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Grand Pharmaceutical Group Limited

遠大醫藥集團有限公司*

(Incorporated in Bermuda with limited liability)

(Stock Code: 00512)

**RESULTS ANNOUNCEMENT
FOR THE YEAR ENDED 31 DECEMBER 2023**

Financial summary

- For the year ended 31 December 2023 (the “Year”), the business of the Group grew steadily and recorded a revenue of approximately HK\$10,529.59 million (2022: HK\$9,562.29 million), representing a year-on-year increase of approximately 10.1%. If disregarding the impact of exchange rate fluctuation between RMB and HK\$, it was increased by approximately 15.8% as compared with the same period in 2022.
- The gross profit of the Group was approximately HK\$6,524.07 million (2022: HK\$5,951.48 million), representing a year-on-year increase of approximately 9.6%. If disregarding the impact of exchange rate fluctuation between RMB and HK\$, it was increased by approximately 15.3% as compared with the same period in 2022.
- The normalized profit for the Year attributable to the owners of the Company¹ was approximately RMB 2,036.24 million, a decrease of approximately 4.7% compared to the same period last year. If disregarding the impact of exchange rate fluctuation between RMB and HK\$, it would have increased by approximately 0.2% compared with the same period in 2022.
- It is the objective of the Group to share the operating results of the Group and protect the shareholders’ interests. Based on the good performance during the Year, the board of directors recommends the payment of a final dividend of 26 cents per share, totaling amounted to approximately HK\$905.14 million.
- During the Year, the Group continued to invest in ongoing research projects and the introduction of innovative projects. The Group’s investment in research and development work and projects, including the research and development expenses, capitalized research and development expenses, prepayments for new projects and other investments, was approximately HK\$1,441.00 million.

¹ The normalized profit for the Year attributable to the owners of the Company excluded the impacts from the fair value change of investment in Telix and the impact of one-time penalties.

Chairman’s Statement

INDUSTRY REVIEW

In 2023, macro economy of China has stabilized and rebounded, and various business activities in the pharmaceutical industry have gradually returned to the right track. However, since the global economic trend is weak and the international situation is complex, the development of various industries in China still under certain pressures. Since the third quarter, China has vigorously initiated a campaign to comprehensively curb corruption in the healthcare sector, which has further promote the high-quality development of the pharmaceutical industry. In this context, with accelerated changes in prescription structure and clearing out of low-quality capacity, it is crucial for enterprises to step up innovation and actively explore new business models, while productivity and commercialization capability has become the determining factors in their development. Further, national policies continue to lead the research and development of pharmaceutical products to place more emphasis on clinical value with stricter approval process for homogeneous research and development, supporting accelerated admission of innovative drugs to hospitals, and putting forward higher requirements for the operation and quality supervision and management of pharmaceutical products.

The global biopharmaceutical market has been volatile recently amidst a transitional period. Correspondingly, China’s pharmaceutical industry has been upgrading and evolving on the basis of conventional medical insurance negotiations, resulting in a faster access to new drugs and improving regulations, as well as the acceleration of overseas sales of local innovative pharmaceutical products, which provides a first glimpse of the value and resilience of China’s pharmaceutical innovations. Meanwhile, given the impact of multiple factors such as sluggish demand in the international market and intensified competition in Chinese market, enterprises were confronted with polarization in their operation as the trend of structural differentiation intensified in the market, which has accelerated the mergers and acquisitions and integration of the industry and further optimized the allocation of resources with more prevalent division of labour and co-operation.

BUSINESS REVIEW

During the Year, in the face of the complex and uncertain macro-environment and changes in the industry ecology, the Group has always maintained strategic focus and promoted the operational integration and efficiency enhancement of its business divisions, which has contributed to the steady growth of its operating results. By adopting a multi-pronged approach, the Group has deepened its presence in the cerebro-cardiovascular sector and other fields of strengths, seizing the opportunity of industry consolidation to expand the its scale through investment as well as merger and acquisition. This has put the Group on the fast track of innovation and transformation, with research and development results rolling out one after another, highlighting its resilience for business growth.

During the year, riding on the ongoing momentum of efficient “growth”, the Group achieved new highs in terms of both performance and industrial scale with continuous improvement in its profitability. For the first time, the Group ranked among top 20 on the list of the “Top 100 Companies in China’s Pharmaceutical Industry”. During the year, a total of 30 products were approved for commercialization and 3 major mergers and acquisitions were completed. Currently, the Group has more than 10,000 employees globally, more than 30 subsidiaries at home and abroad, 5 technology platforms and 8 research and development centers, more than 200 products on the National Reimbursement Drug List, and 16 products which worth over 100 million dollars each. The Company has been committed to three major business segments, namely pharmaceutical technology, technologies on nuclear medicine anti-tumor as well as cerebro-cardiovascular precision interventional diagnosis and treatment, and biotechnology, with its business coverage across various sectors such as, among others, cerebro-cardiovascular, Eye, Nose & Throat (“ENT”), respiratory and critical and severe diseases and oncology. In the nuclear medicine anti-tumor field, the Group remained as a national leader in terms of pipeline layout and commercialization, and has been continuously improving and optimizing its industrial chain and global business network, with partners spanning major medical markets in Asia, the Americas, Europe, Oceania, and so on.

During the year, the Group released the momentum of high-quality “innovation” and strengthened its capabilities of independent research and development. Our innovative drugs were successively approved to conduct clinical trials in China, our research progressed smoothly, and our innovation and transformation achieved remarkable results. The Company has a rich pipeline of products, including 46 innovative projects out of a total of 138 projects under research. With the progress made in the past few years, our innovation strategy has gradually started to yield results. In 2023, a total of 77 significant milestones were achieved, 1 new R&D center was established, 17 new core patents were added, and 118 patents were granted. During the year, 5 innovative products were commercialized as scheduled, 5 products entered the new drug application (“NDA”) stage, and 8 new products entered the clinical trial stage. In the nuclear medicine segment, 4 radionuclide-drug conjugates (“RDCs”) are steadily advancing into clinical trials. Among which, TLX591-CDx for prostate cancer diagnosis is in phase III clinical research in China, and it has become a new standard for clinical diagnosis in overseas markets, achieving excellent commercialization results, while TLX250-CDx for kidney cancer diagnosis has also entered the confirmatory clinical stage in China. In the respiratory and critical and severe disease segment, the NDA for Ryaltris Compound Nasal Spray, a global innovative drug for allergic rhinitis, was accepted in China, while APAD and STC3141, global innovative products for the treatment of severe diseases such as sepsis, have been approved to conduct phase I and phase II clinical trials in China. In the ENT segment, GPN00833 for anti-inflammatory and analgesic and CBT001 for the treatment of pterygium have both entered phase III clinical trials, GPN00136 for dry eye syndrome has entered phase II clinical trial, and Investigational New Drug Applications (“IND”) was approved in China for GPN00884, a drug used to prevent and treat myopia. In addition, IND was accepted in China for ARC01, a mRNA therapeutic vaccine, making it the first mRNA tumor vaccine for HPV-positive related tumors approved for clinical research in China.

During the year, the Group efficiently “upgraded” its development, and driven by the dual impetus of “independent research + investment”, it achieved significant breakthroughs in the business segments of its core strength. Through the strategic acquisition of Tianjin Tanabe and Chongqing Duoputai Pharmaceutical Technology, we acquired more than 10 products in the field of chronic diseases including cerebro-cardiovascular diseases and gastrointestinal diseases, achieving a wide coverage from emergency rescue to chronic disease management. In addition, eplerenone, our new mineralocorticoid receptor antagonist (“MRA”) drug, and carglumic acid tablets, our rare disease drug, have been approved for commercialization. Both of them rank among the first generic products in China, filling the gaps in treatment in related fields in China. In the nuclear medicine anti-tumor segment, the market attention and penetration of our core product, Yttrium-90 microsphere injections, continued to rise, whereby it has been officially used in operations in more than 40 hospitals across 17 provinces and cities, and has been accepted for the Supplementary Medical Insurance for Serious Diseases (惠民保) in 36 provinces and cities. The annual revenue growth of the segment has approached 300%. Through the acquisition of Black Swan, two innovative liquid embolic agents, Lava™ and Kona™, were introduced to expand the product pipeline of tumor intervention. The construction project for the nuclear drug R&D and production base in Wenjiang, Chengdu is progressing smoothly. In the cerebro-cardiovascular precision interventional diagnosis and treatment segment, Novasight, the world’s first intravascular dual-mode imaging device, has been approved for commercialization in China. HeartLight X3, the world’s only laser ablation product for the treatment of atrial fibrillation, has submitted an application for commercialization in China and has been accepted, and has completed its first specially-granted adoption in Boao, Hainan, bringing to China a new treatment option for atrial fibrillation that is internationally adopted. CardioNavi’s R&D center in Shanghai, dedicated to the research and development of structural heart disease product, was officially unveiled, making it the Company’s third R&D center for high-end medical device in addition to those in Wuhan and Changzhou.

Steady development leads to long-term success, and innovation paths the way to pioneer. Always adhering to its mission to quality, the Group will fulfill its responsibilities through actions and made firm steps towards its corporate vision of “becoming a pharmaceutical company respected by doctors and patients, and making significant contribution to the society”.

Prospects

In 2024, China's pharmaceutical industry will remain in a critical period of changes, reform and upgrade, approaching a new development stage characterized by compliance, quality and innovation. In addition to strict regulation, the state will also encourage and support innovative medicines. The Healthcare Security Administration will explore the implementation of a first-time pricing mechanism for newly commercialized chemical drugs based on independent quantitative evaluation, which means that the higher the innovation value, the more relaxed the market pricing policy and the more efficient the commercialization process will be.

The "14th Five-Year Plan" period is a critical period for the innovation and high-quality development of China's pharmaceutical industry. According the Ministry of Industry and Information Technology, since the "14th Five-Year Plan", the average annual growth of the Chinese pharmaceutical industry's main business revenue has been 9.3%, and the average annual growth of total profits has been 11.3%. The average annual growth of R&D investment in the entire industry exceeds 20%. Under the premise of Healthy China, citizen' attention to life and health has been raised to an unprecedented high following the improvement of their income and living standards. At the same time, as the population structure ages, the number of patients with chronic diseases such as cerebro-cardiovascular diseases, cancer, ENT diseases, and chronic respiratory illnesses has been rising in recent years, ramping up the public's long-term demand for medical care on a continuous basis.

The Group will continue to focus on its areas of strength and conduct in-depth research on the clinical pain points of its niches such as cerebro-cardiovascular diseases, ENT, and respiratory, so as to meet the disease management needs of chronic patient groups. Further, we will continue to consolidate and expand the Company's influence in the industry, enhance its industrial chain and increase its industrial scale and profitability through various methods, such as strengthening of independent research and development, investments and mergers and acquisitions.

The Group will put more emphasis on technological innovation and strategic leadership to further consolidate the effectiveness of its innovation and transformation. We are speeding up the clinical research process in the fields of nuclear medicine, critical and severe disease, and cerebro-cardiovascular devices. We will strengthen R&D cooperation with leading medical institutions at home and abroad to further enhance the Company's R&D strength in terms of R&D teams and platform construction. In 2024, based on its significant clinical efficacy and the rollout of preliminary hospital admission and doctor training, the sales of Yttrium-90 microsphere injections is expected to keep increasing and benefit more patients. At the same time, the Group will deepen its presence in the field of nuclear drugs and continuously promote the construction of Class A nuclide production platform, to strengthen its edges in industrial chain, striving to become a leading enterprise in the field of nuclear medicine anti-tumor diagnosis and treatment in China and even globally. In the field of respiratory and critical and severe disease, we will be full steam ahead with the phase II sepsis clinical research of STC3141 and strive to fill the gap in the industry as soon as possible. In the field of cerebro-cardiovascular devices, the Company has created a profile of high-end medical device products with considerable advantages and successfully commercialized a number of them. In the future, we will remain focus on the three fronts of channel management, structural heart disease, electrophysiology and heart failure, optimizing their product structure and resource allocation, increasing pipeline synergy, and conducting product commercialization in stages and batches. In the field of biotechnology, with synthetic biology as the core, we will focus on technological improvement and optimization to enhance our quality and efficiency, and diversify amino acid development based on high quality amino acids, which will contribute steady increments to the Company's performance growth.

To travel far and wide, health is of the utmost importance. The Group has always been committed to the development of life and health related businesses, focusing on cutting-edge technologies and differentiated development paths, constantly pursuing technological breakthroughs, and adhering to high-quality research and development. We strive for the well-being of people's health, add impetus to the development of enterprises, and create a healthy society while realizing the long-term sustainable development of the Company.

I would like to express my sincere gratitude to every shareholder, board member, partner, management and staff for their great support and contribution.

Dr. Tang Weikun
Chairman

Management Discussion and Analysis

GROUP POSITIONING

The Group is an international pharmaceutical company of technological innovation. Its core businesses cover three major areas, namely pharmaceutical technology, nuclear medicine anti-tumor diagnosis and treatment and cerebro-cardiovascular precision interventional diagnosis and treatment technology and biotechnology. Based on the pharmaceutical and biological industries, the Group focuses on the needs of patients, and take technological innovation as the driving force. In response to the unmet clinical needs, the Group will increase its investment in global innovative products and advanced technologies, enrich and improve its product pipelines, consolidate and strengthen its industrial chain layout, and fully leverage the Group's industrial strengths and R&D capabilities to provide more advanced and diverse treatment solutions to patients worldwide.

With unremitting efforts in recent years, the Group has laid a more solid foundation for development, consolidated its operation scale, gradually optimized its business structure, continued to improve its operation mode, accelerated its pace of transformation and upgrading, and made various achievements in innovative layout. The Group's profitability continues to improve and help facilitate R&D and innovation; its good ability in mergers and acquisitions and integration continues to consolidate the scale of development; the integration of raw materials and preparations improves the structure of the industrial chain; and the diversification of business and entities has effectively enhanced the comprehensive advantages.

“Maintain stable growth, strive in innovation and strategic planning”, the Group will stick with the development concept of “comprehensive strengths, innovation leading and global expansion” and the strategy of “dual-wheel driving development of independent R&D, global expansion and dual-cycle operation”, the Group has formed a new pattern of domestic and international cycles that synergize with each other, and is committed to becoming an international pharmaceutical company of technological innovation, delivering on its promises for doctors and patients, and making significant contribution to the society.

BUSINESS REVIEW

During 2023 and up to the date of this announcement, the Group had a total of 77 significant milestones, including 42 innovative products, 16 generic products, 9 functional foods, 4 API products with international certification, 3 major merger and acquisition and 2 significant construction projects.

Innovative products

Nuclear medicine anti-tumor diagnosis and treatment:

- The phase III clinical study of TLX591-CDx, an innovative nuclear medicine product for the diagnosis of prostate cancer completed the enrolment of the first patient in China;
- TLX250-CDx, an innovative nuclear medicine product for the diagnosis of clear cell renal cell carcinoma (“ccRCC”) completed the phase I clinical study in China and successfully entered a confirmatory clinical study;
- TLX101, an innovative nuclear medicine product for the treatment of glioblastoma, was approved to conduct a phase I clinical study in China;
- ITM-11, an innovative nuclear medicine product for the treatment of gastroenteropancreatic neuroendocrine tumors (“GEP-NETs”), was approved to conduct a phase I clinical study in China;
- Lava™, an innovative liquid embolic agent for the treatment of peripheral vascular arterial hemorrhage, was approved for commercialization by the U.S. Food and Drug Administration (“FDA”) and was successfully commercialized;
- Kona™, a preoperative embolic agent for the treatment of cerebral arteriovenous malformations, submitted a Premarket Approval (PMA) application to the FDA.
- AuroLase®, a global innovative therapeutic technology for prostate cancer tissue ablation, submitted a PMA application to the FDA.

Cerebro-cardiovascular precision interventional diagnosis and treatment:

- The application for the commercialization of HeartLight X3 laser ablation platform, a global innovative medical device, has been submitted in China;
- HeartLight X3 laser ablation platform, an innovative medical device, completed the first chartered access laser ablation operation for the treatment of atrial fibrillation in China at Ruijin-Hainan Hospital of Shanghai Jiaotong University School of Medicine and Boao Research Hospital (“Ruijin-Hainan Hospital”).
- NOVASIGHT Hybrid, a new medical imaging device for intracavity diagnosis, has been approved for commercialization in China;
- Distal access catheter Pilu® (琵 鷺®), a neurointerventional product, has been approved for commercialization in China;
- Microcatheter Sheti® (蛇 鷓®), a neurointerventional product, has been approved for commercialization in China;
- The registered clinical trial of the adjustable stent retriever GPN00493, an innovative neurointerventional device, has successfully reached clinical endpoint and the application for commercialization was submitted to and was accepted by the National Medical Products Administration of China (“NMPA”).

Respiratory and critical and severe disease:

- Enerzair[®] Breezhaler[®] and Ateectura[®] Breezhaler[®], the two global innovative compound preparations for the treatment of asthma, were successfully included in the National Reimbursement Drug List (2022 edition);
- Ryaltris[®] compound nasal spray, an innovative product for the treatment of allergic rhinitis (“GSP 301 NS”) completed the phase III clinical study in China and reached the clinical endpoint, and the application for commercialization was submitted to and was accepted by the NMPA;
- STC3141, a global innovative drug for the treatment of sepsis, completed the phase Ib clinical study in Australia and Belgium and successfully reached the clinical endpoint;
- STC3141, a global innovative drug for the treatment of sepsis, was approved to conduct a phase II clinical study in China and the first patient was enrolled;
- APAD, a global innovative drug for the treatment of sepsis, was approved to conduct a phase I clinical study in China and the first patient was enrolled;

ENT:

- GPN00833, an improved new drug for anti-inflammatory and pain relief after ophthalmology surgery, was approved to conduct a phase III clinical study in China and the first patient was enrolled;
- CBT-001, an innovative and improved new drug for the treatment of pterygium, was approved to conduct a phase III clinical study;
- BRM421, an innovative drug for the treatment of dry eye, was approved to conduct a phase II clinical research in China;
- GPN00884, an innovative drug for delaying the progression of myopia in children, was approved to conduct a phase I clinical research in China.

Cerebro-cardiovascular:

- Jext[®], a pre-filled epinephrine auto-injector for the treatment of severe allergic reactions, was granted approval for Guangdong-Hong Kong-Macao Greater Bay Area Imported Pharmaceuticals for Urgent Clinical Needs in Mainland China.

mRNA platform:

- ARC01, a therapeutic tumor vaccine for human papillomavirus type 16 (“HPV-16”)-positive late-stage unresectable or recurrent/metastatic solid tumors, was approved to conduct a phase I clinical study in China;

Generic products

16 products have been approved for commercialization, among which eplerenone tablets and carglumic acid dispersible tablets are the first generic products being approved for commercialization in China, and the ophthalmic balanced salt solution (15ml) is the first generic product of this specification being approved for commercialization in China.

Functional foods:

There were 9 functional foods commercialized in China.

API products

There were 4 API products passed the REACH registration of the European Union.

Merger and acquisition

For the nuclear medicine anti-tumor diagnosis and treatment segment, the Group has completed the acquisition of 87.5% equity interests in BlackSwan Vascular, Inc. (“BlackSwan”) in the United States, which has become a non-wholly owned subsidiary of the Group. This acquisition was another industrial deployment by the Group in the field of tumor intervention after the acquisition of Sirtex Medical Limited. (“Sirtex”) in 2018.

For the cerebro-cardiovascular segment, the Group conducted two major mergers and acquisitions, including the acquisition of 75.35% equity interest of Tianjin Tanabe Seiyaku Co., Ltd. (“Tianjin Tanabe”) and 90% equity interest of Chongqing Duoputai Pharmaceutical Technology Co., Ltd. (“Duoputai Technology”). Upon completion of the acquisitions, Tianjin Tanabe and Duoputai Technology will become non-wholly owned subsidiaries of the Group. On the one hand, they further consolidate the Group's leading position in the cerebro-cardiovascular emergency market. On the other hand, they also accelerate the Group's entry into the cerebro-cardiovascular chronic disease market, which is conducive to quickly establishing market advantages.

In addition, the Group has also made significant progress in the construction of its R&D centers and production bases.

R&D center:

The Shanghai R&D Center of Kainowei Medical Technology was officially inaugurated, which mainly focuses on the research and development of mitral valve replacement products in the field of structural heart disease medical devices. The entire R&D center has a flow dynamics-fatigue testing area, mechanical performance testing area, valve processing and chemical testing area, equipped with imported advanced equipment such as stent laser cutting machine, valve laser cutting machine, valve accelerated fatigue testing machine, steady flow performance testing machine, and pulsating flow performance testing machine. It is the third international high-end medical device R&D center under the cerebro-cardiovascular precision interventional diagnosis and treatment segment, in addition to Wuhan Optics Valley Innovative Device R&D Center and Changzhou Innovative Device R&D Center, with “international technology to serve China” as its strategic core.

Production bases:

The amino acid production base in Xiantao City, Hubei Province, China, has officially completed construction, and has fully entered the trial production stage. The operation of the production base will further expand the production capacity of a number of high-quality amino acid varieties of the Group and provide sustainable momentum for the Group's amino acid segment to grow profitably in the future.

BUSINESS INTRODUCTION

The Group has strong technological innovation strength, outstanding internationalization strength, solid industrial foundation, complete industrial chain and significant comprehensive advantages in the integration of raw materials and preparations. The Group has more than 90 products included in the National Essential Drug List (2018 version) and more than 200 products included in the National Reimbursement Drug List for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (2022 version). In June 2023, the Group ranked 19th on the list of "Top 100 Chemical Pharmaceutical Enterprises of China 2022".

PHARMACEUTICAL TECHNOLOGY

With years of experience in the ENT, respiratory and critical and severe disease, as well as cerebro-cardiovascular fields, the Group currently has a number of products with high entry barrier and exclusive products with leading market shares, a strong brand name and a solid market position, and also reserves a number of innovative products.

Through an innovation model combining global technology cooperation and independent R&D, the Group has established the International R&D Center in Optics Valley, Wuhan, the Glycomics R&D Center in Australia and the mRNA R&D Center in Aoluo, Nanjing in the field of pharmaceutical technology. These R&D centers and technology platforms will continue to empower and provide continuous technological support for the Group's R&D and innovation in the field of pharmaceutical technology.

ENT segment

The Group ranks among the top in the industry in terms of the number of product pipelines on sale in the ENT segment, and its treatment areas include diseases in multiple fields such as ophthalmology, otolaryngology, and stomatology, covering chemical preparations, Chinese drug preparations and health products, including prescription drugs, OTC drugs, medical devices, consumer goods and other major categories. With full coverage inside and outside of the hospital, we created a "ENT ecosystem" by integrating "prevention + treatment + health care". In terms of innovation and R&D, the Group has reserved a few world-wide innovative products for the treatment of "myopia", "dry eye", "pterygium" and "anti-inflammatory and analgesic after ophthalmology surgery". In the future, the segment will adhere to the development strategy of combining Chinese and Western medicine as well as utilizing both medicine and medical devices in treatments, so as to continuously strengthen the influence of the industry, and achieve new breakthroughs in the business field.

ENT products

The ENT core products of the Group include Rui Zhu (polyvinyl alcohol eye drop), He Xue Ming Mu tablets, Jinsang Series (Jinsang Kaiyin Tablet/Capsule/Pill/Granules, Jinsang Qingyin Tablet/Capsule/Pill/Granules, Jinsang Liyan Tablet/Capsule/Pill/Granules, Jinsang Sanjie Tablet/Capsule/Pill/Granules) and Nuo Tong (Xylometazoline Hydrochloride) etc.

Rui Zhu (polyvinyl alcohol eye drop):

is a single-piece preservative-free artificial tear and currently the first-line drug for the treatment of dry eye. It is recommended by experts such as the Expert Consensus on Prevention and Control of Cataract Surgery in China (2021) (《中國白內障圍手術期乾眼防治專家共識(2021年)》), the Expert Consensus on Sterily Surgery in China (2020) (《中國乾眼專家共識(2020年)》), the Expert Consensus on Refractive Surgery in Laser Corneal Surgery in China (2019) (《中國激光角膜屈光手術圍手術期用專家共識(2019年)》), and the Expert Consensus on Diagnosis and Treatment of Functional Disorder of Bleacne in China (2017) (《我國驗板腺功能障礙診斷與治療專家共識(2017年)》). Rui Zhu has good brand recognition and was awarded the China Well-known Trademark in 2017; and was awarded the CPEO Gold Award for eight consecutive years from 2016 to 2023, namely the “Healthy China Brand List”. The Group achieved good results growth in the product promotion of prescription drugs and non-prescription drugs. At the same time, the Group strengthened the academic driven development of e-commerce platforms to empower sales and maintain the steady growth of Rui Zhu.

He Xue Ming Mu tablet:

which is produced by three classical formulae, namely the Siwutang (四物湯), Erzhiwan (二至丸) and Shengpuhuangtang (生蒲黃湯), has the functions of cooling blood hemostasis, moisturising dryness and removing blood stasis, and nourishing liver and eye-brightening, and is mainly used for the treatment of retinal hemorrhage caused by the cloudy liver and the heat-burn winding. Since He Xue Ming Mu tablet has been the exclusive product in China, the State Protected Chinese Medicine, the National Reimbursement Drug List (2022 edition) and the National Essential Drug List (2018 edition) for the last 20 years since its commercialization, the Group has accumulated a large number of clinical research data and application experience in the field of retinal hemorrhage, which has been included in a number of guidelines/consensus such as the Practical Ophthalmic Medicine and the Expert Consensus on Clinical Application of He Xue Ming Mu Tablets for the Treatment of Wet Age-related Macular Degeneration (《和血明目片治療濕性年齡相關性黃斑變性臨床應用專家共識》) and provides valuable reference for clinical use of the products, and the sales of products continue to grow steadily.

Jinsang Series Products:

They are exclusive products nationwide, covering all the diseases of the throat, among which, Jinsang Sanjie Capsule is used for the treatment of chronic hoarseness disease caused by heat and poisoning storage and airtight blood stasis (vocal nodules, polyp of vocal cords, thickening of mucosa of vocal cords) and the resulting hoarseness. Jinsang Sanjie Capsule has been widely used in clinical application for more than 30 years since its commercialization. Jinsang Liyan Capsule is the only Chinese patent medicine for the treatment of throat diseases caused by intraocular obstruction of liver depression and phlegm and humidification. It is also an ideal medicine for the treatment of pharyngeal symptoms in clinical operation, gastroesophageal reflux pharyngitis, and chronic and thick pharyngitis. Jinsang Kaiyin Capsule is designed for the rapid effect of acute pharyngitis as well as throat redness, swelling, heat, pain and hoarseness caused by acute pharyngitis. Several products have been included in the Guidelines for the Diagnosis and Treatment of Common Diseases in Otorhinolaryngology of China (《中國耳鼻咽喉科常見病診療指南》) issued by the Chinese Association of Traditional Chinese Medicine, the Clinical Drug Guidelines (《臨床用藥指南》) for the diagnosis and treatment of clinicians, the authoritative monographs of the Manual for Common Traditional Chinese Medicine of Otorhinolaryngology (《常見眼耳鼻咽喉科中成藥手冊》) and the Practical Otorhinolaryngology Head and Neck Surgery (《實用耳鼻咽喉頭頸外科學》), etc., and are included in a number of clinical pathways and expert diagnosis and treatment guidelines. In January 2022, the Expert Consensus on the Clinical Application of Jinsang Sanjie Capsules for the Treatment of Vocal Nodules and Polyp of Vocal Cords (《金嗓散結膠囊治療聲帶小結、聲帶息肉臨床應用專家共識》) was issued by the Chinese Association of Traditional Chinese Medicine, which has also provided new support for the evidence-based development of Jinsang Sanjie products. Jinsang Sanjie and Jinsang Kaiyin Capsules are products on the National Reimbursement Drug List. Jinsang Kaiyin and Qingyin are dual cross-over products with both prescription and over-the-counter drugs.

Nuo Tong:

It is a nasal decongestant to relieve nasal congestion, and is suitable for relieving nasal congestion caused by acute and chronic rhinitis, sinusitis, allergic rhinitis, hypertrophic rhinitis and other nasal disorders. It does not contain hormones or ephedrine and is suitable for both adults and children. Nuo Tong is divided into two dosage forms: nasal drops and nasal spray, of which the nasal spray is the exclusive domestic dosage form and is the leading product among its generic counterparts. The product has been included in clinical guidelines such as Guidelines for the Diagnosis and Treatment of Allergic Rhinitis in China (Revised Edition 2022) (《中國變應性鼻炎診斷和治療指南(二零二二年,修訂版)》), Guidelines for the Diagnosis and Treatment of Allergic Rhinitis in Children (Revised Edition 2022) (《兒童變應性鼻炎診斷和治療指南(二零二二年,修訂版)》) and Recommendations for the Diagnosis and Treatment of Sinusitis in Children (《兒童鼻 — 鼻竇診斷和治療建議》).

Innovative R&D pipeline

While creating an ENT ecosystem, the Group also reserved four innovative drugs in the direction of clear clinical needs for anti-inflammatory and pain relief after ophthalmology surgery, pterygium, dry eye, myopia, etc.:

GPN00833, an improved new drug hormone nano-suspension eye drops for anti-inflammatory and pain relief after ophthalmology surgery:

It is a potent glucocorticoid and has efficient local anti-inflammatory and strong capillary contraction effect. Its unique nano-preparation technique effectively eliminates the low bioavailability and safety risks caused by low water solubility of hormones products. Two overseas phase III clinical studies of the product have successfully reached the clinical endpoints. According to the clinical results, GPN00833 has significant effectiveness in the treatment of postoperative anti-inflammatory and analgesic effects after ophthalmology, and has a good safety profile. It has been approved for commercialization in the U.S. by the FDA in March 2024. Currently, the product has been approved for phase III clinical study in China in April 2023, and the first patient was enrolled and has started administration.

GPN00153, an improved new drug for the treatment of pterygium (CBT-001):

It is an innovative and improved product, Nintedanib, which is used for the treatment of pulmonary fibrosis. It inhibits neovascularization and tissue fibrosis. Currently, the phase II clinical trial has been completed in the United States with high safety and significant clinical efficacy, which can inhibit the growth of pterygium and control the aggravation of the disease. The global phase III clinical trial for CBT-001 has conducted in June 2022 and it has been approved to conduct phase III clinical trial in China by the NMPA in March 2023.

GPN00136, a world-wide innovative drug for dry eye (BRM421):

It is small molecule peptide eye drops that can accelerate the division and proliferation of limbal stem cells, and in turn stimulate the repair of ocular surface. According to the phase II clinical study data completed in the United States, compared to cyclosporine eye drops currently commercialized for the treatment of dry eye, BRM421 has high safety and low irritation, as well as the potential to quickly alleviate the signs and symptoms of dry eye within two weeks. Currently, the product has conducted phase III clinical studies overseas. In terms of registration in China, it was approved to conduct phase II clinical study in April 2023.

Novel ophthalmic preparation GPN00884 for delaying the progression of myopia in children:

It is an innovative drug with a new mechanism jointly developed by the Group and the Eye Hospital of Wenzhou Medical University (“WMU”). Compared with low-concentration atropine eye drops, GPN00884 eye drops have no mydriasis effect, no adverse reactions such as photophobia and decreased accommodation, and the dosing period is not limited, which can improve patient compliance. The product has been approved to conduct phase I clinical study in China in March 2024, which was accepted by the NMPA.

Respiratory and Critical and Severe Disease Segment

The Group's products on sale in the respiratory and critical and severe disease segment covers a wide range of indications such as rhinitis, bronchitis, pneumonia, asthma and chronic obstructive pulmonary disease, etc. The core products, Qie Nuo (Eucalyptol, Limonene and Pinene Enteric Soft Capsules), Enerzair[®] Breezhaler[®] and Atectura[®] Breezhaler[®] are exclusive products nationwide, which are in the leading position in their respective segments.

The innovative strategic plan in this field focuses on the unmet significant clinical needs, with a number of products under research, covering allergic rhinitis, sepsis and Acute Respiratory Distress Syndrome (“ARDS”) etc. In the future, the Group will continue to adopt the R&D concept of independent R&D and global expansion to create a full-cycle management product cluster for chronic airway diseases and a pipeline of products for critical and severe diseases, so as to continuously strengthen the Group's industry position in this field.

Respiratory products

The main products include Qie Nuo, Enerzair[®] Breezhaler[®] and Atectura[®] Breezhaler[®], etc.

Qie Nuo:

It is a soluble and phlegm-free drug for viscosity, and is suitable for acute and chronic rhinosinusitis as well as respiratory diseases such as acute and chronic bronchitis, pneumonia, bronchial dilation, pulmonary abscess, chronic obstructive pulmonary disease, bacterial infection in the lungs, tuberculosis, and silica lungs. It can also be used for bronchoscopic angiography to facilitate the discharge of contrast medium. It is an exclusive product in China independently developed by the Group with two separate types of drugs for adult and children's use and was included in China's National Reimbursement Drug List in 2017 and China's National Essential Drug List in 2018 respectively, and was listed in the Top Brands of the Health Industry in 2023 (二零二三年健康產業品牌銳榜). Currently, there are dozens of guidelines and expert consensus recommending the use of viscosity dissolving promoters for clinical use. Among them, more than 10 guidelines and expert consensus explicitly recommend eucalyptol, limonene and pinene enteric soft capsules or its active ingredients for clinical treatment, such as the Expert Consensus on the Diagnosis and Treatment of Adult Bronchiectasis in China (《中國成人支氣管擴張症診斷與治療專家共識》), Expert Consensus on the Diagnosis and Treatment of Adult Bronchiectasis in China (2021) (《中國成人支氣管擴張症診斷與治療專家共識 (2021)》), Guidelines for the Diagnosis and Treatment of Secretory Otitis Media in Children (2021) (《兒童分泌性中耳炎診斷和治療指南 (2021)》), Diagnosis and Treatment Guidelines for Cough (2021) (《咳嗽的診斷與治療指南(2021)》), the Guidelines for Rational Use of Drugs for Chronic COPD in Primary Care 2020 (《慢性阻塞性肺疾病基層合理用藥指南(2020)》), the Chinese Expert Consensus — Chinese (2015) on High-secretion Management of Gastrointestinal Adhesion for Chronic Gastric Diseases (《慢性氣道炎症性疾病氣道粘液高分泌管理中國專家共識 — 中文版 (2015)》), etc. Its clinical status is prominent, and the level of recognition among doctors and patients is high, continuing to lead the market of oral cough relieving and phlegm relieving drugs.

Enerzair® Breezhaler® (indacaterol acetate, glycopyrronium bromide and mometasone furoate powder for inhalation II) and Ateectura® Breezhaler® (indacaterol acetate and mometasone furoate powder for inhalation II, III):

Enerzair® Breezhaler® is the first triple combination inhalation preparation for asthma indications approved in China for the maintenance treatment of asthma in adults not adequately controlled with the maintenance combination treatment of long-acting beta2 adrenergic agonist (LABA) and inhaled corticosteroid (ICS). The product has clear efficacy, is convenient to use, and has achieved breakthroughs in three aspects: (1) using an optimized drug combination of ICS, LABA and long-acting muscarinic receptor antagonist (LAMA) (i.e. mometasone furoate/ indacaterol acetate/glycopyrronium bromide), the three effective ingredients can provide synergy benefit, and compared with the conventional high dose ICS-LABA and high dose ICS-LABA combined with LAMA opened triple combination, Enerzair® Breezhaler® can effectively improve the clinical symptoms and lung function of patients with moderate to severe asthma, and significantly reduce the risk of acute attacks; (2) dosing once a day, which significantly facilitates the patient and is expected to improve the compliance; (3) using the advanced Breezhaler® inhalation device, which is easy to operate, and provides patients with triple confirmation of dosing as audible, tasteable, and visible, enhancing patients' confidence that the complete dose has been taken. The ARGON phase III clinical study of the product shows that, compared with high dose Salmeterol-Fluticasone powder for inhalation combined with Tiotropium Bromide Spray opened triple combination, Enerzair® Breezhaler® significantly reduce the annualized rate of moderate exacerbations (based on 24 weeks data) by 43%. Ateectura® Breezhaler® is an innovative combination of ICS mometasone furoate and LABA indacaterol acetate for the maintenance treatment of adult and 12 years old above adolescent patients with asthma. Ateectura® Breezhaler® also has the characteristics including “visible and controllable, precise inhalation, once a day” etc. It can significantly improve the lung function of patients and reduce the risk of acute attacks, and is a new choice for optimal treatment of asthma patients. The phase III clinical study of the product shows that, compared with the conventional high dose Salmeterol-Fluticasone powder for inhalation, Ateectura® Breezhaler® can significantly improve the risk of acute attack in patients, and the risk of severe, moderately severe and all acute attack categories is reduced by approximately 26%, 22% and 19% respectively. Both products were officially included in the category-B medicines management scope in China's National Reimbursement Drug List for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (2022 version) (《國家基本醫療保險、工傷保險和生育保險藥品目錄(2022年版)》), and provide new treatment method for people receiving long-term asthma treatment.

Innovative R&D pipeline

Based on unmet clinical needs, the Group has reserved a number of global innovative drugs for the indications of seasonal allergic rhinitis, sepsis and ARDS.

GSP 301 NS, a new compound nasal spray for the treatment of seasonal allergic rhinitis:

GSP 301 NS is a new glucocorticoid and antihistamine compound nasal spray. Currently, the product has been approved for commercialization in the United States, Australia, South Korea, Russia, the United Kingdom, the European Union as well as other countries and regions. In terms of registration in China, it was approved to conduct a phase III clinical trial for the treatment of allergic rhinitis and rhinoconjunctivitis symptoms in patients aged 12 and above in October 2021, and has successfully met the clinical endpoint in September 2023. According to clinical results, the efficacy scores of GSP 301 NS are better than the monomer originator preparations Patanase® NS and Nesuna® NS. Meanwhile, the safety, tolerability and pharmacokinetic features of GSP 301 NS have also met the preset clinical endpoints. The NDA for the product was accepted by the NMPA in February 2024.

STC3141, a global innovative drug for the treatment of severe diseases:

STC3141 is a small molecule compound with a novel mechanism of action independently developed by the Group, which can be used to reverse organ damage caused by excessive immune responses by neutralizing extracellular free histones and neutrophil traps and is applicable to multiple severe disease indications. The product has a novel mechanism and the results of related preclinical research have been published in “Nature Communications” and “Critical Care”, both top academic journal with far-reaching academic influence, in February 2020 and November 2023, respectively. At present, the product has been granted 7 clinical approvals in four indications of sepsis, ARDS, COVID-19, and ARDS caused by COVID-19 in five countries around three continents including China, Australia, Belgium, United Kingdom and Poland. Three patient-specific clinical studies were completed and have successfully met the clinical endpoints. It had been approved to conduct phase Ib clinical studies for the treatment of sepsis in Australia and Belgium in April 2020 and January 2022, respectively, and have successfully met the clinical endpoints in June 2023; it was approved by the NMPA to conduct a phase Ib clinical study for ARDS patients in China in early March 2021, which was completed in October 2022 and has successfully met the clinical endpoints; and it was approved to conduct phase IIa clinical studies for the treatment of severe COVID-19 pneumonia in Belgium, Poland and the United Kingdom in April, September and October 2021, respectively, which were completed in July 2022 and have successfully met the clinical endpoints. All three clinical studies demonstrated good safety profile and potential for clinical benefit in the treatment of severe diseases. Currently, the product was approved to conduct a phase II clinical study in China in July 2023 with the first patient being enrolled in November of the same year.

APAD, a global innovative drug for the treatment of sepsis:

APAD is a small molecule compound with a novel mechanism of action independently developed by the Group, which can antagonize a variety of pathogen-related molecules. The preclinical trial data showed that it can play a therapeutic role in sepsis caused by both bacterial and viral infections, and it is complementary to STC3141’s mechanism of antagonizing the body’s excessive immune response to treat sepsis, which can form a good product portfolio in the treatment of severe diseases such as sepsis. Currently, the product was approved by the NMPA to conduct a phase I clinical study in April 2023 with the first patient being enrolled in August of the same year.

Cerebro-cardiovascular Segment

The Group’s cerebro-cardiovascular segment specializes in both emergency care and chronic disease management. In terms of emergency care, the Group is listed as a “national essential drug production base”, an “emergency medicines manufacturer for national ready reserve” and a “national centralized production base and construction unit for minority-variety medicines (drugs in short supply)”, etc. with nearly 30 varieties, 14 of which are included in the national emergency drugs catalogue of China, while 16 of which are included in the shortage drugs catalogue, which has ranked the top in the industry in terms of product pipeline. Our products cover three major emergency scenarios, namely in-hospital emergency care, pre-hospital emergency care and civilian emergency care. Through this, we continue to provide cerebro-cardiovascular emergency patients in China with a portfolio of safe and effective products with application in multiple scenarios and various choices. In terms of chronic disease management, eplerenone tablets, the Group’s exclusive product, was approved for commercialization by the NMPA in August 2023, bridging the gap of second-generation selective mineralocorticoid receptor antagonist drugs in China.

Currently, there are more than 20 products under research in the cerebro-cardiovascular segment. Among which, Jext[®], a pre-filled epinephrine auto-injector, can be used for self or family or social treatment for severe allergic reactions, filling the gap in China, and in January 2023, the product has been granted approval for Guangdong-Hong Kong-Macao Greater Bay Area Imported Pharmaceuticals for Urgent Clinical Needs in Mainland China. In the future, the Group's cerebro-cardiovascular segment will focus on emergency care and chronic disease management, and will continue to invest in and develop products in the fields of cerebro-cardiovascular emergency and chronic disease treatment that are in urgent clinical need through a combination of independent innovation and research and development and making breakthroughs in difficult generic technologies.

Cerebro-cardiovascular products

The products mainly cover the fields of blood pressure control, vascular active drugs, myocardial metabolism, heart failure and anticoagulation. The main products include Li Shu An (norepinephrine bitartrate injection, epinephrine hydrochloride injection), Nuo Fu Kang (methoxamine hydrochloride injection), Neng Qi Lang (coenzyme Q10 tablets), eplerenone tablets, Maixuekang (Maixuekang capsules and Maixuekang enteric-coated tablets), and Herbesser (合貝爽[®]及合心爽[®], diltiazem hydrochloride tablets/diltiazem hydrochloride extended-release capsule, diltiazem hydrochloride injection), etc.

Li Shu An, the norepinephrine bitartrate injection and epinephrine hydrochloride injection:

It is used for blood pressure control in acute low blood pressure state, and can also be used for blood pressure maintenance after the resuscitation from cardiac arrest. The epinephrine hydrochloride injection is suitable for severe respiratory difficulties caused by bronchospasm, which can quickly relieve the allergic shock caused by drugs, and is a major rescue medication for cardiopulmonary resuscitation of cardiac arrest caused by various reasons. Both products are included in the National Reimbursement Drug List and the National Essential Drug List, and the norepinephrine bitartrate injection passed the consistency evaluation for the first time in China in 2021. As important emergency medicines, the two products are recommended by a number of guidelines and expert consensus, such as the Expert Consensus on the Application of Vasopressors in Emergency Shock (2021) (《血管加壓藥物在急診休克中的應用專家共識(2021)》), the Consensus of Chinese Emergency Medicine Experts on Diagnosis and Treatment of Post-Adult Cardiac Arrest Syndrome (2021) (《成人心臟驟停後綜合症診斷和治療中國急診專家共識(2021)》), the Expert Consensus on Perioperative Management of Elderly Septic Patients (2021) (《老年膿毒症患者圍術期管理專家共識(2021)》), the European Academy of Allergy and Clinical Immunology Guidelines: Guidelines for Anaphylaxis (2021) (《歐洲變態反應與臨床免疫學會指南：嚴重過敏反應指南(2021版)》), European Resuscitation Council Guidelines (2021) (《歐洲復蘇學會指南(2021)》), the Guidelines for the Treatment of Sepsis/Septic Shock in Emergency in China (2018) (《中國膿毒症/膿毒性休克急診治療指南(2018)》), the Expert Consensus on Diagnosis and Treatment of Cardiogenic Shock in China (2018) (《心源性休克診斷和治療中國專家共識(2018)》), the Consensus of Chinese Emergency Medicine Experts on Diagnosis and Treatment of Traumatic Hemorrhagic Shock in China (2017) (《創傷失血性休克診治中國急診專家共識(2017)》), the Guidelines for Diagnosis and Treatment of ESC Urgent and Chronic Heart Failure in 2016 (《2016 ESC 急、慢性心力衰竭診斷和治療指南》), and the Guidelines for Rational Use of Medication for Heart Failure (2nd Edition) (《心力衰竭合理用藥指南(第2版)》), and the clinical status of the products is remarkable.

Epinephrine hydrochloride injection (pre-filled):

In July 2022, the “epinephrine hydrochloride injection (pre-filled)” independently developed by the Group was approved for commercialization. It is currently the first epinephrine pre-filled preparation being commercialized in China. At present, all other epinephrine products for commercialization in China are packaged in ampoule bottles and are required to be prepared on site for use, resulting in wastage of drug solution and inevitable generation of glass chips and causing the risk of secondary contamination. The Group’s pre-filled packaging products do not need to be prepared and can be used directly, with the characteristics of convenient operation, accurate medication, avoiding the generation of glass chips, and reducing secondary contamination. While optimizing the quality of the products, it can maximize the precious rescue time for patients and provide a more efficient product portfolio for doctors and patients to cope with more complex clinical emergency scenarios.

Nuo Fu Kang, the methoxamine hydrochloride injection:

It is used for the treatment of low blood pressure during general anesthesia and to prevent the occurrence of abnormal heart rate, to treat low blood pressure induced by the internal obstruction of the vertebral tube and to terminate arrays of ventricular hyperactivity. The product is the first generic drug of the Group in China and has been commercialized for more than 30 years. It has been recommended for use by guidelines and expert consensus, including the Guiding Opinions on the Management of Peripheral Anesthesia in Chinese Geriatric Patients (2014/2017/2020) (《中國老年患者圍術期麻醉管理指導意見 (2014/2017/2020)》), the Expert Consensus on Anesthesia Management for Cranial Brain Disease Intervention in China (2016) (《中國顱腦疾病介入治療麻醉管理專家共識(2016)》), the Expert Consensus on Perioperative Use of α_1 Adrenergic Receptor Agonists (2017 Edition) (《 α_1 腎上腺素能受體激動劑圍術期應用專家共識(2017版)》), the Expert Consensus on Obstetric Anesthesia in China (2018/2020) (《中國產科麻醉專家共識(2018/2020)》), and the Consensus on the Clinical Management of Chinese Experts in the Peripheral Anesthesia Period of Non-cardiac Surgery in Patients with Cardiac Disease (2020) (《心臟病患者非心臟手術圍麻醉期中國專家臨床管理共識(2020年)》).

Neng Qi Lang, the coenzyme Q10 tablets:

It is used to improve myocardial metabolism and energy supply, with the function of promoting oxidization phosphorylation reaction and protecting structural integrity of biological membranes. For patients with chronic cardiac insufficiency, it can significantly improve the symptoms of shortness of breath and fatigue, effectively combine with regular treatment to improve the prognosis of patients, and improve their quality of life. The product has been commercialized for more than 30 years and has been successively included in 20 guidelines and expert consensus, including the Chinese Practice Guidelines for Diagnosis and Treatment of Migraine (2023 edition) (《中國偏頭痛診斷與治療指南 2023 版》), the Expert Consensus on Diagnosis and Treatment of Severe Fever with Thrombocytopenia Syndrome (《重症發熱伴血小板減少綜合徵診治專家共識》), the Chinese Expert Consensus on the Clinical Application of Drugs to Improve Myocardial Metabolism (2021) (《改善心肌代謝藥物臨床應用中國專家共識 (2021)》), the Chinese Expert Consensus on Diagnosis and Treatment of Chronic Heart Failure for the Elderly (2021) (《老年人慢性心力衰竭診治中國專家共識(2021)》), the 2020 Expert Consensus on Prevention and Treatment of Heart Failure after Myocardial Infarction (《2020 心肌梗死後心力衰竭防治專家共識》) and the Diagnosis and Treatment Advice for Children’s Heart Failure (《兒童心力衰竭診斷和治療建議》).

Eplerenone tablets:

It is a new MRA drug. It can block heart disease and vascular damage caused by excessive activation of mineralocorticoid receptor (“MR”) by binding to the MR. The Guidelines for Prevention and Treatment of Hypertension in China (2018 Revision) (《中國高血壓防治指南(2018年修訂版)》), The Guidelines for Diagnosis and Treatment of Heart Failure in China (《中國心力衰竭診斷和治療指南》) and The Multidisciplinary Expert Consensus for Clinical Application of Mineralocorticoid Receptor Antagonists in China (2022) (《鹽皮質激素受體拮抗劑臨床應用多學科中國專家共識(2022)》) recommend the clinical use of MRA drugs in the treatment of cardiovascular diseases such as heart failure and hypertension. Compared with the first-generation MRA drug Spironolactone, Eplerenone has higher MR selectivity and lower affinity for androgen receptor and progesterone receptor, so it has less side effects and is a safe and effective new generation of MRA drug.

Maixuekang, Maixuekang capsules and Maixuekang enteric-coated tablets:

It has the effects of anticoagulation, antithrombosis, antifibrosis, and improvement of blood circulation, and can be used in the treatment of cerebro-cardiovascular diseases such as coronary heart disease, acute cerebral infarction, ischemic stroke, and unstable angina. It is included in the National Reimbursement Drug List and the Essential Drug List, and is currently the only Chinese patent medicine that is labeled with antithrombin activity units in China (each capsule/tablet is equivalent to 14 units of antithrombin activity). It has been included in many authoritative clinical guidelines, such as the Guideline for the Diagnosis and Treatment of Cerebral Infarction with the Integrated Traditional Chinese and Western Medicine, the Guidelines for Rational Use of Proprietary Chinese Medicines for Promoting Blood Circulation for Removing Blood Stasis, the Clinical Practice Guideline for Chinese Medicine in the Treatment of Idiopathic Membranous Nephropathy, and the Expert Consensus on the Use of Maixuekang Capsule (Enteric-coated Tablet) for Patients with Cardiovascular and Cerebrovascular diseases in Clinical Practice.

Herbesser (合貝爽®及合心爽®, diltiazem hydrochloride tablets/diltiazem hydrochloride extended-release capsule, diltiazem hydrochloride injection):

As a typical calcium channel blocker with clear clinical efficacy and high safety features. It is available in immediate-release oral dosage form, extended-release dosage form and injectable dosage form, which can greatly satisfy the clinical needs of patients with hypertension, coronary heart disease and other cerebro-cardiovascular diseases. It has been included in many authoritative clinical guidelines, such as the Guidelines for Prevention and Treatment of Hypertension in China (《中國高血壓防治指南》), the Guidelines for the Rational Use of Drugs for Hypertension (《高血壓合理用藥指南》), the Guidelines for the rational use of drugs for coronary heart disease (《冠心病合理用藥指南》), the Guidelines for the Diagnosis and Treatment of Stable Coronary Heart Disease (《穩定性冠心病診斷與治療指南》), the Guideline for Rational Medication of Supraventricular Tachycardia in Primary Care (《室上性心動過速基層合理用藥指南》), the Guidelines for the Diagnosis and Treatment for Chinese Adult Patients with Hypertrophic Cardiomyopath (《中國成人肥厚型心肌病診斷與治療指南》) and the Chinese Guidelines on Diagnosis and Management of Atrial Fibrillation (《心房顫動和治療中國指南》).

Innovative R&D pipeline

GPN00816, Jext[®] pre-filled epinephrine auto-injector:

GPN00816 is a one-off automatic syringe embedded with the sterile solution of epinephrine. By injecting single-dose epinephrine to the outside of the leg muscle (muscle injection), the product can urgently treat sudden and life-threatening anaphylaxis caused by insect bites, food, drugs or exercise. The product has been approved for commercialization in 21 countries or regions such as Spain, the United Kingdom, France, Germany, Korea and Hong Kong, China, etc., and has been launched worldwide for more than 10 years. Its safety and efficacy have been fully verified. At present, the product has been granted approval for Guangdong-Hong Kong-Macao Greater Bay Area Imported Pharmaceuticals for Urgent Clinical Needs in Mainland China in January 2023, and patients can purchase the product in designated medical institutions in the Guangdong-Hong Kong-Macao Greater Bay Area (“**Greater Bay Area**”) of China.

Pharmaceutical Raw Materials Segment

The Group’s pharmaceutical raw materials segment has a rich product pipeline and significant advantages in terms of product concentration. As an important link in the front-end of the integrated supply chain of raw materials and preparations, the Group owns a series of modernized production bases of pharmaceutical raw materials with complete equipment, superb technique, outstanding industrialization capability and standardized quality control, and has already constructed a comprehensive industrial system for integrated raw materials and preparations. With the strategy of “focusing on its advantages, pursuing steady improvements, and combining imitation and innovation”, the Group focuses on four major areas, namely cerebro-cardiovascular, anti-infection, antipyretic analgesic and the digestive system, and fully supports the production of preparations in the field of pharmaceutical technology, so as to ensure high quality standard and consistency of the Company’s preparations at the source, and truly realize the integration of upstream and downstream industrial advantages.

mRNA platform

With mRNA technology as the core, the Group’s mRNA platform focuses on the development of anti-tumor and anti-infection mRNA drugs. Currently, the Group has completed the establishment of mRNA production technology and liposomal nanoparticles (“LNP”) delivery technology platform. ARC01 (A002), a therapeutic tumor vaccine against human papillomavirus type 16 (“HPV-16”)-positive advanced unresectable or recurrent/metastatic solid tumors, which is under development by the platform, is currently the first mRNA therapeutic tumor vaccine against HPV-positive tumors that has been approved for clinical trials in China. Through the LNP delivery technology, mRNAs encoding E6 and E7 antigens of HPV-16 transfect autologous host cells and are translated into corresponding antigens, and then stimulate the body to produce specific humoral and cellular immunity under the joint action of TriMix[®] immunoadjuvant, which can ultimately achieve anti-tumor effects. Among them, the LNP delivery technology and TriMix[®] adjuvant technology are exclusive patented technologies that can significantly enhance the body’s immune response and improve the immunotherapeutic effect of the vaccine.

NUCLEAR MEDICINE ANTI-TUMOR DIAGNOSIS AND TREATMENT AS WELL AS CEREBRO- CARDIOVASCULAR PRECISION INTERVENTIONAL DIAGNOSIS AND TREATMENT TECHNOLOGY

By fully capitalizing “accurate and stable business development capabilities at home and abroad, the introduction and digestion of international leading technologies, excellent marketing and sales capabilities”, the Group is aiming at the frontier areas of technological innovation and focusing on the layout of the “nuclear medicine anti-tumor diagnosis and treatment” and “cerebro- cardiovascular precision interventional diagnosis and treatment” segments. It has become a leading enterprise in nuclear medicine anti-tumor diagnosis and treatment in China, and a comprehensive cerebro-cardiovascular precision interventional diagnosis and treatment technology platform with international cutting-edge technologies.

Nuclear Medicine Anti-tumor Diagnosis and Treatment Segment

In the nuclear medicine anti-tumor diagnosis and treatment segment, the Group has achieved a comprehensive layout in the fields of R&D, production, sales, regulatory qualifications and established a complete industrial chain. The Group has obtained a series of domestic licenses for the production and operation of radiopharmaceuticals, including the license for the production of radiopharmaceuticals, the license for the operation of radiopharmaceuticals and the license for the safety of radiation, with steady progress of commercialization in China. At the same time, the Group also participated in the formulation of the Technical Guidelines for Clinical Evaluation of Radioactive Therapeutic Drugs (《放射性體內治療藥物臨床評價技術指導原則》) and other regulatory documents to promote the healthy development of the nuclear medicine industry in China.

The nuclear medicine anti-tumor diagnosis and treatment segment is one of the most globalized segments of the Group. Currently, it has nearly 600 employees, with approximately 30% of them holding master’s degree and doctoral degree. The Group, together with Sirtex, cooperated with Telix Pharmaceutical Limited (“Telix”) and ITM Isotope Technologies Muncich SE (“ITM”) to establish a world-class tumor intervention technology platform and a RDC technology platform. The Group adheres to the treatment concept of integrated oncology diagnosis and treatment. Currently, the Group has 14 innovative products in the pipeline, covering six radionuclides including ^{68}Ga , ^{177}Lu , ^{131}I , ^{90}Y , ^{89}Zr and $^{99\text{m}}\text{Tc}$ as well as seven cancers including liver cancer, prostate cancer and brain cancer. In terms of product types, it covers two types of radionuclide drugs for diagnosis and therapy, providing patients with global leading anti-tumor solutions with multi-indication treatment options, multi-means and integrated diagnosis and treatment. At the same time, the Group and Shandong University jointly established Grand Pharma — Shandong University Radiopharmaceutical Research Institute (遠大醫藥-山東大學放射藥物研究院) to carry out the R&D of RDC drugs.

With the continuous expansion of the product pipeline, the registration and application of innovative products in China is also progressing smoothly. In 2022, Yttrium-90 microsphere injections have been commercialized successfully. At present, four RDC have been approved for clinical trials. At the same time, the Group has been advancing the construction of Class A qualification nuclide production platform in an orderly manner. In the future, the Group will continue to strengthen the R&D in and establishment of the nuclear medicine anti-tumor diagnosis and treatment segment, as well as enrich and improve the product pipeline and industrial layout, forming a nuclear medicine anti-tumor diagnosis and treatment product cluster with the core of Yttrium-90 microsphere injections, which continuously consolidates the Group’s global leading position in the field of nuclear medicine anti-tumor diagnosis and treatment.

Core products

Yttrium-90 microsphere injections, the global innovative product:

The Group's global blockbuster innovative product, Yttrium-90 microsphere injections, is the only product in the world for selective internal radiation therapy (SIRT) for colorectal cancer liver metastases. It has been used by more than 150,000 people in over 50 countries and regions around the world. It is also recommended by the treatment guidelines issued by different international authoritative organizations such as Barcelona Clinic Liver Cancer Guidelines (BCLC), National Comprehensive Cancer Network (NCCN), European Society for Medical Oncology (ESMO), European Association for the Study of the Liver (EASL), National Institute for Health and Care Excellence (NICE), etc. and has been included in several authoritative clinical practice guidelines in China, including the "2022 CSCO Guidelines for Diagnosis and Treatment of Primary Liver Cancer" (《二零二二年 CSCO 原发性肝癌诊疗指南》), the "Guidelines for Diagnosis and Treatment of Primary Liver Cancer (2022 edition)" (《原发性肝癌诊疗指南(2022版)》), "Chinese Guidelines for Diagnosis and Comprehensive Treatment of Colorectal Cancer Liver Metastases (2018 edition)" (《中国结直肠癌肝转移诊断和综合治疗指南(2018版)》), "Clinical Practice Guidelines for Liver Cancer and Liver Transplantation in China (2018 edition)" (《中国肝癌肝移植临床实践指南 (2018版)》), etc.

In January 2022, the Group received the approval from the NMPA for commercialization of Yttrium-90 microsphere injections, for the treatment of patients with unresectable colorectal liver metastases who have failed standard of care. The product will provide a new and effective treatment modality for patients with liver malignancies in China, offering the opportunity for translational therapy and further surgical resection to achieve clinical cure, bridging the gap in the local treatment of liver metastases from colorectal cancer, improving the long-term treatment outcome of the Chinese patient population with liver cancer, and marking the arrival of a new international precision interventional treatment option in the field of liver malignancies in China.

In May 2022, Yttrium-90 microsphere injections was officially commercialized in China. The treatment of liver malignancies in China has entered a new "Y-90 era". Since the official commercialization of YiGanTai[®], nearly 60 hospitals have completed the nuclide transfer procedures, its official surgeries have been carried out in nearly 40 hospitals in 17 provinces and cities in China, while 7 surgery, treatment and training centers have been established. The follow-up results showed that the overall response of patients who take YiGanTai[®] surgery was satisfactory, and most patients achieved favorable clinical therapeutic effect and prolonged survival. As at the date of this announcement, more than 10 patients have successfully achieved liver cancer tumor downstaging transform and took liver cancer resection, achieving clinical cure. Among patients who could be followed up for 3 months or more, the objective response rate of YiGanTai[®] for liver cancer reached 60%, and more than half of the patients had achieved tumor size remission. Among them, the symptoms of more than 30 patients were completely relieved with no resection required, and the disease control rate of the follow-up patients was approximately 75%, showing a remarkable therapeutic effect.

In order to speed up the implementation and popularization of YiGanTai® microsphere injections precise interventional therapy in China, the Group, based on the surgeon supervision and training system approved by China NMPA and U.S. FDA, concentrated global resources to provide comprehensive training to surgeons in China on patient screening knowledge, surgical operation skills, and prognosis assessment methods, helping doctors to master and accumulate clinical experience to ensure a wider, safe and effective applications of the product, and assisted domestic doctors in conducting multiple personalized practical trainings by well-known overseas clinical experts. At present, the Group has trained more than 1,000 doctors in 70 hospitals on the surgery theory or skills of YiGanTai®, more than 120 doctors have obtained the surgeon registration for YiGanTai®. Among which, 38 doctors have obtained the operation qualification of independent surgery through strict one-to-one training by international and domestic renowned experts, and 48 doctors have been qualified as assistants in surgical operation. Another 7 experts have obtained the qualification of training instructor, which will further accelerate the clinical popularization of YiGanTai® radioactive interventional operation.

Since its commercialization, Yttrium-90 microsphere injection has been included in 36 inclusive insurances such as Shanghai Hu Hui Bao (上海滬惠保), Nanjing Ning Hui Bao (南京寧惠保), Jiangsu Yi Hui Bao (江蘇醫惠保) and Beijing Pu Hui Jian Kang Bao (北京普惠健康保) and 1 special medical insurance, which covers 20 provinces and 27 cities with a significant increase in the accessibility of such product to patients with liver cancer.

Innovative R&D pipeline

The products of the nuclear medicine anti-tumor diagnosis and treatment segment are mainly divided into two categories: interventional therapy and RDC.

Interventional therapy:

GPN00289, a global innovative temperature sensitive embolic agent:

GPN00289 is an NMPA innovative medical device approved temperature sensitive embolic material for the treatment of vascular- rich benign and malignant tumors. At room temperature, the gel has good flowability and is delivered to the vasculature of the diseased tissue through a microcatheter. The gel is then solidified in situ at body temperature from the peripheral vessels to the main donor vessel to achieve embolization of the diseased tissue. It is suitable for the embolization of various vascular-rich solid organ tumors, especially benign and moderate malignant tumors in the liver. Currently, the model inspection of the product was completed, and the preparation before its registered clinical study is underway.

Lava™, a global innovative liquid embolic agent:

Lava™ is the first innovative liquid embolic agent approved for the treatment of peripheral vascular arterial hemorrhage in the United States. Its radiopacity makes the product less prone to artifacts during the imaging process, thus giving a better imaging effect. Lava™ can be easily prepared in 3 minutes, while it takes about 20 minutes to prepare similar products, saving doctors' preparation time in emergency situations and increasing the probability of patient survival; the solid embolization upon conversion offers two viscosities which can be used flexibly for patients with different conditions. Lava™ can create synergies with radioisotopes brachytherapy and interventional therapies, which is expected to be used in combination with the Group's Yttrium-90 microsphere product to expand its indications to other tumors in the future. Currently, the product was approved for commercialization in the United States in April 2023 and its formal commercialization commenced in October of the same year.

Kona™, a global innovative liquid embolic agent:

The product, for the treatment of preoperative embolization of cerebral arteriovenous malformations, is developed with a transient radiopacity that diminishes over time, targeting to present clear post-operative organ visualization. In addition, with its drug loading potential, Kona™ can either be used in combination with the Yttrium-90 microspheres products to lay a foundation for the expansion of Yttrium-90 microspheres products into indications beyond liver tumor, or to load other chemical or radiopharmaceuticals to develop new drug-device combination products, so as to provide more diversified treatment options for the treatment of other tumors or vascular diseases. Currently, an application for Premarket Approval (PMA) has been submitted to the FDA for Kona™.

AuroLase®, a global innovative solid tumor ablation therapy:

AuroLase® is a global innovative therapeutic technology for prostate cancer tissue ablation that uses a new type of optically tunable nanoparticle, delivered intravenously and enriched in the tumor, to selectively absorb laser energy and convert light into heat, thereby precisely destroying the tumor and the blood vessels supplying it without severely damaging the surrounding healthy tissue. AuroLase® therapy can maximize treatment outcomes while minimizing the side effects associated with surgery, radiation and alternative focal therapies compared to surgery, radiation or traditional alternative focal therapies. Currently, an application for PMA has been submitted to the FDA for the product.

RDC drugs:

There are currently 9 product candidates under research and a number of products have made important progress during the Period.

TLX591/TLX591CDx/TLX599CDx, global innovative products for prostate cancer diagnosis and treatment:

TLX591 is a therapeutic RDC drug targeting prostate-specific membrane antigen (PSMA), while TLX591-CDx and TLX599-CDx are diagnostic RDC drugs targeting PSMA, forming an integrated radiotherapy portfolio for prostate cancer. TLX591-CDx was approved for commercialization in Australia in November 2021 and in the United States in December of the same year, and was granted a special license in Brazil for pre-approval sales. At the same time, an application for commercialization of the product in the United Kingdom and the European Union was also underway. In August 2023, the first patient enrolment for the phase III clinical study of TLX591-CDx conducted in China was completed. In November of the same year, the first patient enrolment for the overseas phase III international multi-regional clinical study of TLX591 was completed.

TLX250/TLX250CDx, global innovative products for the treatment of clear cell renal cell carcinoma:

TLX250 and TLX250-CDx form an integrated radiotherapy portfolio for clear cell renal cell carcinoma (ccRCC). TLX250-CDx was granted a breakthrough therapy by the FDA in July 2020, and the overseas phase III clinical study successfully met clinical endpoints in November 2022. According to the study results, for the patients with renal masses suggested by computerized tomography (CT) or magnetic resonance imaging (MRI) but unable to determine whether it is ccRCC, the sensitivity and specificity of positron emission tomography (PET) imaging with TLX250-CDx in the diagnosis of ccRCC reached 86% and 87% respectively, which far exceeded the preset threshold required by the FDA (both sensitivity and specificity higher than or equal to 70%). Its positive predictive value has reached 93%. For early ccRCC in stage T1a, which is currently difficult to diagnose (the tumor is confined to the kidney with the largest tumor diameter smaller than or equal to 4 cm), the sensitivity and specificity of TLX250-CDx diagnosis reached 85% and 89% respectively. These breakthrough clinical results demonstrate that TLX250-CDx is expected to provide a highly accurate and non-invasive diagnostic solution for ccRCC, and has the potential to become a new clinical diagnostic standard for ccRCC. Currently, the application for commercialization of TLX250-CDx has been submitted to the FDA. Moreover, clinical studies of TLX250-CDx on a number of extended indications such as triple-negative breast cancer (TNBC), non-muscle invasive bladder cancer (NMIBC) and Urothelial carcinoma are progressing worldwide. In September 2022, TLX250-CDx was approved by the NMPA to conduct a phase I clinical trial and a confirmatory clinical trial in China, and the first patient enrolment and administration for its phase I clinical study was completed in July 2023. Its phase I clinical study was completed by now and it is currently in the stage of confirmatory clinical trial. TLX250 is undergoing a phase II clinical study overseas.

ITM-11/TOCscan[®], a global innovative product for the treatment of gastroenteropancreatic neuroendocrine tumors (“GEP-NETs”):

ITM-11 and TOCscan[®] form an integrated radiotherapy portfolio for GEP-NETs. ITM-11 has received an orphan drug status from FDA and European Medicines Agency (“EMA”) and is in phase III clinical studies overseas. For the registration in China, the phase I clinical study of the product was approved by the NMPA in May 2023. TOCscan[®] has been approved for commercialization in Germany, Austria and France in 2018.

TLX101, a global innovative product for glioblastoma treatment:

TLX101 is a RDC drug for the treatment of glioblastoma multiforme. It can pass through the blood-brain barrier entering the brain freely, and targets the overexpressed L-type amino acid transporter 1 (LAT-1) in glioblastoma to precisely irradiate cancer cells, and promote their apoptosis to achieve therapeutic effect. The product has been granted orphan drug designation by the FDA and is currently in phase I/II clinical trials in Europe and Australia. In April 2023, the phase I clinical study of TLX101 to be conducted in China was approved by the NMPA.

ITM-41, a global innovative product for the treatment of bone metastasis in malignant tumors:

ITM-41 is a therapeutic RDC drug that targets bone metastasis in malignant tumors by conjugating no-carrier-added 177 Lu with zoledronic acid. The product can precisely target hydroxyapatite at the metastasis site, inhibiting bone metastasis from malignant tumors while minimizing radiation to normal tissues, greatly improving patient survival and potentially further reducing skeletal-related events in patients with severe bone metastases. The product is currently in clinical phase I studies overseas.

Cerebro-cardiovascular Precision Interventional Diagnosis and Treatment Segment

The Group adheres to the treatment concept of “interventional without implantation” and conducts comprehensive layout in three directions, namely channel management, structural heart disease, electrophysiology and heart failure, to build a high-end medical device product cluster. At present, the segment has reserved 16 products, of which 7 products in channel management have been approved for commercialization in China, NOVASIGHT Hybrid has been approved for commercialization in China by the NMPA in May 2023, and HeartLight X3 laser ablation platform has been submitted for commercial registration in China, while other products are also being actively promoted for clinical registration in China in order to achieve the stage-by-stage commercialization for innovative products in the coming years, driving the business in this segment to achieve leapfrog growth.

The Group has completed the comprehensive construction of the “active + passive” innovative device platform in this segment. Among them, the Active Equipment R&D and Production Base in Optics Valley, Wuhan and the Passive Equipment R&D and Production Base in Changzhou have been put into use. The Shanghai Device R&D Center, which focuses on the field of structural heart disease, was officially inaugurated. The construction of R&D bases in Germany, Canada, Italy, etc. are also progressing in an orderly manner. At present, the Group has carried out technology cooperation with clinical centers or R&D platforms in the Unites States, Canada, Germany, Italy and Switzerland, and gradually started a new process of globalized R&D. The segment has over 200 employees and nearly 60 R&D team members, with over 60% of them holding master’s degrees and doctoral degrees. With a comprehensive background in medicine, pharmacy, materials, machinery, electronics, etc., it helps to achieve stable and long- term development in R&D and innovation. The Group is committed to developing this segment into a leading “cerebro-cardiovascular precision interventional therapy platform” in China and worldwide.

Cerebro-cardiovascular precision intervention diagnosis and treatment products

The Group’s two drug-coating balloons for sale in China, namely RESTORE DEB® and APERTO® OTW adopt the unique patented SAFEPAX technology. Both drug coating products are stable with small decay rate, which have been recognized by clinical doctors and patients with good market reputation since its commercialization. In May 2023, the Group’s Novasight Hybrid System (“Novasight”), a global innovative intravascular dual-mode imaging device for coronary artery imaging, was successfully approved for commercialization in China. The product can achieve ultrasound and optical imaging at the same time, which can simultaneously meet the doctor’s requirements for resolution and penetration, simplify the doctor’s operation and improve the accuracy of imaging, thereby providing a more accurate vascular imaging solution for patients who need percutaneous coronary intervention (“PCI”) treatment and satisfying personalized clinical needs. On the front of neurointervention, the Group’s self-developed and self- produced innovative global neurointerventional products, including the OTW (Over The Wire) intracranial balloon dilatation catheter Cai Yu® (彩鵲®), the acute ischemic stroke treatment products, occlusion balloon catheter Ti Hu® (鵝鵲®), the distal access catheter Pilu® (琵琶®) and the microcatheter Sheti® (蛇鵲®), both for building access to neurovascular and peripheral vascular system intervention surgeries, were approved for commercialization in China.

RESTORE DEB®, a coronary drug-coating balloon:

RESTORE DEB® is the first drug-coating balloon with the dual indications of original coronary artery disease mutation and stent restenosis in China. Its clinical research results were published in the important journal “JACC (Journal of the American College of Cardiology) Cardiovascular Interventions” in the field of cardiovascular disease, and its clinical status was also affirmed in the guidelines and expert consensus such as the Guidelines for Treatment of Percutaneous Coronary Intervention (中國經皮冠狀動脈介入治療指南) and the Chinese Expert Consensus on Clinical Application of Drug Coated Balloon (藥物塗層球囊臨床應用中國專家共識).

APERTO® OTW, a drug coated balloon for dialysis access:

APERTO® OTW is the first drug-coating balloon for the indication of arteriovenous fistula stenosis in dialysis patients. This product has the dual characteristics of high pressure resistance and drug coating. Compared with ordinary high pressure balloon, APERTO® OTW has a significant advantage in the passing rate of target lesions for six months after surgery, which will greatly contribute to the extension of the life time of fistula and the improvement of the quality of life of dialysis patients. Its clinical research results are published in American Journal of Kidney Diseases, an important journal in the field of kidney disease treatment.

Novasight, an intravascular dual mode imaging system:

Novasight combines two imaging technologies, namely intravascular ultrasound (“IVUS”) and optical coherence tomography (“OCT”) and can simultaneously show the ultrasound and optical image with the same direction, axis and phase, which, on one hand, better provides doctors with histological and morphological information on intravascular plaque and vascular wall, facilitating doctors to provide patients with more accurate treatment options. On the other hand, it also reduces the diagnosis and treatment procedures for patients and reduces their medical burden. In addition, the product is the first intravascular ultrasound and optical dual mode imaging system approved by the FDA of the United States. It has been commercialized both in Canada and Japan with a promising prospect in the field of coronary artery imaging and intracavitary interventional surgery.

Cai Yu® (彩鸚®), an intracranial balloon dilatation catheter:

Cai Yu® (彩鸚®) is the first OTW-designed intracranial balloon dilatation catheter in China, which is suitable for the interventional surgery for patients with non-acute symptom intracranial atherosclerotic stenosis (非急性期症狀性顱內動脈粥樣硬化性狹窄), and can deliver the balloon to the place with distal vascular lesion through guide wire during the surgery, carry out balloon dilatation, restore blood delivery, and thus improve blood flow and perfusion in blood vessels at the lesion. Cai Yu® (彩鸚®) intracranial balloon dilatation catheter has the properties of fast passing and accuracy, which provide high efficiency and convenience for clinical use. With a variety of specifications and unique designs, it provides better compatibility and precision for clinical use while meeting safety requirements.

Ti Hu® (鴉鵲®), an occlusion balloon catheter

Ti Hu® (鴉鵲®) is an occlusion balloon catheter developed by the Group for intracranial ischemic diseases. The main structure of this product consists of a balloon, an inner and outer tube and a catheter holder, wherein the balloon is coaxial. It is one of the products in the overall solution for acute ischemic stroke in the neurointerventional direction of our cardiovascular and cerebrovascular precision interventional diagnosis and treatment section. Ti Hu® (鴉鵲®) is suitable for temporary peripheral vascular or neurovascular occlusion, and can also selectively block or control blood flow. It can be delivered intraoperatively via a guidewire to the proximal vascular of the lesion to be occluded, and the catheter holder is then filled with fluid to dilate the balloon and block or control blood flow. Ti Hu® (鴉鵲®) has high balloon compliance, which allows for a better fit to the vessel wall to block blood flow and reduce embolic escape, striking a balance between safety and efficacy. It also has favorable device compatibility to meet a wide range of clinical options.

Pilu[®] (琵琶[®]), a distal access catheter:

Pilu[®] (琵琶[®]) is one of the Group's self-developed neurointerventional series products for the establishment of access to neurovascular and peripheral vascular system intervention surgeries. The product has a variety of specifications and models with 3 inner and outer diameter specifications and 5 length specifications, which provides better device compatibility while meeting more clinical surgical needs. The product adopts a composite reinforced structure which enables stable transition through various stages to achieve a perfect balance between pushability, support and durability. The sufficiently effective distal flexible section of the catheter can smoothly pass through distal tortuous blood vessels, providing intracavity devices with a support closer to the place of the lesion. Its shapeable, non-invasive tapered tip can reduce blood vessel damage while enhancing the tortuous blood vessel passage and improving the placement to distal blood vessels.

Sheti[®] (蛇鳗[®]), a microcatheter:

Sheti[®] (蛇鳗[®]) is one of the Group's self-developed neurointerventional series products for the establishment of access to neurovascular and peripheral vascular system intervention surgeries, which is used to selectively deliver liquid or other devices or drugs to the target parts of the neurovascular and peripheral vascular during diagnosis and treatment procedures, with a wide range of models and specifications available to doctors. The smooth transition of outer material with multiple gradations of hardness achieves the best balance between flexibility and stability, ensuring successful placement and stability during treatment. The tube body is made of coiled spring structure and a specific resin material, which provides excellent maneuverability, good kink resistance and support, and facilitates stable delivery and release of therapeutic devices such as stents. The full- closed-loop development ring design can achieve 360-degree clear development and accurately locate the catheter position during surgery. The steam-shaped tip is durable and stable.

Innovative and R&D pipeline

Access management direction:

LEGFLOW[®] OTW, a global innovative drug-coated balloon:

LEGFLOW[®] OTW is a drug-coated balloon for the treatment of peripheral arterial stenosis by adopting SAFEPAX patented technology. The product has completed full patient enrollment for registered clinical study, and is expected to submit a commercial registration application in China in the first half of 2024.

IVL CAD/IAL PAD, a global innovative shock wave balloon:

IVL CAD/IAL PAD is an intravascular shock wave calcium treatment system for the treatment of moderate to severe arterial calcification. It utilizes a universal balloon dilatation catheter platform that integrates shock wave lithotripsy and balloon catheter angioplasty to deliver the catheter to the lumen of the lesion in an interventional manner. The shock wave destroys the calcified foci without causing damage to the soft tissues of the vessel wall/intima, reducing the complications of balloon dilatation and stenting. The product is highly versatile and is the latest generation of vascular calcification treatment. The product is currently in preclinical development stage.

LONG, a global innovative neurological stent retriever:

LONG is a stent retriever product against ischemic stroke. With reference of mature interventional technology and stent of coronary and peripheral, neurological stent retriever can extend an ischemic stroke patient's treatment window from 6 hours to 24 hours of drug treatment, becoming a new clinical method for the treatment of cerebral stroke. At present, the product has been submitted to the NMPA and accepted for commercial registration.

aXess, a global innovative endogenous tissue repair product:

aXess is a global innovative endogenous tissue repair product for end-stage renal disease (ESRD) patients with arteriovenous graft (AVGs) for hemodialysis treatment. The product is expected to provide a safer and more effective blood access for dialysis patients by providing a basic structural framework for autologous tissue repair of patients, accelerating the establishment of dialysis access, and reducing the incidence of thrombosis and related complications. aXess can further synergize with APERTO® OTW in the field of hemodialysis. The product is currently in preclinical development stage.

Structural heart disease direction:

Saturn, a global innovative mitral valve replacement system:

Saturn is a global innovative medical device for mitral valve replacement. The product is implanted in an interventional manner via a room septum to minimize surgical trauma and shorten post-operative recovery time, and innovatively combines annular reconstruction technology with valve replacement technology to enhance device adaptability and suitability for all common mitral valve structures. The product is currently in the preclinical development stage.

Electrophysiology and heart failure direction:

HeartLight X3, a global innovative laser ablation platform:

HeartLight X3 is a global innovative laser ablation product for the treatment of atrial fibrillation ("AF") approved by the FDA for commercialization in May 2020, and is the only product in the world that can achieve circumferential ablation of AF through laser. HeartLight X3 adopts direct tissue visualization, adjustable laser energy and compliant balloon technology to achieve precise and continuous energy delivery, taking into account the adjustable energy point-to-point precision ablation characteristics of traditional radiofrequency catheter ablation and the simplicity of cryoablation with short operation time and significantly reduced dependence on the operator, making it the latest generation of AF ablation technology platform. In February 2023, the first chartered-access laser ablation operation for atrial fibrillation in China was successfully completed with the product in Rujin-Hainan Hospital, introducing a new option with world-class precision to the field of atrial fibrillation treatment in China. The HeartLight X3 laser ablation platform has submitted an application for commercialization registration in China.

CoRISMA, a global innovative ventricular assisted device:

CoRISMA is a fully implanted transcatheter ventricular assisted medical device for the treatment of class III and end-stage heart failure. By adopting the world's most advanced energy transmission technology for wireless power supply, it provides a minimally invasive, safe, power-line infection-free and complication-free treatment for patients with end-stage heart failure through minimally invasive surgery. Currently, the Group is working with an innovative medical device company incubated by Yale University on product development.

Biotechnology

The Group pursues the concept of green, low-carbon and sustainable development and promotes high-quality development of the segment with the world's leading innovative technology in synthetic biotechnology. The amino acid products and biopesticides are the core business in the field of biotechnology, and it is positioned as a global premium supplier of high-quality amino acids and high-end biopesticides. The Group's development in the biological field focuses on technological innovation and the construction of high-quality systems. Currently, we have 110 R&D personnel with professional backgrounds in cross-disciplinary disciplines such as microbiology, applied chemistry, biochemistry, pharmacology and food science, hold more than 200 invention patents and has promoted the formulation and publication of nearly 60 national and industrial standards with ongoing effort in promoting the formulation of over 25 national and industrial standards. We have a complete domestic and international quality system certification, and have won many honors such as the National and Provincial Specialized New Enterprise (國家和省級專精特新企業), the National Intellectual Property Advantage Enterprise (國家級知識產權優勢企業) and the Provincial Hidden Champion Enterprise (省級隱形冠軍企業).

Amino acids segment

The Group has been cultivating in the field of amino acids for more than 20 years and has always adhered to the spirit of technological innovation, taking synthetic biology as the core, it pioneered a world's leading innovative technology in China based on biotechnology method to produce various amino acids by biological method, which filled the gap in the industry. The Group has undertaken the "one-stop" application demonstration project for national industrial strong foundation engineering and high-end amino acid products and the industrial foundation transformation project of the PRC to ensure the safety and stability of the supply chain and industrial chain of high-quality amino acids in China. The Group's core product, Cysteine series, ranks first in the world in terms of market position and production capacity, while Taurine ranks second in the world in terms of production capacity.

The Group has always adhered to the core business philosophy of "new technology, high quality, industrial chain, and internationalization" and has continued to strengthen the expansion of the amino acid industry. Based on pharmaceutical-grade amino acids and by leveraging our industrial advantages, the Group continues to expand into diversified amino acids.

New technology:

With synthetic biology as the core and after years of scientific research, at present, we have built eight technology platforms, including synthetic biology, enzyme engineering, fermentation engineering, process optimization, quality research and application transformation, while taking initiatives in construction of cell factory, fine control of fermentation processes, and development of the full technology chain of separation and purification. It has formed unique technological leadership at multiple levels including front-end R&D, engineering and industrialization, and some of the processes have filled the domestic gaps in China. Currently, the Group has established long-term strategic cooperation relationship with a number of scientific research institutions such as Tsinghua University, Wuhan University, East China University of Science and Technology, Tianjin University of Science and Technology and Huazhong Agricultural University, under which, a new amino acid fermentation technology and an enzyme expression system were developed, constructing high-efficiency bacterial strains with independent intellectual property rights and in line with the requirements for the registration of APIs. Meanwhile, the technological development of cell culture media-level amino acid has been further deepened, providing technical support to the cell cultivation application study of amino acids, which is the key raw material of cell media required for biological drugs. We have applied the technologies of molecular biology and proteomics to modify the structure of reactive enzymes, thus improving the activity of reactive enzymes and enhancing the yield and quality of the products. Through the innovation and integration of several sub technology areas, we have built an integrated synergistic system with new product development, new technology engineering, industrialization and application solutions, which provides strong support for continuous technological innovation and industrialization transfer. Among them, the fermentation production process with strain construction optimization as the core and the enzyme conversion production process with immobilized enzymes as the core can not only replace the traditional synthesis process, but also significantly reduce the emission of carbon dioxide during the production process, which fully proves the development concept of energy saving, emission reduction and green environment protection of emission peak and carbon neutrality, showing great economic and environmental benefits. By continuously optimizing the fermentation and isolation purification process, we have achieved the leading position in the industry in terms of key indicators such as production volume and yield. The integrated technology of fermentation and enzymatic process, i.e., industrial microbial fermentation for the production of industrial enzymes, and the patented technology of immobilized enzymes can significantly shorten the time of enzyme conversion, significantly improve the yield and reduce the unit cost of products. Replacing dangerous processes in traditional synthesis routes by bio-enzymatic methods can also significantly reduce synthesis costs and significantly improve production safety. The industrial technology highway built by the Group in the amino acid segment is beginning to take shape, which has laid a solid foundation for technological innovation at source and product industrialization.

The Group attaches great importance to the construction of R&D team and the close integration of production and research. At present, the amino acid segment has a core technical team led by talents from the 100 Talents Plan of Hebei Province (湖北省百人計劃). The innovative model of combining academia, research and application in this segment, as well as the echelon of technical innovation talents with clear division of labor and complementary strengths, has yielded fruitful results with the number of granted invention patents ranking at the leading level in the same industry. The core subsidiaries in the segment have won many honors, such as the National and Provincial Specialized New Enterprises (專精特新企業), the National Intellectual Property Advantage Enterprises (國家級知識產權優勢企業), the China Light Industry Green Manufacturing Engineering Technology Research Centers for Sulfur-containing Amino Acids (中國輕工業含硫氨基酸綠色製造工程技術研究中心), the China Foreign Trade Export Leading Indicator (ELI) Sample Enterprises (中國外貿出口先導指數(ELI)樣本企業), and the Provincial Hidden Champion Enterprises. At the same time, the Group is also the only enterprise in Hubei Province that has been selected as one of the “Standardization Pilot Demonstration Projects in Hubei Province” in 2023 based on the concept of “Same production line, Same standard, Same quality”.

High quality:

The Group's amino acid products have a complete quality certification system at home and abroad. Many products have passed the drug/food system certification and registration in Europe, the United States, Japan, Southeast Asia, China and other countries and regions, including European Union GMP certification, European Union REACH certification, the Accreditation certificate of foreign drug manufacturer in Japan, KFDA Registration in Korea, MAPA certification in Brazil, Free Sale Certificate Attestation in Argentina; as well as the ISO quality management system certification, the FSSC22000 food system certification, GRAS certification in the United States, the HALAL certification, the KOSHER certification, etc. Meanwhile, the Group has also made efforts to increase registration in new economies such as South America. Our comprehensive system certification and registration have demonstrated the Group's strong competitiveness for business expansion in overseas markets.

Industrial chain:

The Group has nearly 50 types of amino acids and their derivatives, including Cysteine series, Arginine series, Taurine series, etc. It has 24 registered amino acid APIs, covering more than 70% of the registration certificates in the same category and is the pharmaceutical company with the largest number of registered amino acid APIs in China. The rich amino acid product cluster can better meet the customized needs of the downstream market, provide one-stop services of multiple varieties and specifications, and enhance customer adhesion in high-end application scenarios. In addition to raw material products, the Group is also actively expanding its pharmaceutical products. Two of the self-developed functional dietary supplements, namely the U.S. patented citrulline and taurine preparations (which is used to enhance exercise endurance) and the acetylcysteine preparations (which protects respiratory health and enhances immunity) have obtained the U.S. FDA approval and was officially commercialized in the United States for sales in 2021. During the reporting period, nine functional foods developed by the Group was commercialized in China.

Internationalization:

The sales network of the Group's amino acid segment covers more than 140 countries and regions worldwide, including mainstream markets in Europe, the United States, Japan, Southeast Asia and China, with overseas business accounting for more than 50% of the total. Among which, some of our amino acid varieties ranking among the top three in terms of market share. Relying on technological breakthroughs and cost advantages, the core products have long served domestic and international high-quality customers including Zambon, Sanofi, Nestle and other Fortune 500 companies, and established long-term and stable cooperative relationships with customers in the upstream and downstream of the industrial chain as well as a high brand awareness and market reputation worldwide, which has laid a solid customer base for the continuous and rapid growth of the segment's performance.

In the future, the Group will continue to rely on its world-leading new bio-method manufacturing process in the field of high-quality amino acids, solid industrial base and industrial accumulation, rich amino acid product clusters, high-standard quality certification systems, strong international registration and commercialization capabilities, with a focus on high-end parenteral nutrition preparations, innovative peptide drugs, cell culture base and other pharmaceutical-related high value-added fields, as well as functional dietary supplements such as sports protection, special medical and infant food, beauty and pet food and other large health consumer areas. The extensive market space and huge development potential of the downstream segment will provide the Group's amino acid segment with strong and sustainable development momentum.

FINANCIAL REVIEW

Revenue and profit

For the year ended 31 December 2023 (the “Year”), the business of the Group grew steadily and recorded a revenue of approximately HK\$10,529.59 million (2022: HK\$9,562.29 million), representing a year-on-year increase of approximately 10.1%. If disregarding the impact of exchange rate fluctuation between RMB and HK\$, it was increased by approximately 15.8% as compared with the same period in 2022. The profit attributable to the owners of the Company for the Year was approximately HK\$1,880.00 million, a year-on-year decrease of approximately 9.6% as compared with the same period in 2022. The normalized profit for the Year attributable to the owners of the Company¹ was approximately RMB 2,036.24 million, a decrease of approximately 4.7% compared to the same period last year. If disregarding the impact of exchange rate fluctuation between RMB and HK\$, it would have increased by approximately 0.2% compared with the same period in 2022. During the Year, the gross profit margin of the Group is approximately 62.0%, compared with approximately 62.2% for the same period in 2022.

During the Year, the Group recorded a revenue of approximately HK\$6,813.24 million from pharmaceutical technology products, representing an increase of approximately 17.1%² as compared with the same period of 2022 (HK\$6,120.15 million), as the continuous marketing of the core products led to a steady growth in demand. In particular, we recorded a revenue of approximately HK\$1,374.62 million from the respiratory and critical and severe disease sector, representing an increase of approximately 38.2%² as compared with the same period of 2022 (HK\$1,045.76 million); a revenue of approximately HK\$2,313.62 million from the ophthalmology and otorhinolaryngology sector, representing an increase of approximately 10.0%² as compared with the same period of 2022 (HK\$2,211.26 million); and a revenue of approximately HK\$2,447.49 million from the cerebro-cardiovascular emergency sector, representing an increase of 15.9%² as compared with the same period of 2022 (HK\$2,221.62 million).

During the Year, the Group recorded a revenue of approximately HK\$3,380.96 million from biotechnology products, representing an increase of approximately 12.4%² as compared with the same period of 2022 (HK\$3,163.70 million), due to the introduction of new products and the steady growth in core products. In particular, we recorded a revenue of approximately HK\$2,757.76 million from the amino acid sector (including taurine), representing an increase of approximately 16.1%² as compared with the same period of 2022 (HK\$2,498.15 million).

During the year, the Group recorded a revenue of HK\$335.39 million from the nuclear medicine anti-tumor diagnosis and treatment and cerebro-cardiovascular precision interventional diagnosis and treatment technology products, representing an increase of approximately 26.7%² as compared with the same period of 2022 (HK\$278.44 million). In particular, we recorded a revenue of HK\$217.45 million from the nuclear medicine anti-tumor sector, representing an increase of approximately 279.5%² as compared with the same period of 2022 (HK\$60.26 million), due to rapid growth in the core products; and a revenue of HK\$117.95 million from the cerebro-cardiovascular precision interventional diagnosis and treatment sector.

¹ The normalized profit for the Year attributable to the owners of the Company excluded the impacts from the fair value change of investment in Telix of HK\$159.94 million and the impact of one-time penalties of HK\$316.18 million.

² Disregard the impact of exchange rate fluctuation between RMB and HK\$.

Distribution costs and administrative expenses

For the year ended 31 December 2023, the Group's distribution costs and administrative expenses were approximately HK\$2,567.63 million and HK\$1,234.38 million respectively as compared to approximately HK\$2,306.52 million and HK\$1,090.03 million respectively for the same period of 2022. The distribution costs increased by approximately HK\$261.10 million, mainly due to the substantial increment in revenue recorded during the Year. The administrative expenses also increased by approximately HK\$144.35 million as compared to the corresponding period of last year since the Group continuously increased its R&D investment.

Finance costs

For the year ended 31 December 2023, the Group's finance costs was approximately HK\$205.15 million as compared to approximately HK\$137.49 million for the same period of 2022. The increase in finance costs was due to US dollar interest rate hike.

R&D and project investment

For the year ended 31 December 2023, the Group continuously invested resources in the stages of research project and introduction of innovative projects. If including the R&D expenses and also the capitalized R&D expenses, prepayments for new projects and other investments, the Group's investment in R&D and various projects was approximately HK\$1,441 million.

Receivables and payables

As of 31 December 2023, the Group's trade and other receivables amounted to approximately HK\$3,068.06 million, representing an increase of approximately HK\$70.68 million as compared to the balance in 2022, mainly due to the increase in business during the Year.

As of 31 December 2023, the Group's trade and other payables amounted to approximately HK\$2,829.70 million, representing an increase of approximately HK\$341.57 million as compared to the balance in 2022, mainly due to the increase in business during the Year.

Significant Investments

The Group's investments with value over 5% of value of its total assets are considered as significant investments. As at 31 December 2023, Group's significant investments includes (i) Grand Pharma Sphere Pte Limited ("**Grand Pharma Sphere**") and (ii) Shanghai Xudong Haipu Pharmaceutical Company Limited ("**Xudong Haipu**").

Grand Pharma Sphere is the holding company of a group of companies principally engaged in the research and development, manufacturing and sales of nuclear medicine and interventional oncology products. The Group effectively owned approximately 57.98% equity interests of it. For the year ended 31 December 2023, the Group's share of loss in Grand Pharma Sphere was approximately HK\$89.07 million (for the year ended 31 December 2022: approximately HK\$41.00 million).

Xudong Haipu and its subsidiaries is a group of companies principally engaged in the manufacturing and sales of pharmaceutical injections of various volumes. The Group effectively owned 55% equity interests of it. For the year ended 31 December 2023, the Group's share of profit in Xudong Haipu was approximately HK\$106.4 million (for the year ended 31 December 2022: approximately: HK\$110.3 million).

The quote fair value of significant investments in associates is not available, since the significant associates are private entities and do not have quoted market price. The results and assets and liabilities of associates are incorporated in the consolidated financial statements of the Group using the equity method of accounting.

The Group may consider to make investments in these associates due to different criteria, mainly including:

1. Looking for opportunities to enter into new markets and expand product pools. For instance, the investment in Grand Pharma Sphere offered an opportunity for the Group to venture into the field of nuclear drug anti-tumor, and investment in other associates may help the Group get into other markets like grasp advanced technology and step into the global market of cardiovascular interventional medical devices;
2. Looking for synergy effect to the Group's existing products and markets. For example, Xudong Haipu's core product line may create synergy with the Group's preparation products, and enrich the Group's core product pool in the areas of emergency medications and cerebro-cardiovascular and respiratory products. It can also strengthen the Group's product quality, market share and brand in those areas; and
3. Seeking opportunities to cooperate with companies in early R&D stage and obtain the commercial rights for products with strong potentials.

For further details of the product R&D and business prospects of these associates, please refer to the section with heading "Business Review and Prospects" above.

Research and development

The Group has sufficient innovation pipeline. During the Period, there were accumulatively 138 projects under research and 46 innovation projects, which were in different stages from preclinical to new drug commercialization application. The pipeline layout was reasonable, forming a good echelon effect.

Research and development pipeline

Field	Sector	Direction	Product	Indication	R&D progress							
					Preclinical	IND/Model Inspection	Phase I	Phase II	Phase III	NDA/Registration	Launch	
Pharmaceutical Technology	Ophthalmology and otorhinolaryngology	Ophthalmology	GPN00136 (BRM421)	Dry eye				●	●			
			GPN00153 (CBT-001)	Pterygium					●			
			GPN00833	Eye inflammation					●			
			GPN00884	Myopia prevention and control			●					
	Respiratory and severe disease	Respiratory	Ryaltris	Allergic rhinitis						●	●	
		Severe disease	STC3141	Sepsis			●	●				
	Cerebro-cardiovascular mRNA platform	Emergency	APAD	Sepsis			●					
			GPN00816	Anaphylaxis		●					●	
	Technologies on nuclear medicine and anti-tumor diagnosis and treatment as well as cerebro-cardiovascular precision interventional diagnosis and treatment	Nuclear medicine and anti-tumor diagnosis and treatment	Interventional treatment	ARC01 (A002)	HPV16 positive solid tumor			●	●			
				Y-90 microsphere injection	Primary hepatic cancer					●		
Thermosensitive embolic agent product				Hypervascular parenchymal organs tumor		●						
Lava				Arterial bleeding from peripheral Vascular*							●	
Kona				Cerebral arteriovenous malformation							●	
AuroLase				Prostate cancer							●	
TLX591 (177Lu-rossatamab)				Prostate cancer	●					●		
TLX591-CDx (68Ga-PSMA-11)				Prostate cancer -diagnosis						●	●	
TLX599-CDx (99mTc-EDDA/HYNI C-iPSMA)				Prostate cancer - diagnosis	●					●		
TLX250 (177Lu-girentuximab)				Clear cell renal cell carcinoma	●				●			
TLX250-CDx (89Zr-girentuximab)		Clear cell renal cell carcinoma - diagnosis						●	●			
TLX101 (131I-IPA)		Glioblastoma			●	●						
TOCscan*		Gastroenteropancreatic neuroendocrine tumor - diagnosis	●						●			
ITM-11		Gastroenteropancreatic neuroendocrine tumor			●			●				
ITM-41		Malignant tumor bone metastases	●		●							
Cerebro-cardiovascular precision interventional diagnosis and treatment		Access management	Coronary artery vascular intervention	IVL CAD	Moderate/severe coronary artery/peripheral arterial calcification	●						
			Peripheral vascular intervention	IAL PAD		●						
				aXess	Hemodialysis		●					
			Neurointervention	LEGFLOW DCB	Peripheral vascular disease					●	●	
		Structural heart disease	Stent retriever	Ischemic stroke						●		
	DCB		Intracranial stenosis	●								
	Electrophysiology and heart failure	Structural heart disease	Saturn	Mitral regurgitation	●	●						
		Electrophysiology	Heartlight X3	Atrial fibrillation						●	●	
		Heart failure	CoRisma	Heart failure	●	●						

● Mainland China

● Overseas

R&D Center

Currently, the Group is involved in and has established a number of R&D technology platforms and R&D centers around the world:

In the field of pharmaceutical technology, the International R&D Center in Optics Valley in Wuhan, China is the main R&D body of the Group in the pharmaceutical technology field in China, providing technical support for the R&D of the Group's high-end preparation products; the Glycomics technology platform is located at the R&D center in Australia, focusing on the development of antiviral drugs; the mRNA technology platform is located in Nanjing, China, focusing on the development of anti-tumor and anti-infective mRNA drugs, and will further expand into the fields of rare disease and protein replacement therapy in the future.

In the sector of nuclear medicine anti-tumor diagnosis and treatment, the tumor intervention technology platform and the RDC technology platform involve the Boston R&D Center in the United States and the Grand Pharmaceutical — Shandong University Radiopharmaceutical Research Institute in China, respectively.

In the cerebro-cardiovascular precision interventional diagnosis and treatment sector, the Group's high-end medical device R&D technology platform comprises the International R&D Center in Optics Valley in Wuhan, China, the Changzhou Device R&D Center in China and the Device R&D Center in Shanghai, China.

R&D Team

As a technology-based innovative pharmaceutical enterprise, the Group has long been committed to building a high-end innovative R&D talent system to promote the global development of innovative projects. During the year, the Group, together with its associates, has a total of over 700 R&D personnel, of which nearly 450 are master's degree and doctoral degree holders, accounting for over 60%. All professional leaders and core team members of each segment have academic background in clinical medicine or pharmacy, while some of whom also have overseas education or working experience.

Development of Generic Drugs

During 2023 up to the date of this announcement, eplerenone tablets, carglumic acid dispersible tablets, digoxin injection, warfarin sodium tablets, ophthalmic balanced salt solution (15ml), moxifloxacin hydrochloride eye drops, sodium hyaluronate eye drops (0.1%), levosimendan injection, travoprost eye drops and dobutamine hydrochloride injection have been issued drug registration certificates by the NMPA, among which the eplerenone tablets and carglumic acid dispersible tablets are among the first generic products being approved for commercialization in China, and the ophthalmic balanced salt solution (15ml) is the first generic product of such specification being approved for commercialization in China.

Consistency Evaluation

During 2023 up to the date of this announcement, carglumic acid dispersible tablets, digoxin injection, warfarin sodium tablets, ophthalmic balanced salt solution (15ml), moxifloxacin hydrochloride eye drops, sodium hyaluronate eye drops (0.1%), levosimendan injection, travoprost eye drops, dobutamine hydrochloride injection, telmisartan and hydrochlorothiazide tablets, atropine sulfate injection, tramadol hydrochloride injection and fluorouracil injection were approved or deemed to have passed the consistency evaluation, and new applications were made for magnesium sulfate injection, vigabatrin powder, compound tropicamide eye drops, hydroxychloroquine sulfate tablets, olopatadine hydrochloride eye drops, levofloxacin eye drops, minoxidil topical solution, metaraminol bitartrate injection, eltrombopag olamine tablets, sodium hyaluronate eye drops (0.3%), neostigmine methylsulfate injection, flumazenil injection, nicorandil for injection. At present, a total of 33 products of the Group have been approved or deemed to have passed the consistency evaluation, and other 17 products are under review.

Intellectual Property Protection

During the Period under review, the Group had an addition of 17 core patents and 75 peripheral patents. There were 118 new patents being granted, of which 71 were invention patents, accounting for over 60%, and 5 new foreign patents being granted. The Group has accumulated 722 valid patents, of which 412 are valid invention patents. In terms of innovative products, we have applied for 31 new patents and made 1 new PCT application in the field of nuclear medicine. 10 new patents were applied and 1 new PCT application was made for the mRNA technology platform. We actively expanded our presence in the anti-infection field with 8 new patents applied. In particular, we have made 4 international PCT applications for the STC3141 project, including the applications for a total of 51 patent family members, and the core patents have been granted in the United States, Japan, Israel and Singapore. We were also making progress in the applications for patents in other countries.

Commercialization Capability

The Group's performance continued to improve, and the continuous commercialization of innovative products and profit contribution cannot be separated from the continuous improvement of commercialization capabilities. As of 31 December 2023, the Group had over 3,900 sales personnel, of which more than 3,400 were in the pharmaceutical area (including OTC), covering nearly 70,000 hospitals and primary medical and healthcare institutions in China, of which 13,000 were ranked hospitals. In the OTC area, we had over 1,000 sales personnel with a reach of more than 250,000 pharmacies in China. The cerebro-cardiovascular precision interventional diagnosis and treatment segment had a sales team comprising over 100 staff covering nearly 2,000 hospitals. The nuclear medicine anti-tumor diagnosis and treatment segment has over 320 sales personnel worldwide, with its global sales network covering more than 50 countries and regions. It has also actively carried out the hospital admission and academic promotion of Yttrium-90 microsphere injections in China.

International Standard

The Group continues to accelerate the pace of globalization and has a number of independently operating overseas companies in the fields of nuclear medicine anti-tumor diagnosis and treatment, cerebro-cardiovascular precision interventional diagnosis and treatment, and critical and severe diseases, etc. The Group has advanced overseas clinical trials of a number of global innovative products and obtained eight clinical approvals in five countries, including the United States, Australia, Belgium, Poland and the United Kingdom, involving a number of indications such as primary liver cancer and sepsis. Currently, the Group has over 330 employees overseas.

Material Investment, M&A and Cooperation

The Group continued to implement the development strategy of “independent R&D + global expansion”, further exploring high-quality innovative projects around the world to expand the Group’s product pipeline and enhance the Group’s comprehensive strengths and putting vigorous efforts in transformation towards innovation and internationalization. During 2023 and as of the date of this announcement, the Group has carried out the following material investment, M&A and cooperation:

- **Acquiring equity interests from Blackswan**

In April 2023, the Group entered into a share purchase agreement to acquire 87.5% equity interests of BlackSwan Vascular, Inc. (“**BlackSwan**”) from its original shareholder at a consideration of not more than US\$37.5 million, and it has become a non-wholly owned subsidiary of the Group. After the completion of this acquisition, the Group will own the global rights and interests of Lava™ and Kona™. On the one hand, these two products will form a product profile with the Group’s Yttrium-90 microspheres product, which is expected to expand the indications of Yttrium-90 microspheres product to other solid tumors. On the other hand, these two products will form a new drug-device profile with other chemical drugs or radiopharmaceuticals, expanding the Group’s product pipeline in the field of tumor intervention. In addition, the Group’s existing global R&D team and sales network can facilitate Lava™ and Kona™ to be approved for commercialization on a global scale and achieved high sales volume. It will develop new business markets while strengthening its existing global business through these two products.

Acquisition of Equity Interest in Tianjin Tanabe

In December 2023, the Group entered into an equity interest acquisition agreement (the “**Acquisition Agreement**”) with Mitsubishi Tanabe Pharma Corporation (“**MTPC**”), Japan, pursuant to which Grand Pharma (China) will acquire 75.35% equity interest of Tianjin Tanabe Seiyaku Co, Ltd. (“**Tianjin Tanabe**”) with approximately HKD 400 million (equivalent to approximately RMB 367.7 million) after the relevant conditions as agreed in the Acquisition Agreement are fulfilled. After the completion of this acquisition, the Group and Tianjin Tanabe will achieve comprehensive integration and upgrading of resources. On one hand, the Group can accelerate the market expansion and promotion of Tianjin Tanabe’s core products through its current sales capabilities, thereby creating new profit growth, and benefit more patients with chronic diseases. At the same time, the Group’s industrial advantages in the field of Active Pharmaceutical Ingredients can accelerate the integration of raw materials and preparations of Tianjin Tanabe’s core products, further reducing production costs and enhancing product profitability. On the other hand, the Group can rapidly enter into the chronic disease market through Tianjin Tanabe, which greatly saves the time costs of exploring new markets. It is conducive to quickly establishing market advantages, thereby achieving the Group’s full coverage in the field of cerebro-cardiovascular disease treatment, from emergency rescue to chronic disease management, from injection preparations to oral preparations. This has significantly expanded and improved the product portfolio of the Group’s cerebro-cardiovascular segment, and hence further consolidating and enhancing the Group’s comprehensive market competitiveness. In the future, the increasing unmet medical demands in the field of chronic diseases and acute and severe diseases will create huge market opportunities, and will also provide momentum for the sustained growth of the Group’s performance. The Group and MTPC will continue to maintain strategic cooperation and are committed to building Tianjin Tanabe into a chronic disease platform to bring more safe and effective treatment options to patients in China.

Acquisition of Equity Interest in Duoputai Pharmaceutical Technology

In December 2023 and January 2024, the Group entered into two equity interest acquisition agreements with Chongqing Duoputai Pharmaceutical Co., LTD. (“**Duoputai Pharmaceutical**”) to acquire 90% equity interest of Chongqing Duoputai Pharmaceutical Technology Co., Ltd.* (重慶多普泰醫藥科技有限公司, “**Duoputai Pharmaceutical Technology**”) at a consideration of approximately RMB631.80 million in aggregate. After the completion of the equity transfer, Duoputai Pharmaceutical Technology will become a non-wholly owned subsidiary of the Group. The acquisition is a significant strategic plan of the Group in the field of cerebro-cardiovascular disease treatment, which further enriched the product pipeline of the Group, consolidating and enhancing the Group’s comprehensive market competitiveness in the field of cerebro-cardiovascular disease treatment, as well as providing the driving force for the sustained growth of the Group’s performance.

INVESTOR RELATIONS

The Group has been committing to improving its corporate governance to ensure the long-term development. During the year, the Group published annual reports, annual results announcements, and other announcements and circulars on the websites of the Company and the Hong Kong Exchanges and Clearing Limited, and issued voluntary announcements, so as to disclose the latest business developments of the Group to shareholders and investors.

At the same time, the Group actively maintains close communication with investors through various channels, including securities company roadshows, large-scale telephone conferences, one-on-one meetings and other diversified communication methods, to introduce the Group's business situation, development progress and overseas member companies' businesses to investors, and simultaneously releases the latest business updates through different media channels, aiming to build an open, two-way, transparent and sincere communication platform, so that investors can keep abreast of the Group's business progress and development prospects. During the year, the Group actively communicated with the capital market and investors through results announcements, R&D open days, joint roadshows with strategic partners, and participated in a number of summits, forums, strategy conferences and special roadshows held by large investment banks and securities companies, attracting hundreds of institutional investors and analysts. Through communication with investors, the Group hopes to listen to more valuable opinions and extensively collect feedback from investors by establishing an active and efficient information and communication mechanism, so as to further enhance its corporate governance.

The Group's investor relations management is conducive to establishing a high-quality corporate image and delivering the core strategy of technological innovation. It has been highly recognized in the industry in multiple dimensions. In January 2023, it received the "Investment and Customs Pioneer Award" of the Royal Flush Enterprise and "2022 Listed Companies Most Concerned by Investors" by HSTONG. In April 2023, it won the accolade of the "6th New Fortune Best IR of Hong Kong Listed Companies (H-share)". In October 2023, it was honored with the title of "Top 10 R&D Innovative Pharmaceutical Listed Companies in China in 2023" by E Medicine Manager. In November 2023, it was named as the "Listed Bio-pharmaceutical Company with the Largest Growth" by National Business Daily. In December 2023, it was awarded the "Best Innovation Value Award of the Year" by Cailian Press in 2023, the "2023 Most Concerned by Investors Award" by HSTONG, the "Best Capital Market Communication Award" in the 7th China Excellent IR Award by Road Show China and the "Most Valuable Pharmaceutical and Healthcare Company" in the 8th Zhitong Finance Listed Company Selection, and the Investor Relations team was awarded the "Best Investor Relations Team Award". In February 2024, it received the accolade of the Best Investor Relations Company of the Year Award (Pharmaceutical and Healthcare Industry) of 'Gathering of Directors and Secretaries 2023 (聚董秘)'".

Other Significant Matters

(I) Litigations

With reference to the disclosure in the annual reports of the Company between 2016 to 2023, Tianjin Jingming, an indirect non-wholly owned subsidiary of the Company, is undertaking certain litigations related to a product quality incident, and it is also claiming the original shareholders of Tianjin Jingming for the indemnification of those possible loss suffered by the Company. Up to 31 December 2023, the court has concluded 74 cases, and 1 case is under hearing processes at the people's court. Among the final and effective judgements, Tianjin Jingming has paid the compensation and the related legal charges of approximately RMB39.22 million in according to the court orders. The other related litigations of the product quality incident have not yet been concluded. Given that (1) such product is not the core product of the Group, and (2) according to the terms of the agreement for the acquisition of Tianjin Jingming, the original shareholders of Tianjin Jingming should be responsible for the compensation of such product incident until 30 June 2015, and in April 2021 Grand Pharm (China) had claimed the original shareholders of Tianjin Jingming for the indemnification of those possible loss suffered. According to the final judgment by the court, the original shareholders of Tianjin Jingming should compensate to us approximately RMB27.09 million as the existing compensate and liquidated damages at the point of the judgment. After the execution of the enforcement order from the people's court, Grand Pharm (China) has got properties and cash at approximately RMB7.27 million in aggregate from the original shareholders of Tianjin Jingming, and the outstanding amount is still under enforcement processes. Also Grand Pharm (China) has the right to raise litigation claiming the original shareholders of Tianjin Jingming for the subsequent payment of the indemnification related to such product quality incident made by Tianjin Jingming. Hence, the Directors are of the view that the said incident and the related litigations do not have material impact to the Group.

According to the terms of the agreement for the acquisition of Tianjin Jingming, the vendors have undertaken to the Group that the net profit after tax (the “**Actual Profit**”) from domestic sales (only include the net profit generated from domestic sales and shall not include the profit generated from the sales of irrigating solutions (灌注液)) of Tianjin Jingming for the period commencing on 1 January 2015 and ending on 30 June 2015 shall not be less than RMB5 million (the “**Performance Guarantee**”). If the above Performance Guarantee cannot be met, the Group can claim for a refund of part of the share transfer consideration in according to the formula set out in the announcement of the Company dated 22 December 2014. The Group raised a litigation against those vendors in related to the said Performance Guarantee, and after the first trial, second trial and retrial from the court, the court granted the final judgement in December 2020. It was concluded that the Group can get back the RMB10 million share transfer consideration (recovered) deposited in the bank account jointly controlled by the Group and the vendors. The vendors should also additionally refund approximately RMB11.20 million share transfer consideration to the Group in according to the terms of the agreement for the acquisition of Tianjin Jingming. Up to now, the case has been applied to the People's Court for enforcement and has been accepted. The Group has followed the judgement from the court and got back the RMB10 million deposited its interest of RMB644,135 in the bank account jointly controlled by the Group and the vendors.

(II) Penalties

On 28 May 2023, Grand Pharmaceutical (China) Company Limited, a non-wholly owned subsidiary of the Company, received the Notice of Administrative Decision (the “Notice”) issued by the China State Administration for Market Regulation. According to the China State Administration for Market Regulation, from June 2016 to July 2019, the Subsidiary entered into and implemented a monopoly agreement for the sale of Norepinephrine Bitartrate Injection API and Epinephrine API; from May 2010 to April 2021, the Subsidiary abused its dominant position in the Chinese market of Norepinephrine Bitartrate Injection API and Epinephrine API, violated the Anti-Monopoly Law of the People’s Republic of China (the “Anti-Monopoly Law”), constituted the implementation of a monopoly agreement and the abuse of a dominant market position. Considering that the Subsidiary actively cooperated with the follow-up investigation works, provided relevant evidence materials, and actively self-checked and rectified, according to the provisions of the Anti-Monopoly Law and the “Administrative Punishment Law of the PRC”, the China State Administration for Market Regulation has punished the Subsidiary and order the Subsidiary to stop the violation, confiscated the gain approximately RMB149 million from such behavior, and imposed fine of approximately RMB136 million, which is calculated based on 3% of the sales of the company in China in 2019.

The company attaches great importance to and actively cooperates with the investigation of the State Administration for Market Regulation, it accepts the punishment and organizes rectification according to requirements, maintains active communication with the competent authorities, improves the sales and compliance system, actively and properly solves relevant rectification requirements, has terminated relevant monopoly agreements, actively communicates with customers, and supplies relevant raw materials to the market in compliance with laws and regulations. At the same time, further strengthen the legal compliance consciousness and responsibility consciousness of subsidiaries and relevant employees, continue to improve and optimize the operation management and compliance risk control system. The company has quickly implemented internal rectification measures, organized repeated internal training and employee learning on compliance system, increased channels and methods of internal communication, reporting, supervision and self-examination through traditional and digital means, actively carried out comprehensive self-examination, and made rectification according to requirements and self-examination, so as to continuously strengthen the legal awareness and responsibility awareness of the Subsidiary and employees.

The above fine amount accounted for approximately 3.0% and 16.82% of the audited consolidated operating income and profit attributable to the Company’s holders in the most recent fiscal year of the Group respectively. The Company considers that this administrative fine will not have any material adverse impact on the business operations and financial position of the Group.

(III) Petition for bankruptcy and liquidation by a former associate

On 14 June 2023, OncoSec Medical Incorporated (“**OncoSec**”), a former associate of the Group, filed a petition with the relevant regulatory authorities in the United States of America for voluntary liquidation under Chapter 7 of the US Bankruptcy Code. On 14 June 2023, but before OncoSec filed its petition for bankruptcy and liquidation, both directors appointed by the Group to OncoSec had resigned and the Group had lost its right to influence its operation and finance, and therefore it ceased to be an associate of the Group.

The Group made a loss provision of approximately HK\$59.65 million, representing approximately 3.2% of the profit attributable to the holder of the Company for the most recent financial year, as a result of the bankruptcy and liquidation of OncoSec, and the products of OncoSec are still in the research and development stage and have not yet hit the market, therefore, the Company considers that this matter will not have any material adverse impact on the business operation and financial position of the Group.

Financial Resources and Liquidity

As at December 31, 2023, the Group had current assets of HK\$7,016.15 million (31 December 2022: HK\$6,886.92 million) and current liabilities of HK\$5,731.44 million. (31 December 2022: HK\$6,454.60 million). The current ratio was 1.22 at 31 December 2023 as compared with 1.07 at 31 December 2022.

The Group's cash and bank balances as at 31 December 2023 amounted to HK\$1,339.71 million (31 December 2022: HK\$1,444.01 million), of which approximately 5.1% was denominated in Hong Kong dollars, United States Dollars, Australian Dollars, Euros, and 94.9% in RMB.

As at December 31, 2023, the Group had outstanding bank loans of approximately HK\$3,284.52 million (31 December 2022: HK\$3,741.38 million) were granted by banks in the PRC and Hong Kong. All bank loans were denominated in RMB, USD and HK\$. The interest rates charged by banks ranged from 2.50% to 7.07% (31 December 2022: 2.70% to 5.61%) per annum, in which approximately HK\$642.0 million bank loans were charged at fixed interest rate. Certain bank loans were pledged by assets of the Group with a net book value of HK\$121,030,000 million (31 December 2022: HK\$167.2 million). The gearing ratio of the Group, measured by bank borrowings as a percentage of shareholders' equity, was approximately 21.5% as at 31 December 2023 while it was also approximately 26.3% as at 31 December 2022.

Since the Group's principal activities are in the PRC and the financial resources available, including cash on hand and bank borrowings, are mainly in RMB and Hong Kong Dollars, the exposure to foreign exchange fluctuations is relatively low.

The Group intends to principally finance its operations and investing activities with its operating revenue, internal resources and bank facilities. The Directors believe that the Group has a healthy financial position and has sufficient resources to satisfy its capital expenditure and working capital requirement. The Group adopted a conservative treasury policy with most of the bank deposits being kept in Hong Kong dollars, or in the local currencies of the operating subsidiaries to minimize exposure to foreign exchange risks. As at 31 December 2023, the Group did not have foreign exchange contracts, interest or currency swaps or other financial derivatives for hedging purposes.

Significant Investment

Save as disclosed above, there was no other significant investment during the year.

Contractual and Capital Commitments

As at 31 December 2023, the Group as lessor had operating lease commitments of HK\$0.38 million (2022: HK\$0.65 million).

As at 31 December 2023, the Group had capital commitments of HK\$1,246.60 million (2022: HK\$140.49 million).

Contingent Liabilities

As at 31 December 2023, the Directors were not aware of any material contingent liabilities.

Events after the Reporting Period

Save as disclosed above, no subsequent events occurred after 31 December 2023 which may have a significant effect, on the assets and liabilities of future operations of the Group.

Share Option Scheme

As at 31 December 2023 and 2022, the Company did not adopt any share option scheme and no outstanding share options.

No share options were granted or exercised under any share option scheme, and there were no outstanding share options as at 31 December 2023 and 2022.

Share Award Scheme

On 1 September 2021, the Company has adopted the Share Award Scheme (“Scheme”) in which the Group’s employees, directors or consultants will be entitled to participate. Details of the Scheme are set out in the Company’s announcement dated 1 September 2021.

The Group has paid to the trust established for the Scheme approximately HK\$278.56 million, and including the dividend belongs to the shares acquired previously, the trustee used approximately HK\$268.73 million to purchase 47,761,500 shares of the Company (“Shares”) as part of the trust fund, and such Shares are held by the trustee for the benefit of the eligible participants under the trust and are the total number of award shares available for grant under the Scheme, representing approximately 1.35% of the issued Shares of the Company. Where the trustee has received instructions from the Group to acquire Shares and necessary funds, the trustee shall acquire such number of Shares on-market at the prevailing market price as soon as reasonably practicable.

Save for the aforesaid, as at 31 December 2023, the Group did not grant any awards nor caused to pay the trustee the trust fund for purchase nor subscription of Shares. When any awards were granted later, the number of Shares to be awarded, award price, vesting criteria and vesting schedule of awards of each participant will be subject to the applicable Listing Rules and other applicable regulations by that time, and will inform the participants in the form of an award letter. The Board shall not make any award of Shares which will result in the aggregate number of the Shares awarded by the Board under the Scheme exceeding 5% of the number of issued Shares of the Company as at the adoption date of the Scheme (i.e. 177,478,557 Shares), and the maximum entitlement of each participant under the Scheme in every 12-months in aggregate shall not exceed 1% of the issued Shares as at the adoption date of the Scheme (i.e. 35,495,711 Shares).

Purchase, Sale or Redemption of Shares

During the year ended 31 December 2023, neither the Company nor any of its subsidiaries has purchased, sold or redeemed any of the Company's shares, except that the trustee of the Scheme, pursuant to the terms of the rules and trust deed of the Scheme, purchased on the Stock Exchange a total of 17,461,500 Shares at a total consideration of approximately HK\$81.24 million.

Employees and Remuneration Policy

As at 31 December 2023, the Group employed about 10,534 staff and workers in Hong Kong and the PRC (31 December 2022: about 10,175). The Group remunerates its employees based on their performance and experience and their remuneration package will be reviewed periodically by the management. Other employee benefits include medical insurance, retirement scheme, appropriate training program and share option scheme.

Competing Interest

Save that Dr Niu Zhanqi, former executive Director (resigned in June 2023), is the former director of Huadong Medicine Co., Ltd. (resigned in June 2023), and thus may have interest in businesses which competes or is likely to compete, either directly or indirectly, with the business of the Group, so far as the Directors are aware of, no Directors or the management shareholders of the Company (as defined in the Listing Rules) had an interest in a business which competes or may compete with the business of the Group.

Directors' Interests in Transaction, Arrangements or Contracts

No transaction, arrangement or contract of significance to which the Company, or any of its holding company, subsidiaries or fellow subsidiaries was a party, and in which a director of the company had a material interest, subsisted at the end of the year or at any time during the year.

Model Code for Securities Transactions

The Company has adopted the Model Code for Securities Transactions by Directors of Listed Issuers (the "Model Code") as set out in Appendix 10 of the Listing Rules as its own code of conduct for securities transactions by directors. Having made specific enquiry of the Company's directors, all directors have confirmed their compliance with all the relevant requirements as set out in the Model Code during the year ended 31 December 2023.

Independence of Independent Non-executive Directors

The Company has received from each independent non-executive director an annual confirmation for independence pursuant to Rule 3.13 of the Listing Rules. The independent non-executive directors have confirmed that they are independent.

Code of Corporate Governance Practices

The Company has complied with all of the code provisions of the Corporate Governance Code and Corporate Governance Report (the "CG Code") as set out in Appendix 14 of the Listing Rules during the year ended 31 December 2023.

Audit Committee

The Company has established the audit committee for the purpose of monitoring the integrity of the financial statements and overseeing the financial reporting process and the internal control system of the Group. Currently, the audit committee is chaired by independent non-executive director Ms. So Tosi Wan, Winnie and other members include the two independent non-executive directors Mr. Hu Yebi, and Dr. Pei Geng.

The Group's audited annual financial results for the year ended 31 December 2023 has been reviewed by the audit committee.

Remuneration Committee

The Company has established the remuneration committee to consider the remuneration of all directors and senior management of the Company. Currently, the remuneration committee is chaired by independent non-executive director Ms. So Tosi Wan, Winnie and other members include the executive director Dr. Tang Weikun and the independent non-executive director Mr. Hu Yebi.

Nomination Committee

The Company has established the nomination committee to assist the Board in the overall management of the director nomination practices of the Company. Currently, the nomination committee is chaired by independent non-executive director Ms. So Tosi Wan, Winnie and other members include the executive director Mr. Zhao Chao and the independent non-executive director Mr. Hu Yebi.

Annual General Meeting

The annual general meeting of the shareholders of the Company will be held at the Unit 3302, The Centre, 99 Queen's Road Central, Hong Kong on Tuesday, 4 June 2023 and the notice of annual general meeting will be published and dispatched to the shareholders in the manner as required by the Listing Rules in due course.

Closure of Register of Members

The register of members of the Company will be closed during the following periods:

- (i) from Friday, 31 May 2024 to Tuesday, 4 June 2024 both days inclusive, for the purpose of ascertaining shareholders' entitlement to attend and vote at the annual general meeting of the Company to be held on Tuesday, 4 June 2024. In order to be eligible to attend and vote at the annual general meeting of the Company, all share certificates with completed transfer forms either overleaf or separately must be lodged for registration with the Company's branch share registrar in Hong Kong, Computershare Hong Kong Investor Services Limited at Shops 1712-1716, 17th Floor, Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong for registration no later than 4:30pm on Thursday, 30 May 2024; and
- (ii) on Tuesday, 11 June 2024, for the purpose of ascertaining shareholders' entitlement to the proposed final dividend. In order to establish entitlements to the proposed final dividend, all share certificates with completed transfer forms either overleaf or separately must be lodged for registration with the Company's branch share registrar in Hong Kong, Computershare Hong Kong Investor Services Limited at Shops 1712-1716, 17th Floor, Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong for registration no later than 4:30pm on Monday, 10 June 2024. The final dividend will be paid on or about Thursday, 27 June 2024 to the shareholders whose names appear on the register of members as on Tuesday, 11 June 2024.

Scope of Work of HLB Hodgson Impey Cheng Limited

The figures in respect of the Group's consolidated statement of financial position, consolidated statement of profit or loss and other comprehensive income and the related notes thereto for the Year as set out in this announcement have been agreed by the Group's auditors, HLB Hodgson Impey Cheng Limited ("HLB"), to the amounts set out in the Group's audited consolidated financial statements for the year. The work performed by HLB in this respect did not constitute an assurance engagement and consequently no opinion or assurance conclusion has been expressed by HLB on this preliminary announcement.

PUBLICATION OF ANNUAL RESULTS AND ANNUAL REPORT

The annual results announcement will be published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.grandpharm.com) and the Company's 2023 Annual Report will be dispatched to Shareholders and published on the Company's and the Stock Exchange's websites in due course.

By order of the Board
Grand Pharmaceutical Group Limited
Chairman
Dr. Tang Weikun

Hong Kong, 19 March 2024

As at the date of this announcement, the Board comprises four executive directors, namely, Dr. Tang Weikun, Mr. Zhou Chao, Dr. Shi Lin and Mr. Yang Guang, and three independent nonexecutive directors, namely, Ms. So Tosi Wan, Winnie, Dr. Pei Geng and Mr. Hu Yebi.

** For identification purpose only*

The board (the “**Board**”) of directors (the “**Directors**”) of Grand Pharmaceutical Group Limited (the “**Company**”) is pleased to announce the audited consolidated annual results for the year ended 31 December 2023 of the Company and its subsidiaries (collectively the “**Group**”), together with comparative figures for the previous period as follows:

**CONSOLIDATED STATEMENT OF PROFIT OR LOSS
AND OTHER COMPREHENSIVE INCOME**

For the year ended 31 December 2023

	<i>Notes</i>	2023 HK\$'000	2022 HK\$'000
Revenue	4	10,529,590	9,562,285
Cost of sales		(4,005,524)	(3,610,806)
Gross profit		6,524,066	5,951,479
Other income, gains and losses, net		(107,810)	211,572
Distribution costs		(2,567,628)	(2,306,519)
Administrative expenses		(1,234,377)	(1,090,032)
(Provision)/reversal of expected credit losses, net		(58,664)	23,017
Impairment loss recognised in respect of goodwill		(39,136)	(36,442)
Impairment loss on interest in an associate		(59,652)	-
Fair value change on financial assets at fair value through profit or loss	5	148,921	(94,623)
Fair value change on derivative financial instruments		(31,370)	39,720
Share of results of associates		(25,008)	(43,786)
Finance costs	6	(205,145)	(137,493)
Profit before tax		2,344,197	2,516,893
Income tax expense	7	(448,755)	(418,642)
Profit for the year	8	1,895,442	2,098,251

	<i>Notes</i>	2023 HK\$'000	2022 HK\$'000
Other comprehensive loss, net of income tax			
<i>Items that will not be reclassified to profit or loss:</i>			
Fair value loss on investment in equity instruments at fair value through other comprehensive income		(185,919)	(70,706)
Share of other comprehensive income/(loss) of associates		5,717	(31,311)
<i>Items that may be reclassified subsequently to profit or loss:</i>			
Exchange difference on translating foreign operations		<u>(86,192)</u>	<u>(788,439)</u>
Other comprehensive loss for the year, net of income tax		<u>(266,394)</u>	<u>(890,456)</u>
Total comprehensive income for the year, net of income tax		<u>1,629,048</u>	<u>1,207,795</u>
Profit for the year attributable to:			
- Owners of the Company		1,879,998	2,079,419
- Non-controlling interests		15,444	18,832
		<u>1,895,442</u>	<u>2,098,251</u>
Total comprehensive income for the year attributable to:			
- Owners of the Company		1,595,334	1,182,143
- Non-controlling interests		33,714	25,652
		<u>1,629,048</u>	<u>1,207,795</u>
Earnings per share	10		
- Basic and diluted (HK cents)		<u>53.60</u>	<u>58.70</u>

Details of the dividends for the year ended 31 December 2023 are disclosed in note 9.

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As at 31 December 2023

	<i>Notes</i>	2023 <i>HK\$'000</i>	2022 HK\$'000
Non-current assets			
Property, plant and equipment		3,533,202	3,505,138
Right-of-use assets		452,451	436,764
Investment properties		175,817	175,112
Interests in associates		7,864,366	7,704,161
Equity instruments at fair value through other comprehensive income		357,554	567,320
Goodwill		588,622	644,047
Intangible assets		1,656,879	1,397,992
Deferred tax assets		25,111	24,585
Prepayments	11	845,179	1,029,022
		15,499,181	15,484,141
Current assets			
Inventories		1,388,649	1,340,466
Trade and other receivables	11	3,068,059	2,997,384
Amounts due from related companies		52,467	33,747
Financial assets at fair value through profit or loss		1,134,590	1,038,582
Derivative financial instrument		-	31,370
Pledged bank deposits		32,672	1,357
Cash and cash equivalents		1,339,708	1,444,014
		7,016,145	6,886,920
Current liabilities			
Trade and other payables	12	2,829,697	2,488,127
Contract liabilities	12	198,173	318,824
Bank and other borrowings		2,317,986	3,243,126
Lease liabilities		34,611	9,785
Amounts due to related companies		16,576	22,670
Amount due to the immediate holding company		2,331	2,331
Income tax payable		332,063	369,738
		5,731,437	6,454,601
Net current assets		1,284,708	432,319
Total assets less current liabilities		16,783,889	15,916,460
Non-current liabilities			
Bank and other borrowings		990,028	1,162,288
Lease liabilities		61,614	60,083
Deferred tax liabilities		221,626	220,148
Deferred income		240,105	265,281
		1,513,373	1,707,800
Net assets		15,270,516	14,208,660

	<i>Notes</i>	2023 HK\$'000	2022 HK\$'000
Capital and reserves attributable to owners of the Company			
Share capital	13	35,496	35,496
Reserves		15,122,222	14,104,842
Equity attributable to owners of the Company		15,157,718	14,140,338
Non-controlling interests		112,798	68,322
Total equity		15,270,516	14,208,660

Notes:

1. GENERAL INFORMATION

Grand Pharmaceutical Group Limited (the “**Company**”) is incorporated in Bermuda on 18 October 1995 as an exempted company under the Companies Act 1981 of Bermuda with its shares listed on The Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”) since 19 December 1995. The addresses of the registered office and principal place of business of the Company are disclosed in “Corporate information” section of the annual report.

The Company and its subsidiaries (hereinafter collectively referred to as the “**Group**”) are principally engaged in the manufacture and sales of pharmaceutical preparations and medical devices, bio-technology products and health products, specialised pharmaceutical raw materials and other products, in the People’s Republic of China (the “**PRC**”).

The directors consider that Outwit Investments Limited (“**Outwit**”) is the parent company of the Company and China Grand Enterprises Incorporation is the ultimate holding company of the Company. The ultimate controlling party is Mr. Hu Kaijun.

The consolidated financial statements are presented in Hong Kong dollars (“**HK\$**”), which is the same as functional currency of the Company, and the functional currency of the most of the subsidiaries in Renminbi (“**RMB**”). The board of directors considered that it is more appropriate to present the consolidated financial statements in HK\$ as the shares of the Company (the “**Shares**”) are listed on the Stock Exchange. The consolidated financial statements are presented in thousands of units of HK\$ (HK\$’000), unless otherwise stated.

2. APPLICATION OF AMENDMENTS TO HONG KONG FINANCIAL REPORTING STANDARDS (“**HKFRSs**”)

Amendments to HKFRSs that are mandatorily effective for the current year

The Group has applied the following new and amendments to HKFRSs issued by Hong Kong Institute of Certified Public Accountants (the “**HKICPA**”) for the first time in the current year, which are mandatorily effective for the annual period beginning on or after 1 January 2023 for the preparation of the consolidated financial statements:

HKFRS 17 (including the October 2020 and February 2022 Amendments to HKFRS 17)	Insurance Contracts
Amendments to HKAS 1 and HKFRS Practice Statement 2	Disclosure of Accounting Policies
Amendments to HKAS 8	Definition of Accounting Estimates
Amendments to HKAS 12	Deferred Tax related to Assets and Liabilities arising from a Single Transaction
Amendments to HKAS 12	International Tax Reform-Pillar Two model Rules

The application of the new and amendments to HKFRS Standards in the current year has had no material impact on the Group’s financial performance and positions for the current and prior years and/or on the disclosures set out in these consolidated financial statements.

New and amendments to HKFRSs that have been Issued but not yet effective

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

Amendments to HKFRS 10 and and HKAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture ²
Amendments to HKFRS 16 Amendments to HKAS 1	Lease Liability in a Sale and Leaseback ¹ Classification of Liabilities as Current or Non- current and related amendments to Hong Kong Interpretation 5 (2020) ¹
Amendments to HKAS 1 Amendments to HKAS 7 and HKFRS 7 Amendments to HKAS 21 Hong Kong Interpretation 5 (Revised)	Non-current Liabilities with Covenants ¹ Supplier Finance Arrangements ¹ Lack of Exchangeability ³ Presentation of Financial Statements – Classification by the Borrower of a Term Loan that contains a Repayment on Demand Clause ²

¹ Effective for annual periods beginning on or after 1 January 2024.

² Effective for annual periods beginning on or after a date to be determined.

³ Effective for annual periods beginning on or after 1 January 2025.

The directors anticipate that the application of all other new and amendments to HKFRSs will have no material impact on the consolidated financial statements in the foreseeable future.

3. BASIS OF PREPERATION OF CONSOLIDATED FINANCIAL STATEMENTS

The consolidated financial statements have been prepared in accordance with HKFRSs issued by the HKICPA. For the purpose of preparation of the consolidated financial statements, information is considered material if such information is reasonably expected to influence decisions made by primary users. In addition, the consolidated financial statements include applicable disclosures required by the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (“**Listing Rules**”) and by the Hong Kong Companies Ordinance.

The consolidated financial statements have been prepared on the historical cost basis except for certain properties and financial instruments that are measured at fair values at the end of each reporting period, as explained in the accounting policies set out below.

Historical cost is generally based on the fair value of the consideration given in exchange for goods and services.

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, regardless of whether that price is directly observable or estimated using another valuation technique. In estimating the fair value of an asset or a liability, the Group takes into account the characteristics of the asset or liability if market participants would take those characteristics into account when pricing the asset or liability at the measurement date. Fair value for measurement and/or disclosure purposes in these consolidated financial statements is determined on such a basis, except for share-based payment transactions that are within the scope of HKFRS 2 Share-based Payment, leasing transactions that are accounted for in accordance with HKFRS 16, and measurements that have some similarities to fair value but are not fair value, such as net realisable value in HKAS 2 Inventories or value in use in HKAS 36 Impairment of Assets.

In addition, for financial reporting purposes, fair value measurements are categorised into Level 1, 2 or 3 based on the degree to which the inputs to the fair value measurements are observable and the significance of the inputs to the fair value measurement in its entirety, which are described as follows:

- Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the entity can access at the measurement date;
- Level 2 inputs are inputs, other than quoted prices included within Level 1, that are observable for the asset or liability, either directly or indirectly; and
- Level 3 inputs are unobservable inputs for the asset or liability.

4. REVENUE AND SEGMENT INFORMATION

For the years ended 31 December 2023 and 2022, the Group is principally engaged in manufacture and sales of pharmaceutical preparations and medical devices, bio-technology products, health products, specialised pharmaceutical raw materials and other products. The board of directors, being the chief operating decision maker of the Group, reviews the operating results of the Group as a whole to make decisions about resource allocation. The operation of the Group constitutes one single reportable segment under HKFRS 8 and accordingly, no separate segment information is prepared.

The Group's revenue represents the invoiced value of goods sold, net of discounts and sales related taxes.

Geographical information

The Group's operations are mainly located in the PRC (country of domicile) and it also derives revenue from America, Europe and Asia (other than the PRC).

Information about the Group's revenue from external customers is presented based on geographical location of the customers and information about the Group's non-current assets is presented based on geographical location of the assets are detailed below:

	Revenue from external customers		Non-current assets	
	2023 HK\$'000	2022 HK\$'000	2023 HK\$'000	2022 HK\$'000
The PRC	8,721,927	7,453,795	9,369,147	9,675,884
America	687,446	956,036	317,744	-
Europe	562,250	566,532	-	-
Asia other than the PRC	512,093	480,809	107,564	66,228
Others	45,874	105,113	-	-
Total	10,529,590	9,562,285	9,794,455	9,742,112

Note: Non-current assets excluded equity instruments at fair value through comprehensive income, deferred tax assets and a part of interests in associates.

Information about major customers

For the years ended 31 December 2023 and 2022, none of the Group's sales to a single customer amounted to 10% or more of the Group's total revenue.

REVENUE

Disaggregation of revenue from contracts with customers

	2023 <i>HK\$'000</i>	2022 HK\$'000
Type of goods and services		
Manufacture and sales of pharmaceutical preparations and medical devices	6,813,239	6,120,145
Sales of bio-technology products and health products	3,380,958	3,163,702
Sales of specialised pharmaceutical raw materials and other products	335,393	278,438
Total revenue recognised at point in time	<u>10,529,590</u>	<u>9,562,285</u>
Revenue disclosed in segment information		
External customers	<u>10,529,590</u>	<u>9,562,285</u>
Timing of revenue recognition		
At a point in time	<u>10,529,590</u>	<u>9,562,285</u>

All of the Group's revenue are recognised at point in time when carrier designated by the customers, or after the customer's acceptance or upon transfer of control of the goods to customer. All of the Group's revenue is generated in the PRC based on where goods are sold. All revenue contracts are for period of one year or less, as permitted by practical expedient under HKFRS 15, the transaction price allocated to these unsatisfied contacts is not disclosed.

5. FAIR VALUE CHANGE ON FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT OR LOSS

	2023 <i>HK\$'000</i>	2022 HK\$'000
Gain/(loss) in fair value change of listed equity securities in Hong Kong	833	(18,833)
Gain/(loss) in fair value change of equity instruments outside Hong Kong	172,615	(48,407)
Loss in fair value change of debt instruments	(24,527)	-
Realised loss on disposal of financial assets at fair value through profit or loss	-	(27,383)
	<u>148,921</u>	<u>(94,623)</u>

6. FINANCE COSTS

	2023 <i>HK\$'000</i>	2022 HK\$'000
Interest on bank and other borrowings	198,397	132,977
Interest on lease liabilities	6,748	4,516
	<u>205,145</u>	<u>137,493</u>

7. INCOME TAX EXPENSE

	2023 <i>HK\$'000</i>	2022 HK\$'000
Current tax:		
The PRC Enterprise Income Tax	463,184	383,904
Deferred tax	<u>(14,429)</u>	<u>34,738</u>
	<u>448,755</u>	<u>418,642</u>

No provision for Hong Kong profits tax has been made in the consolidated financial statements as the Company did not have any assessable profits subject to Hong Kong profits tax for both years. Provision on profits assessable elsewhere has been calculated at the rate of tax prevailing to the countries to which the Group operates, based on existing legislation, interpretations, and practices in respect thereof.

Under the Law of the PRC on Enterprise Income Tax (the “EIT Law”) and Implementation Regulation of the EIT Law, the tax rate of the PRC subsidiaries is 25% for both years.

According to the relevant the PRC tax regulations, High-New Technology Enterprise (the “HNTE”) operating within a High and New Technology Development Zone are entitled to a reduced Enterprise Income Tax (the “EIT”) rate of 15%. Certain subsidiaries are recognised as HNTE and accordingly, are subject to EIT at 15%. The recognition as a HNTE is subject to review on every three years by the relevant government bodies.

8. PROFIT FOR THE YEAR

	2023 <i>HK\$'000</i>	2022 HK\$'000
Profit for the year is stated after charging:		
Depreciation of property, plant and equipment	323,268	328,712
Depreciation of right-of-use assets	39,855	33,859
Amortisation of intangible assets	<u>29,087</u>	<u>32,341</u>
Total depreciation and amortization	<u>392,210</u>	<u>394,912</u>
Cost of inventories recognised as an expense	4,005,524	3,610,806
Auditors' remuneration		
- Audit services	3,980	3,880
- Non-audit services	-	-
Research and development expenditure	571,985	531,924
Marketing and promotion expenses	567,201	498,692

9. DIVIDEND

(i) Dividends payable to equity shareholders of the Company attributable to the year

	2023 <i>HK\$'000</i>	2022 HK\$'000
Final dividend proposed after the end of report HK\$0.26 per share (2022: HK\$0.14)	<u>905,141</u>	<u>496,940</u>

(ii) Dividends payable to equity shareholders of the Company attributable to the previous financial year, approved and paid during the year

	2023 <i>HK\$'000</i>	2022 HK\$'000
Final dividend in respect of the previous financial year, approved and paid during the year, of HK\$0.14 per share (2022: HK\$0.11)	<u>496,940</u>	<u>390,450</u>

10. EARNINGS PER SHARE

Basic earnings per share is calculated by dividing the profit attributable to equity owners of the Company by the weighted average number of ordinary shares outstanding during the Period, excluding ordinary shares purchased by the Group and held as treasury shares.

	2023 <i>HK\$'000</i>	2022 HK\$'000
Earnings		
Earnings for the purpose of basic earnings per share calculation	<u>1,879,998</u>	<u>2,079,419</u>
	2023 <i>'000</i>	2022 '000
Number of shares		
Weighted average number of ordinary shares for the purpose of basic earnings per share calculation (Note)	<u>3,507,754</u>	<u>3,542,258</u>

Note:

As at 31 December 2023 and 2022, treasury shares are deducted from total shares in issue for the purpose of calculating earnings per share.

Diluted earnings per share is the same as the basic earnings per share for the year ended 31 December 2023 and 2022 as there were no potential dilutive ordinary shares in issue.

11. TRADE AND OTHER RECEIVABLES

	2023	2022
	<i>HK\$'000</i>	HK\$'000
Trade receivables, net	958,261	1,093,854
Bills receivables	1,057,238	819,880
Deposits and prepayments (Note)	1,641,560	1,853,237
Other tax receivables	73,782	68,700
Other receivables, net	182,397	190,735
	3,913,238	4,026,406
Less: non-current portion of prepayments	(845,179)	(1,029,022)
	3,068,059	2,997,384

Note:

During the year ended 31 December 2023, prepayment mainly comprised of the prepayment for the acquisition of technical know-how, and the deposits for trade and rental deposits.

The Group generally allows a credit period of 30 - 180 days (2022: 30 - 180 days) to its trade customers. The Group does not hold any collaterals over the trade and other receivables. The following is an aged analysis of trade receivables presented based on the invoice date at the reporting date.

	2023	2022
	<i>HK\$'000</i>	HK\$'000
Within 90 days	753,866	788,026
91-180 days	157,602	218,252
181-365 days	46,793	87,576
	958,261	1,093,854

12. TRADE AND OTHER PAYABLES AND CONTRACT LIABILITIES

	2023 <i>HK\$'000</i>	2022 HK\$'000
Trade payables	720,063	687,731
Bills payables	610,348	185,129
Accruals and other payables	1,427,233	1,517,066
Other tax payables	72,053	98,201
	<u>2,829,697</u>	<u>2,488,127</u>
Contract liabilities (note (a))	<u>198,173</u>	<u>318,824</u>

Notes:

- (a) *Contract liabilities in relation to sales of finished goods are expected to be settled within one year. The entire amount of contract liabilities as at 1 January 2023 is all recognised as revenue during current year.*

The following is an aged analysis of trade payables presented based on the invoice date at the end of the reporting period:

	2023 <i>HK\$'000</i>	2022 HK\$'000
Within 90 days	361,607	516,952
Over 90 days	358,456	170,779
	<u>720,063</u>	<u>687,731</u>

The average credit period on purchases of goods is 90 days.

The bills payables are mature within 180 days from the end of the reporting period.

13. SHARE CAPITAL

	Number of shares at		Share capital at	
	31	31	31	31
	December	December	December	December
	2023	2022	2023	2022
	'000	'000	HK\$'000	HK\$'000
Authorized				
Ordinary shares of HK\$0.01 each	100,000,000	100,000,000	1,000,000	1,000,000
Issued and fully paid				
At 1 January, 31 December 2022, 1 January 2023 and 31 December 2023	<u>3,549,571</u>	<u>3,549,571</u>	<u>35,490</u>	<u>35,490</u>

Notes:

- (a) *As at 31 December 2023, the Company, through a trust, held 47,761,500 (2022: 30,300,000) shares in treasury for the purpose of a share award scheme. The fair value of the purchased shares was deducted from equity as "Treasury shares reserve" for an amount of approximately HK\$268,730,000 (2022: HK\$187,500,000).*

14. ACQUISITION OF A SUBSIDIARY

Acquisition of assets

On 24 April 2023, the Group entered into an share purchase agreement to acquire 87.5% equity interests of BlackSwan Vascular, Inc. (“BlackSwan”), from its original shareholder, at a consideration of approximately USD32,537,000 (equivalent to approximately HK\$255,417,000), an aggregate amount of base cash consideration of USD22,607,000 (equivalent to approximately HK\$177,464,000) and contingent consideration of approximately USD9,930,000 (equivalent to approximately HK\$77,953,000).

Upon completion of the acquisition, BlackSwan has become a non-wholly owned subsidiary of the Group, and its financial position and performance has been consolidated into the Group’s consolidation financial statement. BlackSwan is a US incorporated company mainly engaged in the research of development of liquid embolism. At the acquisition date, BlackSwan owned product license of Lava™ and Kona™ which are identifiable intangible assets.

Assets acquired and liabilities recognised at the date of acquisition

	<i>2023</i> <i>HK\$’000</i>
Property, plant and equipment	578
Intangible assets	317,918
Trade and other receivables	17
Cash and cash equivalents	1,040
Trade and other payable	(11,198)
Bank and other borrowing	(16,450)
Non-controlling interest	(36,488)
Total identifiable net assets acquired	<u>255,417</u>

Net cash outflow on acquisition of a subsidiary:

	<i>2023</i> <i>HK\$’000</i>
Cash consideration paid	177,464
Less: Cash and cash equivalents balances acquired	(1,040)
	<u>176,424</u>

15. COMPARATIVE FIGURE

Certain comparative figures have been reclassified to conform to the current year’s presentation.