本集團逾90%之收益源自於中華人民共和國(「**中國**」)進行之業務，故此並無呈列地區分部資料。

4. OTHER INCOME

4. 其他收益

		For the three months ended 30 September 截至九月三十日止三個月		For the nine months ended 30 September 截至九月三十日止九個月	
		2021 **二零二一年** **HK$'000** **千港元** **(unaudited)** **(未經審核)**	2020 二零二零年 HK$'000 千港元 (unaudited) (未經審核)	**2021** **二零二一年** **HK$'000** **千港元** **(unaudited)** **(未經審核)**	2020 二零二零年 HK$'000 千港元 (unaudited) (未經審核)
Interest income on:	下列各項之利息收入：				
Bank deposits	銀行存款	**535**	959	**1,927**	5,725
Financial assets at fair value through profit or loss	按公平值透過損益列賬之財務資產	**–**	–	**83**	–
Advance to associates	墊付予聯營公司之款項	**868**	700	**2,447**	1,616
Total interest income	利息收入總額	**1,403**	1,659	**4,457**	7,341
Compensation income	補償收入	**–**	–	**–**	41,208
Development and government grants	開發及政府補助	**2,443**	6,355	**13,058**	18,003
Incentives from vendor	供應商獎勵	**–**	2,860	**–**	2,860
Rental and utilities income	租金及公共服務收入	**3,801**	321	**8,721**	934
Research and development service income	研究及開發服務收入	**8,205**	2,587	**53,209**	4,892
Sundry income	雜項收入	**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.

本集團收到地方政府認可本集團表現及開發高新科技藥品而授予之開發補助。

5. TAXATION

5. 稅項

		For the three months ended 30 September 截至九月三十日止三個月		For the nine months ended 30 September 截至九月三十日止九個月	
		2021 二零二一年 HK$'000 千港元 (unaudited) (未經審核)	2020 二零二零年 HK$'000 千港元 (unaudited) (未經審核)	**2021 二零二一年 HK$'000 千港元 (unaudited) (未經審核)**	2020 二零二零年 HK$'000 千港元 (unaudited) (未經審核)
Current tax	即期稅項				
Hong Kong Profits Tax	香港利得稅	**(7,120)**	8,019	**8,082**	30,845
PRC Enterprise Income Tax	中國企業所得稅	**1,993**	–	**1,993**	–
		(5,127)	8,019	**10,075**	30,845
Under (over) provision in prior years	過往年度撥備不足（超額撥備）				
Hong Kong Profits Tax	香港利得稅	**171**	–	**171**	–
PRC Enterprise Income Tax	中國企業所得稅	**(1)**	–	**(531)**	(228)
		170	–	**(360)**	(228)
Deferred tax	遞延稅項				
Origination and reversal of temporary differences	產生及撥回暫時差額	**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.

按照利得稅兩級制，截至二零二一年九月三十日止三個月及九個月之香港利得稅就首2百萬港元估計應課稅溢利按8.25%（截至二零二零年九月三十日止三個月及九個月：8.25%）及就2百萬港元以上估計應課稅溢利按16.5%（截至二零二零年九月三十日止三個月及九個月：16.5%）計算。

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.

於中國產生之稅項按中國現行稅率計算。於其他司法權區產生之稅項按有關司法權區之現行稅率計算。

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).

6. 股息

本公司於二零二一年八月二十六日宣派並其後於二零二一年十月六日派付截至二零二一年六月三十日止六個月的中期股息每股0.030港元，合共約為17,665,000港元（截至二零二零年六月三十日止六個月：每股0.027港元，合共約為15,879,000港元）。

董事會不建議派付截至二零二一年九月三十日止九個月之其他中期股息（截至二零二零年九月三十日止九個月：無）。

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:

7. 每股盈利

本公司擁有人應佔每股基本及攤薄盈利乃基於下列數據計算：

		For the three months ended 30 September 截至九月三十日止三個月		For the nine months ended 30 September 截至九月三十日止九個月	
		2021 二零二一年	2020 二零二零年	**2021 二零二一年**	2020 二零二零年
		HK$'000 千港元	HK$'000 千港元	**HK$'000 千港元**	HK$'000 千港元
		(unaudited) (未經審核)	(unaudited) (未經審核)	**(unaudited) (未經審核)**	(unaudited) (未經審核)
Earnings:	*盈利：*				
Net profit attributable to the owners of the Company for the purpose of basic and diluted earnings per share	就計算每股基本及攤薄盈利而言之本公司擁有人應佔純利	**13,843**	25,024	**2,169,043**	122,006

7. EARNINGS PER SHARE (CONTINUED)

7. 每股盈利(續)

		For the three months ended 30 September 截至九月三十日止三個月		For the nine months ended 30 September 截至九月三十日止九個月	
		2021 二零二一年 Share(s)'000 千股 (unaudited) (未經審核)	2020 二零二零年 Share(s)'000 千股 (unaudited) (未經審核)	**2021 二零二一年 Share(s)'000 千股 (unaudited) (未經審核)**	2020 二零二零年 Share(s)'000 千股 (unaudited) (未經審核)
Number of shares:	*股份數目：*				
Weighted average number of ordinary shares for the purpose of basic earnings per share	就計算每股基本盈利而言之普通股加權平均數	**588,835**	588,125	**588,586**	588,119
Effect of dilutive potential ordinary shares:	潛在攤薄普通股之影響：				
Options	購股權	**195**	351	**282**	4
Weighted average number of ordinary shares for the purpose of diluted earnings per share	就計算每股攤薄盈利而言之普通股加權平均數	**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.

8. 關聯方交易

於報告期內，本集團與關聯方進行以下交易。董事認為，下列交易乃於本集團日常業務過程中產生。

(a) Transactions with associates

(a) 與聯營公司之交易

		For the nine months ended 30 September 截至九月三十日止九個月	
		2021 二零二一年 HK$'000 千港元 (unaudited) (未經審核)	2020 二零二零年 HK$'000 千港元 (unaudited) (未經審核)
Interest income	利息收入	**2,447**	1,616
Rental and utilities income	租金及公共服務收入	**4,231**	934
Research and development service income	研究及開發服務收入	**21,798**	–
Purchase of consumable	採購消耗品	**2,850**	632

8. RELATED PARTY TRANSACTIONS (CONTINUED)

8. 關聯方交易(續)

(b) Compensation of key management personnel

(b) 主要管理人員之補償

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

期內，董事及其他主要管理人員之薪酬如下：

		For the nine months ended 30 September 截至九月三十日止九個月	
		2021 二零二一年	2020 二零二零年
		HK$'000 千港元	HK$'000 千港元
		(unaudited) (未經審核)	(unaudited) (未經審核)
Short-term employee benefits	短期僱員福利	**39,292**	17,829
Share-based payments	以股份支付之款項	**8,343**	7,504
Retirement and other post-employment benefits	退休及其他離職後福利	**18,012**	19,713
– Defined contribution plan	－定額供款計劃	**12**	27
– Retirement benefits	－退休福利	**18,000**	19,686
		65,647	45,046

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

(c) 向李氏大藥廠－李杜靜芳獎學金有限公司(「李杜靜芳獎學金」)作出捐獻

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.

於截至二零二一年九月三十日止九個月，向李杜靜芳獎學金捐獻約1,250,000港元(截至二零二零年九月三十日止九個月：約1,275,000港元)。本公司董事李燁妮女士及李小芳女士亦為李杜靜芳獎學金之主要管理層成員，而李杜靜芳獎學金被視為本集團之關聯方。

8. RELATED PARTY TRANSACTIONS (CONTINUED)

(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.

8. 關聯方交易(續)

(d) 發行附屬公司股份予美創集團有限公司(「美創集團」)

於截至二零二零年九月三十日止九個月，中國腫瘤醫療有限公司按比例發行18,620股股份予美創集團。李燁妮女士、李小芳女士及李小羿博士均為本公司董事及美創集團之主要股東，故美創集團被視為本集團之關聯方。就發行股份收取之總代價為4,003,300美元(相當於約31,226,000港元)。於截至二零二一年九月三十日止九個月內並無發生有關事項。

(e) 來自美創集團之股東貸款之利息開支

於截至二零二零年九月三十日止九個月，財務成本包括來自美創集團之貸款之利息開支147,000港元。來自美創集團之貸款已於二零二零年度全數結清，於截至二零二一年九月三十日止九個月內並無產生任何利息開支。

9. CAPITAL COMMITMENTS

9. 資本承擔

		At 30 September 2021 於二零二一年九月三十日 HK$'000 千港元 (unaudited) (未經審核)	At 31 December 2020 於二零二零年十二月三十一日 HK$'000 千港元 (audited) (經審核)
Capital commitments contracted for in respect of:	有關下列各項之已訂約資本承擔：		
– Financial assets at fair value through other comprehensive income	－按公平值透過其他全面收益列賬之財務資產	**40,931**	10,750
– Intangible assets – license fee and development cost	－無形資產－專利費及開發成本	**114,123**	88,458
– Property, plant and equipment	－物業、廠房及設備	**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.

購買、出售或贖回上市證券

於截至二零二一年九月三十日止九個月，本公司或其任何附屬公司並無購買、出售或贖回本公司任何上市證券。

DIVIDEND

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

股息

董事會不建議派付截至二零二一年九月三十日止九個月之股息(截至二零二零年九月三十日止九個月：無)。

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

承董事會命
李氏大藥廠控股有限公司
主席
李小芳

Hong Kong, 25 November 2021

香港，二零二一年十一月二十五日

As at the date of this report, 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.

於本報告日期，執行董事為李小芳女士(主席)及李燁妮女士；非執行董事為李小羿博士；而獨立非執行董事為陳友正博士、林日昌先生及詹華強博士。

LEE'S PHARM.

李 氏 大 藥 廠