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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)

**ANNOUNCEMENT OF ANNUAL RESULTS  
FOR THE YEAR ENDED 31 DECEMBER 2022**

**Financial Summary**

- In year 2022 the Group maintained stable growth even the Group was affected by the pandemic. The revenue for the year ended 31 December 2022 amounted to approximately HK\$9,562.29 million (2021: HK\$8,597.98 million), representing an increment of approximately 11.2% as compared with the same period of last year. If disregarding the exchange rate fluctuation between RMB and HK\$, it was increased by approximately 15.1% as compared with the same period of last year. For the profit attributable to the owners of the Company, if disregarding the effect from fair value change and disposal of investment in Telix, it was approximately HK\$2,137.33 million and was increased by approximately 11.5% as compared with the same period of last year. If disregarding the exchange rate fluctuation between RMB and HK\$, it was increased by approximately 15.4% as compared with the same period of 2021.
- In 2020, the Group invested in Telix by applying approximately AUD35 million to acquire approximately 20.95 million shares of Telix at AUD1.69 each. In August 2022, the Group disposed 10 million Telix shares (equivalent to approximately half of holdings) at AUD7.25 each and got AUD72.5 million cash. This not only represented that all investment costs have been recovered, but also brought additional AUD37.5 million (equivalent to approximately HK\$200 million) cash return. As a 31 December 2022, share price of Telix is at AUD7.27 each. The Group is still holding approximately 10.95 million shares of Telix and amounted to approximately AUD79.6 million (equivalent to approximately HK\$424 million).
- The gross profit margin for the year ended 31 December 2022 was approximately 62.2% (2021: 61.0%) with an increase of approximately 1.2 per cent points as compared with the same period of last year.
- In 2022, the Group had commercialized three innovative products, namely radioactive medicine Yttrium-90 microsphere injections for treatment of liver tumor, and two global innovative compound preparations for the treatment of asthma Enerzair<sup>®</sup> Breezhaler<sup>®</sup> and Ateectura<sup>®</sup> Breezhaler<sup>®</sup>.
- For the year ended 31 December 2022, our existing business continuously maintained constant growth, and the Group invested a large amount in product development and layout, with a total investment amount of over HK\$2.45 billion.
- It is the long-term objective of the Group to provide continuous growing dividend return to shareholders. This year the Board proposed a 2022 final dividend of 14 HK cents per share, amounted to approximately HK\$496.94 million.

## **CHAIRMAN'S STATEMENT**

### **INDUSTRY REVIEW**

In 2022, the biopharmaceutical industry, a vital pillar for the nation's economy, has maintained a steady progress in its high-quality development despite a tougher external environment. According to the National Bureau of Statistics of China, the operating revenue of pharmaceutical manufacturing industry in China grew from RMB2.16 trillion as at 2017 to RMB2.91 trillion as at 2022, representing an accumulated growth of 34.7%. Currently, China is developing into a longevity society, and the pharmaceutical and health industry, always driven by the state's frequent roll-out of favorable industrial policies, rising per capita disposable income and further increase in people's health needs, is also moving towards a new period of development dividend. It is worth mentioning that in 2022, China introduced its first five-year bio-economic plan: the "14th Five-Year Plan for Bio-Economic Development", which explicitly proposes to enhance the original innovation capacity of biomedicine for the protection of people's life and health and national biosecurity, where pharmaceutical companies are further encouraged and promoted to pick up the "acceleration rate" of their R&D and production of original drugs. Moreover, the centralized and volume-based procurement of pharmaceuticals, negotiation on the medical insurance catalogue access and reform of DRG/DIP payment methods have been pushed forward and implemented on a continuous basis, and the coverage of commercial health insurance, represented by the inclusive insurance, was also gradually expanded, giving further support for innovative products to benefit more patients and meet urgent clinical needs. Innovation and internationalization have become an important keynote in the development of Chinese pharmaceutical companies. At the same time, China always maintains strict supervision and strong regulation in its regulatory policy on the pharmaceutical and health industry, which also puts higher requirements on enterprises in terms of innovation and research, product commercialization capability and development sustainability.

### **BUSINESS REVIEW**

In 2022, in the face of the complex and volatile external environment, as well as the various pressures and challenges posed by the decline in market supply and demand under the impact of the pandemic, the Group has braved through the adversity and managed to achieve steady growth in revenue and operating profit.

During the year, the Group was committed to its pursuit of "high-quality". With the Company's ever-growing industrial scale, where we have more than 10,000 employees worldwide and dozens of domestic and overseas enterprises, together with a consolidated and enhanced industry chain emphasising on industrialization, refinement, and systematization, our physical operation structure is under continuous improvement, and the Company's comprehensive advantages are always enhancing. The Company has been honored with the title of "National Model Enterprise of Technology Innovation" by the Ministry of Industry and Information Technology of the PRC, ranked 24th on the list of "Top 100 Chemical and Pharmaceutical Companies of China", and won the title of "Most Valuable Pharmaceutical and Medical Company" among Hong Kong listed stocks for seven consecutive years, gradually showing its advantage in value. The Group was determined to actively promote the implementation of its five-year development strategic plan under the development principle of "comprehensive strengths, leading in innovation and global expansion", so as to achieve sustainable and steady development of its business in terms of products, profits, operation and management.

During the year, the Group strengthened the foundation of "stability" and continued to promote the upgrading of products and processes in respiratory, ophthalmology, cerebro-cardiovascular emergency and biotechnology, its traditional areas of strength, so as to consolidate the foundation of advanced manufacturing. The Group has 17 products with annual sales of over RMB100 million. It has established overseas marketing centers for biologics and, on the domestical front, initiated a reform to integrate the provincial/regional marketing system for pharmaceuticals, covering hospitals, pharmacies and third terminal sales networks with a faster pace. The Group has completed one merger and acquisition and introduced 16 amino acid APIs to continuously optimize the layout of its biotechnology industry chain, and pushed forward the commencement of construction/production of three production bases to help strengthen the Company's development foundation.

During the year, the Group maintained the "advancing" momentum. By strengthening the implementation of the diversified business strategy model, we managed to consolidate our core barriers and strengthen the innovative mindset, which aims to build our core competitiveness in the global R&D and innovative scene. During the year, we obtained 13 launch approvals, 17 clinical progresses, 3 international registrations and 15 core patents, successfully introduced 4 innovative products, and

established 42 R&D projects. The International R&D Center in Optics Valley, Wuhan, the mRNA R&D Centers in Nanjing, the Grand Pharma – Shandong University Radiopharmaceutical Research Institute (遠大醫藥 – 山東大學放射性藥物研究院) and the Innovative Device R&D and Production Base in Wuhan were officially put into operation, which further enhanced the Group’s R&D capabilities in innovative drugs, mRNA technology and nuclear medicine, as well as the capability to localize innovative medical devices and the independent R&D and production capacity. The blockbuster innovative product of the nuclear medicine anti-tumor diagnosis and treatment segment, the Yttrium-90 microsphere injections, was successfully launched to bring a long-awaited blessing to patients with liver cancer and colorectal liver metastases in China. It was a difficult and challenging situation during the pandemic period, but since the launch of Yttrium-90 microsphere injections, through expansion to more hospitals, development of communication channels and provision of training to doctors, it recorded over HK\$60.0 million revenue during the first year of launch. It formed a solid foundation for the nuclear medicine segment and built up a remarkable future. In the meanwhile, there were breakthrough developments in 4 innovative RDC medicines and were ready to launch. In the cerebro-cardiovascular precision interventional diagnosis and treatment segment a global innovative endogenous tissue repair product, aXess, was introduced. Cai Yu<sup>®</sup> intracranial balloon dilatation catheter and Ti Hu<sup>®</sup> occlusion balloon catheter, were approved for commercialization, and the first chartered access atrial fibrillation (AF) laser ablation operation in China was successfully completed with our HeartLight X3 laser ablation platform. These strengthen our advantages in the technologically innovative high-end medical devices. In the respiratory and severe disease anti-infection segment, two innovative compound asthma products were successfully launched and included in the China’s National Reimbursement Drug List. Innovative product STC3141 for sepsis and ARDS, and innovative oral small molecule 3CL protease inhibitor GS221 achieved substantial clinical development, showing our boldness and courage of being a pioneer in medical development. In the cerebro-cardiovascular emergency segment, we layout three major emergency scenarios and maintain steady development. The first generic of epinephrine hydrochloride injection (pre-filled) was launched and Jext<sup>®</sup>, a pre-filled epinephrine auto-injector, was licensed in the Guangdong-Hong Kong-Macao Greater Bay Area. In the ophthalmology segment, several innovative drugs recorded significant development progresses. The Group is moving forward along a high-quality development path, enhancing its strengths and accelerating innovation to constantly empower its long-term development.

The Group strongly upholds the value of “Offering Quality Products, Honoring Code of Ethics”, and is firmly committed to the vision of becoming a pharmaceutical company respected by doctors and patients, and making significant contribution to the society.

## **Prospects**

2023 is the inaugural year for the full implementation of the spirit of the 20th CPC National Congress, as well as a crucial linkage for the implementation of the 14th Five-Year Plan. The strategic positioning of safeguarding people's health and the “14th Five-Year Plan for the Development of Biological Economy” both bring unlimited development opportunities to medical and healthcare industry in China in the long run, which indicate that the pharmaceutical industry shall take the path of innovation and high-quality development in the future. For integrated pharmaceutical companies, sustainable development and growth can only be achieved by “striving for internal and external improvement” through polishing their own innovation capabilities and focusing on their existing strengths, while pursuing external innovations with greater differentiation and clinical advantages.

The Group has rich product pipelines and solid foundation in the ophthalmology, respiratory and cerebro-cardiovascular emergency segment, and will be the base of the Group’s future development. Following the launch of Yttrium-90 microsphere injections, the Group will continuously work hard for the leading position of global nuclear medicine anti-tumor diagnosis and treatment segment. The Group adheres to the treatment concept of integrated oncology diagnosis and treatment, and is developing the layout covering R&D, production and sales quality supervision. In 2023, after the PRC government’s adjustment on pandemic prevention and control policies, which lead to a gradual recovery in the volume of tumor diagnosis, treatment and surgery, more and more outpatients have been enquiring about YiGanTai<sup>®</sup> treatment, and a number of hospitals have opened YiGanTai<sup>®</sup> specialized clinics to meet patients’ needs. YiGanTai<sup>®</sup> treatment is expected to achieve a persistent and rapid growth. For the cerebro-cardiovascular precision intervention 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. Furthermore, given the enhancement of people’s living quality and asking more for health, the Group will develop our bio-technology products to the large health industry and aim for developing new driving force.

The Group will seize the future opportunities arising from the high-quality development of the pharmaceutical industry, closely aligning the Company's development direction with national strategies and policy guidance. On the one hand, the Group will focus on the present and continuously enrich its product pipelines, optimise its product structure and strengthen its industrial chain layout, so as to maintain its pace in business expansion and achieve various performance targets with remarkable results. On the other hand, the Group will place more emphasis on stable growth in the mid to long term. By leveraging its comprehensive strengths and driven by technological innovation, the Group will continue to deploy its innovative products and advance its technologies global-wise in a differentiated manner, ensuring that its innovation advances steadily, its operational management is efficient and coordinated, its corporate development and business are prosperous and sustainable, and its industry position improved steadily.

2023 is sure to be a year full of opportunities, which is also crucial to the Group in terms of achieving the strategic goals of its five-year plan. Grand Pharma will redouble its efforts and, with perseverance and determination, remain steadfast to its business goals, lifting the Group to new heights and making new achievements for a healthy China.

I would like to express my sincere gratitude to every shareholder, board members, partners, management and staff for their long-term support and contribution to the Group.

**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 2022 and up to the date of this announcement, the Group had a total of 38 significant milestones, including 25 innovative products, 9 generic products, 3 API products and 1 major merger and acquisition.

#### *Innovative products*

Nuclear medicine anti-tumor diagnosis and treatment:

- Yttrium-90 microsphere injections, a blockbuster product of the nuclear medicine anti-tumor segment, was approved for commercialization in China;
- The Investigational New Drug ("IND") application for the global innovative nuclear medicine product TLX591-CDx was submitted and approved in China;
- The IND application for the global innovative nuclear medicine product TLX250-CDx was submitted and approved in China, and successfully met the clinical endpoint of phase III of an overseas clinical study;
- The IND application for the global innovative nuclear medicine product TLX101 was submitted and accepted in China;
- The IND application for the global innovative nuclear medicine product ITM-11 was submitted and accepted in China.

Cerebro-cardiovascular precision interventional diagnosis and treatment:

- OTW intracranial balloon dilatation catheter Cai Yu<sup>®</sup> (彩鸕<sup>®</sup>), a neurointerventional product, was approved for commercialization in China;
- Occlusion balloon catheter Ti Hu<sup>®</sup> (鵝鵝<sup>®</sup>), a neurointerventional product, was approved for commercialization in China;
- The application for NOVASIGHT Hybrid, a new medical imaging device for intracavity diagnosis, was accepted for commercialization in China;
- aXess, a global innovative endogenous tissue repair product for hemodialysis, was introduced to expand the R&D product pipeline;
- 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, a global 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**”).

#### Respiratory and severe disease anti-infection:

- Enerzair<sup>®</sup> Breezhaler<sup>®</sup> and Ateectura<sup>®</sup> Breezhaler<sup>®</sup>, the two global innovative compound preparations for the treatment of asthma, were successfully included in the National Reimbursement Drug List (2022 edition);
- The first patient was dosed in the phase III clinical trial of Ryaltris compound nasal spray, an innovative product, in China;
- The phase IIa clinical trial of STC3141, a global innovative drug, for the treatment of severe COVID-19 in Europe successfully met the primary clinical trial endpoint;
- The phase Ib clinical trial of STC314, a global innovative drug, for the treatment of acute respiratory distress syndrome (“**ARDS**”) in China successfully met the primary clinical trial endpoint;
- STC3141, a global innovative drug, was approved to commence the phase Ib clinical trial for the treatment of sepsis in Belgium;
- The phase Ib clinical trial of STC3141, a global innovative drug, for the treatment of sepsis has completed the enrolment and dosing of all patients;
- The clinical trials of GS221, an innovative oral small molecule 3CL protease inhibitor against COVID-19 virus were successfully conducted and the results showed that GS221 has potential clinical benefits for the patients;
- The IND application for APAD, a global innovative drug for the treatment of sepsis, was submitted and accepted in China;

#### Ophthalmology:

- GPN00884, a new ophthalmic preparation for myopia control, was introduced to expand the R&D product pipeline;
- The IND application for BRM421, a global innovative drug for the treatment of dry eye, was submitted and accepted in China;
- The IND application for GPN00833, an improved new drug for anti-inflammatory and pain relief after ophthalmology surgery, was submitted and accepted in China;
- CBT-001, an innovative and improved new drug for the treatment of pterygium, was approved by the National Medical Products Administration of China (the “**NMPA**”) to commence a Phase III clinical study;
- The application for the commercialization of trypan blue ophthalmic anterior capsule staining agent, an innovative device, was submitted and accepted in China.

#### Cerebro-cardiovascular emergency drug:

- Jext<sup>®</sup>, 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.

#### *Generic products*

There were 9 products approved for commercialization, among which, the epinephrine hydrochloride injection (pre-filled) is the first type 3 generic products being approved for commercialization in China.

#### *API products*

There were 3 API products passed the CEP registration of the European Union.

#### *Merger and acquisition*

In the field of biotechnology, the Group has completed the acquisition of 100% equity interest in Hubei Bafeng Pharmaceuticals & Chemicals Share Co., Ltd. (湖北省八峰藥化股份有限公司 (“**Hubei Bafeng**”). Currently, we have 24 API registration certificates for amino acids, covering more than 70% of registration certificates in the same category, and became the pharmaceutical company with the largest numbers of API registration certificates for amino acids in China.

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

### *R&D centers:*

The International R&D Center in Optics Valley, Wuhan, the mRNA R&D Center in Nanjing, Grand Pharma – Shandong University Radiopharmaceutical Research Institute (遠大醫藥 – 山東大學放射性藥物研究院) and the Innovative Device R&D and Production Base in Wuhan were officially put into operation, which further enhanced the Group's R&D capabilities in innovative drugs, mRNA technology and nuclear medicine, as well as the capability to localize innovative medical devices and the independent R&D and production capacity;

The International R&D Center in Optics Valley, Wuhan is used to develop innovative products in the fields of ophthalmology, respiratory and severe disease anti-infection, oncology, cerebro-cardiovascular emergency and other treatments. With a gross floor area of more than 13,000 square meters, the R&D center is equipped with international advanced scientific research equipment and instruments to conduct the research and development of small molecular drugs, polypeptide drugs and high-end complex dosage drugs, and has established special laboratories for new drug efficacy evaluation, process thermal safety evaluation, crystallization process and continuous flow process research. The Group has the qualifications for R&D innovation and technology platforms at the provincial level and above, such as the National Enterprise Technology Center (國家級企業技術中心), the Hubei Provincial Engineering Technology Research Center of Ophthalmic Pharmaceuticals (湖北省眼用製劑工程技術研究中心) and the Hubei Provincial Engineering Technology Research Center of Chemical Pharmaceuticals for Rare Diseases (湖北省罕見病化學藥品工程技術研究中心), and has established the National Postdoctoral Research Station.

The mRNA R&D Centers in Nanjing/Belgium are mainly engaged in the development of anti-tumor and anti-infection drugs based on mRNA technology. Currently, the Group has built a mRNA antigen design and optimization platform, an organ-targeted LNP technology platform, and a pharmacological and toxicological R&D platform, etc., and establishing GMP-level pilot R&D and production center to bridge the important links from technology R&D to production to meet the requirements of all phases of clinical research for therapeutic and preventive mRNA drugs.

The Group and Shandong University has jointly established the Institute of Radiopharmaceutical Research of Grand Pharma and Shandong University, to carry out in-depth cooperation in product development, academic research, resource sharing and talent training in the field of radiopharmaceutical R&D. The Institute will strengthen the Group's R&D capability of its radiopharmaceutical diagnosis and treatment platform, improve the level of preclinical research and patent technology barriers, and provide technical support and material conditions for the development of new products. At the same time, it will facilitate the cultivation of more high-end technical talents in the field of radiopharmaceuticals and help industrialize the scientific research results in the field of radiopharmaceuticals.

The R&D and production base for innovative devices in Wuhan is a domestic R&D and production base, with active devices, for the diagnosis and treatment technology of cardio-cerebrovascular precision intervention. The base, covering an area of about 4,000 square meters, is equipped with class 10k cleanrooms and partial class 10k clean areas, which can meet the production and assembly needs of three types of medical devices.

### *Production bases:*

The amino acid production base in Xiantao City, Hubei Province, China, has officially started construction, and will be officially put into production in 2023. 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. Also located in Xiantao City, the production base of APIs for minority-variety medicines (drugs in short supply) has been officially commenced operation, which will further expand the production capacity and ensure the market supply of minority-variety medicines in short supply.

## **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).

## PHARMACEUTICAL TECHNOLOGY

With years of experience in the fields of ophthalmology, respiratory and severe disease anti-infection, as well as cerebro-cardiovascular emergency, 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, the mRNA R&D Centers in Nanjing/Belgium and the DNA R&D Center in the United States 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.

### Ophthalmology Segment

The Group has nearly 30 products on sale in the ophthalmology segment, covering the anterior segment and fundus of the eye, mainly focusing on major indications such as dry eye, retinal hemorrhage, glaucoma, cataract, anti-inflammation and myopia, covering chemical preparations, Chinese drug preparations and eye health products, including prescription drugs, OTC drugs, medical devices, consumer goods and other major categories, creating a “public eye care 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 field will adhere to the development strategy of “leading by the blockbuster innovative drugs and devices, and based on the products of the public eye care ecosystem”, continuously strengthen the influence of the industry, and achieve new breakthroughs in the business field.

### Ophthalmology products

The ophthalmology products of the Group include Rui Zhu (polyvinyl alcohol eye drop), He Xue Ming Mu tablets, Fuming series, Bai Nei Ting, Jie Qi, Nuo Ming, 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(二零二一年)》), 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) (《我國睑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 Wellknown Trademark in 2017; and was awarded the CPEO Gold Award for seven consecutive years from 2016 to 2022, 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.

### Innovative R&D pipeline

While creating a public eye care ecosystem, the Group also reserved four innovative drugs in the



direction of clear clinical needs for myopia, dry eye, pterygium and anti-inflammatory and pain relief after ophthalmology surgery:

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 commenced in June 2022 and its phase III clinical trial in China has been approved to commence by the NMPA in March 2023.

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 nanopreparation technique effectively eliminates the risk of low bioavailability and safety due to the low water solubility of hormones products. The completed phase III clinical trial in the United States showed that GPN00833 has good treatment results and safety at lower concentrations, and provides faster clearance of post-operative ocular inflammation, rapid and sustained relief of eye pain and fewer side effects than the US standard of care. Currently, the product has submitted an IND application in China, which was accepted by the NMPA in January 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 entered Phase III clinical studies overseas, and has submitted an IND application for registration in China, which was accepted by the NMPA in January 2023.

GPN00884, a new eye preparation for myopia control:

It is an improved new drug jointly developed by the Group and the Eye Hospital of Wenzhou Medical University (“WMU”) and is currently in an early stage of development. The Eye Hospital of WMU is one of the largest specialized ophthalmology hospitals in China. As a leader in the field of basic research and clinical prevention and control of refractive errors in China, the Eye Hospital of WMU is the only medical institution that has three national platforms, including the State Key Laboratory of Ophthalmology, Optometry and Vision Science, the National Eye Optometry Engineering Technology Research Center, and the National Eye Disease Clinical Medical Research Center. The strategic cooperation with WMU will lay a good foundation for the Group to further expand its presence in the field of myopia treatment.

## **Respiratory and Severe Disease Anti-infection Segment**

The Group has more than 10 products on sale in the respiratory and severe disease anti-infection segment, covering a wide range of indications such as rhinitis, pharyngitis, bronchitis, pneumonia and asthma. The treatment for COVID-19 patients, in particular, allows for essentially full coverage of the course of disease. The core products, Qie Nuo (Eucalyptol, Limonene and Pinene Enteric Soft Capsules) and 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), Enerzair<sup>®</sup> Breezhaler<sup>®</sup> and Aectura<sup>®</sup> Breezhaler<sup>®</sup> are both exclusive products nationwide. A number of products such as Nuo Tong (Xylometazoline Hydrochloride), Li Mei Song (Nimesulide) and Antiviral Oral-Liquid 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, ARDS, parainfluenza and novel coronavirus infection, etc. Among which, the product for the treatment of allergic rhinitis has entered the registration clinical stage. The GS221 clinical trial for the treatment of novel coronavirus infection in China is progressing smoothly. STC3141, a global innovative drug for severe diseases such as sepsis, has received seven clinical approvals in five countries. The Phase Ib clinical study for ARDS in China and the Phase IIa clinical study for severe COVID-19 in Europe have both reached clinical endpoints, while other international global multi-centre clinical trials are also progressing smoothly. The IND application for another global innovative product for the treatment of sepsis, APAD, was submitted and accepted by NMPA. 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 anti-infection products for severe diseases, so as to continuously strengthen the Group's industry position in this field.

## Respiratory products

The main products include Qie Nuo, Jinsang Series, Enerzair<sup>®</sup> Breezhaler<sup>®</sup> and Ateectura<sup>®</sup> Breezhaler<sup>®</sup>, Nuo Tong, Li Mei Song, Antiviral Oral-Liquid 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 a national exclusive product 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 2022 (二零二二年健康產業品牌銳榜). Currently, there are 11 guidelines and 12 expert consensus recommending the use of viscosity dissolving promoters for clinical use. Among them, 9 guidelines and 5 expert consensus explicitly recommend eucalyptol, limonene and pinene enteric soft capsules or its active ingredients for clinical treatment, such as the 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黏液高分泌管理中國專家共識 — 中文版(2015)》), etc. In addition, the Beijing Municipal Health Commission has included Qie Nuo in the Catalogue of Drugs for People Infected with Novel Coronavirus (《新冠病毒感染者用藥目錄》). 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.

### 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》), 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. Jinsang Kaiyin and Liyan have been included in the list of the third batch of medical supply assurance enterprises and drugs for epidemic prevention and control in Shaanxi Province.

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

Enerzair<sup>®</sup> Breezhaler<sup>®</sup> 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<sup>®</sup> Breezhaler<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> Breezhaler<sup>®</sup> significantly reduce the annualized rate of moderate exacerbations (based on 24 weeks data) by 43%. Atecura<sup>®</sup> Breezhaler<sup>®</sup> 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. Atecura<sup>®</sup> Breezhaler<sup>®</sup> 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, Atecura<sup>®</sup> Breezhaler<sup>®</sup> 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.

#### 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)》), Recommendations for the Diagnosis and Treatment of Sinusitis in Children (《兒童鼻-鼻竇診斷和治療建議》) and Guidelines for the Home Treatment of Novel Coronavirus Patients (《新冠病毒感染者居家治療指南》) issued by the Joint Prevention and Control Mechanism of the State Council.

#### Li Mei Song:

It is a non-steroidal anti-inflammatory drug with anti-inflammatory, analgesic and antipyretic effects, and is suitable for the treatment for pain of chronic arthritis (e.g. osteoarthritis), pain after surgery and acute trauma, and symptoms treatment of primary dysmenorrhea. Li Mei Song is a product on the National Reimbursement Drug List and is the only product in China that has passed the consistency evaluation of Nimesulide. It was included in various expert consensus and clinical guidelines such as the Chinese Expert Consensus on the Use of Drugs in Super-drug Labels for Rheumatoid Arthritis (2022 Edition) (《類風濕關節炎超藥品說明書用藥中國專家共識(2022版)》), Expert Consensus on Clinical Pharmacotherapy of Osteoarthritis (《骨關節炎臨床藥物治療專家共識》), Expert Consensus on the Diagnosis and Pain Management of Acute Closed Soft Tissue Injury (《急性閉合性軟組織損傷診療與疼痛管理專家共識》) and Anhui Province Guidelines for the Hierarchical Diagnosis and Treatment of Upper Respiratory Tract Infections (2017 Edition) (《安徽省上呼吸道感染分級診療指南(2017版)》). In the symptomatic treatment of COVID-19, Li Mei Song has significant efficacy. A recent study published in "The Lancet" on novel coronavirus drugs showed that oral Nimesulide was more effective in controlling pain and had fewer gastrointestinal side effects when compared to oral ibuprofen.

#### Antiviral Oral-Liquid:

Antiviral Oral-Liquid, used for wind-heat colds, influenza, is the only product which has sugar free specification that is produced and sold among the TOP10 brands of antiviral oral-liquid market share in retail channels in China. The product was included in 2017, 2019, 2021 and 2022 Edition of China's National Reimbursement Drug List, and was recommended in the Guidelines for the diagnosis and treatment of hand, foot, and mouth disease (2010 Edition) of Ministry of Health of

China. It was included in the Expert Consensus on Clinical Application of Antiviral Oral-Liquid in the Treatment of Influenza\* (《抗病毒口服液治療流感臨床應用專家共識》) formulated by the expert group related to traditional Chinese medicines in 2020; and was included in the Expert Consensus on the Prevention and Treatment of COVID-19 with Proprietary Chinese Medicines\* (《中成藥防治新型冠狀病毒肺炎專家共識》) and the Catalogue of Drugs for People Infected with the Novel Coronavirus (《新冠病毒感染者用藥目錄》) issued by the Beijing Municipal Health Commission in 2022.

### **Innovative R&D pipeline**

Based on unmet clinical needs, the Group has reserved five global innovative drugs for the indications of seasonal allergic rhinitis, sepsis, ARDS, COVID-19 and parainfluenza.

Ryaltris, a new compound nasal spray for the treatment of seasonal allergic rhinitis:

Ryaltris 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 commence a phase III clinical trial for the treatment of allergic rhinitis and rhinoconjunctivitis symptoms in patients aged 12 and above in October 2021, in which the first patient was enrolled in April 2022. At present, the clinical trial is progressing smoothly.

GS221, an oral small-molecule 3CL protease inhibitor against novel coronavirus (SARS-CoV-2) infection:

GS221 is an oral small-molecule 3CL protease inhibitor against novel coronavirus infection developed by the Group with independent intellectual property rights. Preclinical studies showed that GS221 exhibits effective inhibition of SARS-CoV-2 and its various variant strains, and animal studies and phase I clinical trials showed a high level of product safety. Compared with other similar oral products against SARS-CoV-2 infection, GS221 shows better metabolic stability and bioavailability. In September 2022, GS221 received the Notice of Approval for Clinical Trial issued by NMPA and three corresponding clinical trial studies were promptly initiated. The results of the currently completed clinical trials showed a high level of post-drug safety and tolerability in subjects, with no adverse events that are material in nature or required discontinuation of medication being observed. The results also showed tendency of improved clinical symptoms, shorter time for negative result in nucleic acid test, and faster viral load reduction, suggesting the potential clinical benefits of GS221 for patients. It is expected that GS221 and STC3141 are able to cover the treatments for patients with mild, moderate and severe case of COVID-19, providing additional therapeutic services to patients with unmet clinical needs.

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. STC3141 is currently in three clinical studies worldwide. Among which, the phase Ib clinical study for the treatment of patients with ARDS received clinical approval in China in early March 2021, which has successfully reached clinical endpoint in October 2022. According to the study results, no potential safety issues that are material in nature or unintended consequences were shown in the overall safety profile, suggesting a high level of safety and tolerability. Compared to standard treatments, STC3141 showed positive signs in terms of mitigating the severity of ARDS, improving the prognosis of ARDS patients, helping ARDS patients off the ventilator and reducing the length of ICU stay among other indicators. The phase IIa clinical trial for the treatment of severe COVID-19 received clinical approval in Belgium, Poland and the United Kingdom from April to October 2021, respectively, and all clinical studies have been currently completed. The results of the study showed that the study of STC3141 for the treatment of severe COVID-19 has achieved the primary endpoint pre-set by the clinical program, with no serious drug-related adverse reactions found and showing a high level of tolerability in patients. The phase Ib clinical study for the treatment of sepsis received clinical approval in Australia and Belgium in May 2020 and April 2022, respectively. The study completed full patient enrollment and started administration in February 2023, and a clinical study report is expected to be released in the second quarter of 2023.

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 synergy in the treatment of severe diseases such as sepsis. Currently, the IND application for the product was submitted and accepted by the NMPA in January 2023.

GPN00085, a global innovative parainfluenza drug:

GPN00085 is the world's first small molecule compound based on a protein structure that binds the hemagglutinin-neuraminidase (HN) protein that covers the parainfluenza virus and stops the virus from entering the host cell for replication, inhibits the release of progeny virus from infected cells and reduces the number of parainfluenza virus particles with the aim of alleviating the symptoms of infection, inhibiting the further development of the disease and reducing the wider spread of the virus. It is jointly developed by the Group and Griffith University. Currently, it is at the preclinical development stage.

## **Cerebro-cardiovascular Emergency Segment**

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 a total of 24 varieties, 14 of which are included in the national emergency drugs catalogue covering 6 major categories, while 16 of which are included in the shortage drugs catalogue covering 6 major categories, which has ranked the top in the industry in terms of product pipeline. The Group's first generic product, epinephrine hydrochloride injection (pre-filled), was approved for commercialization in July 2022. Compared with the epinephrine products packaged in ampoules commercialized in China, the Group's pre-filled product has various features including convenient for operation, accurate medication, avoiding glass chips, and reducing secondary pollution. While optimizing the quality of the product, it can save valuable rescue time for the patients to a great extent. Currently, there are more than 20 products under research in the field of cerebro-cardiovascular emergency. Among which, Jext<sup>®</sup>, 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 will continue to focus on the three major emergency scenarios, namely in-hospital emergency, pre-hospital emergency and social emergency, and allocate and develop emergency products that are in urgent clinical need.

## **Cerebro-cardiovascular emergency products**

The products mainly cover the fields of platelet inhibitors, blood pressure control, and vascular active drugs. The main products include Li Shu An (norepinephrine bitartrate injection, epinephrine hydrochloride injection), Xin Wei Ning (tirofiban hydrochloride and sodium chloride injection), Nuo Fu Kang (methoxamine hydrochloride injection), Neng Qi Lang (coenzyme Q10 tablets), Rui An Ji (fructose sodium diphosphate oral solution) and deslanoside 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. As a Class 3 chemical drug, this product is currently the first epinephrine pre-filled preparation being commercialized in China. At present, all the 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  $\alpha_1$  Adrenergic Receptor Agonists (2017 Edition) (《 $\alpha_1$  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 accelerate the prognosis of patients, and improve their quality of life. For the reduction of coenzyme Q10 synthesis in patients with statin, exogenous and effective supplementation can be achieved to relieve side effects such as muscle pain, and bring better compliance to patients with statin. For the high incidence of cardiotoxicity caused by cancer radiotherapy drugs, Neng Qi Lang can effectively carry out anti-oxidation, relieve the damage and protect the heart. The product has been commercialized for more than 30 years and has been successively included in 20 guidelines and expert consensus, including 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》), the Diagnosis and Treatment Advice for Children’s Heart Failure (《兒童心力衰竭診斷和治療建議》) and the Expert Advice on the Clinical Management of Myocardial Injury in relation to COVID-19 (《新型冠狀病毒肺炎相關心肌損傷的臨床管理專家建議》).

Rui An Ji, the fructose sodium diphosphate oral solution:

It is mainly used for the treatment of angina pectoris of coronary heart disease, acute myocardial infarction, arrhythmia and myocardial ischemia in heart failure, and viral myocarditis. It is also used for brain ischemic symptoms caused by cerebral infarction and cerebral hemorrhage, and was included in a number of guidelines and expert consensus, such as the Diagnosis and Treatment Suggestions for Children’s Heart Failure (2020 Revision) (《兒童心力衰竭診斷和治療建議(2020年修訂版)》), Expert Consensus on Interventional Treatment of Common Congenital Heart Diseases in Children (《兒童常見先天性心臟病介入治療專家共識》), the National Expert Consensus on Prevention and Treatment of Burst and Shock (2020 Edition) (《燒傷休克防治全國專家共識(2020版)》), the Expert Recommendations for the Management of Novel Coronavirus Pneumonia Comorbidity (2020) (《新型冠狀病毒肺炎合並症處置專家建議(2020)》) and the National

Prescription Set in China (《中國國家處方集》).

Xin Wei Ning, the tirofiban hydrochloride and sodium chloride injection:

It is the first commercialized platelet surface glycoprotein GPIIb/IIIa receptor antagonist in China and the first commercialized intravenous antiplatelet drug in China, which was included in the National Reimbursement Drug List in 2009.

Deslanoside injection:

It is mainly used in patients with acute cardiac insufficiency or acute exacerbation of chronic cardiac insufficiency, and also used to control ventricular rate in patients with atrial fibrillation and atrial flutter with rapid ventricular rate. It was included in a number of guidelines and expert consensus, such as *Guideline for Emergency Management of Acute Heart Failure in China (2022)* (《急性心力衰竭中國急診管理指南(2022)》), the *China Heart Failure Diagnosis and Treatment Guidelines 2018* (《中國心力衰竭診斷和治療指南 2018》), the *2020 China Heart Failure Medical Quality Control Report* (《2020 中國心力衰竭醫療品質控制報告》), the *2021 European Society of Cardiology Guidelines for Acute Heart Failure* (《2021 歐洲心臟病學會急性心力衰竭指南》) and the *Heart Failure Rational Drug Use Guidelines (2nd Edition)* (《心力衰竭合理用藥指南(第2版)》).

### **Innovative R&D pipeline**

GPN00816, Jext<sup>®</sup> 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.

### **Tumor Segment**

In the field of tumor immunotherapy, with mRNA technology as the core, the Group focuses on the development of anti-tumor and anti-infection mRNA drugs. Currently, the Group has completed the establishment of mRNA production technology and LNP delivery technology platform and has carried out scientific cooperation with a number of renowned universities and scientific research institutions. A002, a global innovative mRNA immunotherapeutic product for HPV-positive head and neck cancer is being developed on the platform. The use of the exclusive TriMix mRNA vaccine technology is expected to increase the response rate of tumor patients and improve their clinical prognosis by triggering an adoptive immune response in the body in combination with existing tumor immune checkpoint inhibitor.

### **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 more than 400 employees, with over 40% of them holding master's degree and doctoral degree. The Group, together with Sirtex Medical Pty Limited (“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 13 innovative products in the pipeline, covering six radionuclides including  $^{68}\text{Ga}$ ,  $^{177}\text{Lu}$ ,  $^{131}\text{I}$ ,  $^{90}\text{Y}$ ,  $^{89}\text{Zr}$  and  $^{99\text{m}}\text{Tc}$  as well as eight 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 jointly carry out the R&D of RDC drugs on the basis of radionuclide research by the Laboratory Nuclear Medicine Research Institute (實驗核醫學研究所) of Shandong University.

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 has been commercialized successfully, two diagnostic RDC have been approved for clinical trials, and two therapeutic RDC clinical applications have been accepted. 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 and investment in the nuclear medicine anti-tumor diagnosis and treatment segment, enrich and improve the product pipeline and industrial layout, strive for ten nuclide products to enter the clinical stage within the next three years, realize the pipeline layout of more than twenty-five nuclear medicine anti-tumor diagnosis and treatment products, form a nuclear medicine anti-tumor diagnosis and treatment product cluster with the core of Yttrium-90 microsphere injections, continuously consolidating 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 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 原發性肝癌診療指南》), the “Guidelines for Diagnosis and Treatment of Primary Liver Cancer (2022 edition)” (《原發性肝癌診療指南 (2022 版)》), “Chinese Guidelines for Diagnosis and Comprehensive Treatment of Colorectal Cancer Liver Metastases (2018 edition)” (《中國結直腸癌肝轉移診斷和綜合治療指南 (2018 版)》), “Clinical Practice Guidelines for Liver Cancer and Liver Transplantation in China (2018 edition)” (《中國肝癌肝移植臨床實踐指南 (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.

Based on the huge number of patients with liver cancer, the clinical demand in the field of liver cancer in China is strong, and the commercialization of Yttrium-90 microsphere injections provides



an effective weapon for the multi-disciplinary treatment of liver cancer patients in China. Given that the barriers and innovation of this product, the understanding of the management procedures of this product by the clinical regulatory administration in China is gradually thorough. With a highly responsible attitude toward patients, and based on the surgeon supervision and training system approved by China NMPA and U.S. Food and Drug Administration (“FDA”), the Group 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. With the gradual increase in the number of doctors who have obtained the independent surgical qualifications for Yttrium-90 microsphere injections, the Group is confident to build up such product to be a blockbuster product in the field of liver cancer in China.

In September 2021, relying on the overseas commercialized medical device pilot policy of Boao Lecheng International Medical Tourism Pilot Zone of Hainan Free Trade Port, the Group has successfully carried out the clinical treatment of patients with liver cancer with the licensed access of Yttrium-90 microsphere injections in Boao Super Hospital in Hainan.

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<sup>®</sup>, more than 50 hospitals have completed the nuclide transfer procedures, its official surgeries have been carried out in more than 30 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<sup>®</sup> surgery was satisfactory, and most patients achieved favorable clinical therapeutic effect and prolonged survival. As at the date of this announcement, 5 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<sup>®</sup> for liver cancer was over 50%, and more than half of the patients had achieved tumor size remission. Among them, the symptoms of 5 patients were completely relieved with no resection required, and the disease control rate of the follow-up patients exceeded 95%, showing a remarkable therapeutic effect.

In June 2022, the Group held a commercialization conference for Yttrium-90 microsphere injections in China, gathering a total of 7 academicians from the Chinese Academy of Engineering and the Chinese Academy of Sciences, 30 experts at committee chairperson level to participate 9 conference venues in person, and 500 professors of oncology medicine, interventional medicine, nuclear medicine, surgery and imaging from leading tertiary hospitals in China to attend the meeting. The experts and scholars highly anticipated that Yttrium-90 microsphere injections can be widely used in liver cancer patients in China and achieve clear and significant efficacy. In order to speed up the implementation and popularization of YiGanTai<sup>®</sup> microsphere injections precise interventional therapy in China, the Group relied on the high-quality reputation and practical experience accumulated overseas for the product over the years, assisted domestic doctors in conducting multiple personalized practical trainings by well-known overseas clinical experts. At present, the Group has trained more than 300 doctors in 70 hospitals on the surgery theory or skills of YiGanTai<sup>®</sup>, nearly 20 experts have obtained the operation qualification of independent surgery through strict one-to-one training by overseas experts, and many of them will soon obtain the qualification of training instructor, which will further accelerate the clinical popularization of YiGanTai<sup>®</sup> radioactive interventional operation.

Since June 2022, Yttrium-90 microsphere injection has been included in the inclusive insurance 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 Hainan Le Cheng Special Medical Insurance (樂城特藥險), as well as the global medical device insurances of Taiping Life Insurance Co., Ltd., etc, which covers 11 provinces and 33 cities with a significant increase in the accessibility of such product to patients with liver cancer. In 2023, after the PRC government’s adjustment on pandemic prevention and control policies, which lead to a gradual recovery in the volume of tumor diagnosis, treatment and surgery, more and more outpatients have been enquiring about YiGanTai<sup>®</sup> treatment, and a number of hospitals have opened YiGanTai<sup>®</sup> specialized clinics to meet patients’ needs. YiGanTai<sup>®</sup> treatment is expected to achieve a persistent and rapid growth.

Yttrium-90 microsphere injection recorded approximately HK\$60.26 million revenue since it was approved for commercialization during the Year.

## **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:

Yttrium-90 microsphere injections:

Clinical trial of Yttrium-90 microsphere injections on the treatment of primary liver cancer is progressing smoothly in the United States. A real-world study for the treatment of primary liver malignancies in China is expected to commence in 2023.

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. The product is currently in preclinical development.

Lava™, a global innovative liquid embolic agent:

Lava™ is a peripheral vascular fluid embolization system that is opaque under imaging rays, less prone to artifacts and can be prepared quickly and easily in 3 minutes, saving doctors' preparation time in emergency situations and increasing the probability of patient survival. Currently, the overseas development of the product is progressing smoothly and it is expected to be approved for commercialization in the United States in 2023.

AuroLase®, a global innovative solid tumor ablation therapy:

AuroLase® is a global innovative therapeutic technology for solid tumor 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® for prostate cancer tissue ablation is expected to be the world's first and currently the only ultra-precise focal therapy that maximizes 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, the overseas development of the product is progressing smoothly and the application for commercialization in the United States is expected to be submitted in the first half of 2023.

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 companion diagnostic agents to TLX591, 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, the applications for the commercialization of TLX591-CDx have also been submitted in 17 countries. In clinical studies, a phase I trial of TLX591-CDx was completed in Japan in February 2022 with 10 subjects. The results of the study showed that TLX591-CDx was safe and well tolerated, with no serious adverse events observed in any of the subjects, and systemic and organ-specific radiation dose measurements and pharmacokinetic data showed no significant differences between Japanese and Western populations. In October 2022, TLX591-CDx was approved by the NMPA for clinical bridging study. The overseas clinical studies of other products are also progressing smoothly, while the implementation in China is also progressing as planned.

TLX250/TLX250CDx, global innovative products for the treatment of clear cell renal cell carcinoma (“ccRCC”):

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. 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. TLX250 is currently undergoing a phase II clinical study overseas, with registration in China actively underway.

ITM-11/TOCscan<sup>®</sup>, a global innovative product for the treatment of gastroenteropancreatic neuroendocrine tumors (“GEP-NETs”): ITM-11 and TOCscan<sup>®</sup> 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 IND application was submitted and accepted by the NMPA in February 2023. TOCscan<sup>®</sup> has been approved for commercialization in Germany, Austria and France in 2018. Currently, the registration of the product in China is under active progress.

TLX101, a global innovative product for glioblastoma treatment: TLX101 is a radionuclide-small molecule conjugated therapeutic 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 January 2023, the IND application for TLX101 was accepted 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 based on radionuclide conjugated technology that targets bone metastasis in malignant tumors by conjugating no-carrier-added <sup>177</sup>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 and the registration in China is actively underway.

## **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 4 products in vascular intervention have been approved for commercialization in China, NOVASIGHT Hybrid has been submitted to the NMPA and accepted for commercial registration, 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, and formed the R&D and production layout of two centers in China and multiple overseas bases. 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 establishment of overseas R&D centers in Minnesota, the United States, and the construction of R&D bases in Germany, Canada, Italy, etc. are also progressing in an orderly manner. In the future, the Group will commence the construction of the Shanghai R&D Center, which will mainly focus on the

innovation and R&D of structural heart disease product line, and is planning for the construction of the Beijing R&D Center, which will mainly focus on the research of the technology of biodegradable recycled materials platform, and gradually apply to the channel field of artificial blood vessels. At present, the Group has carried out technology cooperation with clinical centers or R&D platforms in the United States, Canada, Germany, Italy and Switzerland, and gradually started a new process of globalized R&D. The segment has over 200 employees and more than 50 R&D teams, with over 50% 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<sup>®</sup> and APERTO<sup>®</sup> OTW adopt the unique patented SAFEPAX technology. Both drug coating products are stable with small decay rate. The products for sale have been recognized by clinical doctors and patients and good market reputation. In July and September 2022, the commercialization of the Group's self-developed and self-produced innovative global neurointerventional products, including the OTW (Over The Wire) intracranial balloon dilatation catheter Cai Yu<sup>®</sup> (彩鸕<sup>®</sup>), as well as the acute ischemic stroke treatment products, occlusion balloon catheter Ti Hu<sup>®</sup> (鵝鵝<sup>®</sup>), was approved for commercialization in China.

RESTORE DEB<sup>®</sup>, a coronary drug-coating balloon:

RESTORE DEB<sup>®</sup> 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<sup>®</sup> OTW, a drug coated balloon for dialysis access:

APERTO<sup>®</sup> 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<sup>®</sup> 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.

Cai Yu<sup>®</sup> (彩鸕<sup>®</sup>), an intracranial balloon dilatation catheter:

Cai Yu<sup>®</sup> (彩鸕<sup>®</sup>) 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<sup>®</sup> (彩鸕<sup>®</sup>) 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<sup>®</sup> (鵝鵝<sup>®</sup>), an occlusion balloon catheter

Ti Hu<sup>®</sup> (鵝鵝<sup>®</sup>) 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<sup>®</sup> (鵝鵝<sup>®</sup>) 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<sup>®</sup> (鵝鵝<sup>®</sup>) 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.

## **Innovative and R&D pipeline**

### *Access management direction:*

NOVASIGHT Hybrid, a global innovative intravascular diagnostic imaging device:

NOVASIGHT Hybrid combines intravascular ultrasound and optical coherence tomography and can simultaneously show the ultrasound and optical image with the same direction, axis and phase. It is also the first intravascular ultrasound and optical coherence tomography system approved by the FDA with promising prospect in the field of coronary artery imaging and intracavitary interventional surgery. The product has already been commercialized in the United States, Canada and Japan, and was enrolled in the special review approval process of innovative medical device in 2019 for registration in China. Clinical studies have been completed and the application for the commercialization of the product was accepted in June 2022 and it is expected to be approved for commercialization in China in the first half of 2023.

LEGFLOW<sup>®</sup> OTW, a global innovative drug-coated balloon:

LEGFLOW<sup>®</sup> 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 second half of 2023.

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. The product is progressing well and the patient enrollment for registered clinical study has been fully completed. Several other catheter products are already in the registration stage.

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<sup>®</sup> 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. Meanwhile, the HeartLight X3 laser ablation platform has submitted commercialization registration application.

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 are the core business in the field of biotechnology, and it is positioned as a global premium supplier of high-quality amino acids. The Group's development in the biological field focuses on technological innovation and the construction of high-quality systems, and currently holds more than 100 invention patents and has promoted the formulation of nearly 40 national and industrial standards. It has a complete domestic and international quality system certification, and has 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). The Group has also undertaken the "one-stop" application demonstration project for national industrial strong foundation engineering and high-end amino acid products.

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'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. Benefiting from the continuous expansion of the international business and the general health business, the Group's amino acid segment has continued to maintain a high growth rate in recent years.

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, with significant cost and quality advantages. At present, we have built eight technology platforms, including enzyme engineering, fermentation engineering, process engineering, quality research and application transformation, which have formed unique technology leadership in strain construction optimization, metabolic pathway regulation, fermentation control, separation and purification, and product application development, etc. Some of the processes fill the domestic gaps in China. 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 and is entering its best harvesting period, 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), and has established long-term strategic cooperation with many research institutes, including Tsinghua University, Wuhan University and Tianjin University of Science and Technology. There are over 110 R&D personnel with professional backgrounds in cross-disciplinary disciplines such as microbiology, applied chemistry, biochemistry, pharmacology and food science. The innovative model of combining industry, 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.

#### **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, 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. Our comprehensive system certification and registration have demonstrated the Group's strong competitiveness for business expansion in overseas markets.

#### **Industry 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 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) independently developed by the Company have obtained the U.S. FDA approval and was officially commercialized in the United States for sales in 2021.

#### **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 2022 (the “Year”), the Group maintained stable growth even the Group was affected by the pandemic. For the year ended 31 December 2022, it recorded revenue of approximately HK\$9,562.29 million (2021: HK\$8,597.98 million) and was increased by approximately 11.2% as compared with the same period of last year. If disregarding the exchange rate fluctuation between RMB and HK\$, it was increased by approximately 15.1% as compared with the same period of last year. For the profit attributable to the owners of the Company, if disregarding the impact from fair value change and disposal of investment in Telix, it was approximately HK\$2,137.33 million and was increased by approximately 11.5% as compared with the same period of last year. If disregarding the exchange fluctuation of exchange rate between RMB and HKD, it was increased by approximately 15.4% when compared with the same period of 2021. During the Year the gross profit margin of the Group is approximately 62.2%, while it was approximately 61.0% in 2021.

In 2020 the Group invested in Telix by applying approximately AUD35 million to acquire approximately 20.95 million shares of Telix at AUD1.69 each. In August 2022, the Group disposed 10 million Telix shares (equivalent to approximately half of holdings) at AUD7.25 each and got AUD72.5 million cash. This not only represented that all investment costs have been recovered, but also brought additional AUD37.5 million (equivalent to approximately HK\$200 million) cash return. As a 31 December 2022, share price of Telix is at AUD7.27 each. The Group is still holding approximately 10.95 million shares of Telix and amounted to approximately AUD79.6 million (equivalent to approximately HK\$424 million).

### **Distribution costs and administrative expenses**

For the year ended 31 December 2022, the Group’s distribution costs and administrative expenses were approximately HK\$2,306,520,000 and HK\$1,090,030,000 respectively as compared to approximately HK\$2,397,850,000 and HK\$909,620,000 respectively for the corresponding period in 2021. The decrease in distribution costs of approximately 3.8% during the Year was mainly due to the sales staffs’ targeted deployment and work during the Year, to promote new product in a more efficient way. The administrative expenses increased by approximately 19.8% as compared to the corresponding period last year, mainly due to the increase in investment in innovative R&D projects.

### **Finance costs**

For the year ended 31 December 2022, the Group’s finance costs were approximately HK\$137,490,000 as compared to approximately HK\$92,960,000 for the corresponding period in 2021. The increase was due to certain financing arrangements in response to business expansion and higher finance costs due to US dollar interest rate hike.

### **R&D and project investment**

For the year ended 31 December 2022, the Group has invested a large amount of capital 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 throughout 2022 would be approximately HK\$2.45 billion.

### **Receivables and payables**

As at 31 December 2022, trade and other receivables of the Group amounted to approximately HK\$2,997,380,000, representing an increase of approximately HK\$335,940,000 as compared to the balance in 2021, mainly due to the increase in trade receivables of approximately HK\$126,150,000 as a result of the increase in business during the Period. Prepayments have increased by approximately HK\$185,690,000, and was mainly related to the prepayment of approximately HK\$138,420,000 for the acquisition of certain shares in a fund. The transfer procedure of such acquisition was not yet completed as at 31 December 2022.

As at 31 December 2022, the Group’s trade and other payables amounted to approximately HK\$2,488,580,000, representing a decrease of approximately HK\$383,180,000 as compared to the



balance in 2021.

## Research and development

The Group has sufficient innovation pipeline. During the Period, there were accumulatively 136 projects under research and 55 innovation projects, which were in different stages from preclinical to new drug commercialization application. The pipeline layout was reasonable, forming a good echelon effect.

## R&D 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	Ophthalmology	GPN00136 (BRM421)	Dry eye		●							
			GPN00153 (CBT-001)	Pterygium		●							
			GPN00833	Ocular inflammation		●							
			GPN00884	Myopia prevention and control	●	●							
	Respiratory, severe disease and anti-infection	Respiratory	Allergic rhinitis	Ryaltris				●					
				STC3141	Sepsis					●			
		Severe disease and anti-infection	Severe disease and anti-infection	APAD	COVID-19						●		
				GS221	ARDS							●	
	Cerebro-cardiovascular emergency	Emergency	Anaphylaxis	GPN00885	Sepsis	●	●						
				GPN00816	Novel coronavirus infection	●	●						
Anti-tumor	Immunotherapy	HPV-positive head and neck cancer	A002	Parainfluenza	●	●							
					●								
Technologies on nuclear medicine and anti-tumor diagnosis and treatment as well as cerebro-cardiovascular precision intervention diagnosis and treatment	Nuclear medicine and anti-tumor diagnosis and treatment	Interventional treatment	Y-90 microsphere injection	Malignant liver tumor		●							
			Thermosensitive embolic agent product	Hypervascular parenchymal organs tumor		●							
			Lava	Cerebral aneurysm								●	
			AuroLase	Prostate cancer								●	
		Radionuclide-drug conjugate (RDC)	Radionuclide-drug conjugate (RDC)	TLX591 (177Lu-rosatumab)	Prostate cancer	●							
				TLX591-CDx (68Ga-PSMA-11)	Prostate cancer - diagnosis								●
				TLX599-CDx (99mTc-EDDA/HYNIC-PSMA)	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	●	●						
	Cerebro-cardiovascular precision intervention diagnosis and treatment	Access management	Coronary artery vascular intervention	Restore DCB	De novo coronary artery lesions and in-stent restenosis								
				Novasight	Coronary artery imaging and intracavitary interventional surgery	●							
				IVL CAD	Moderate/severe coronary artery/peripheral arterial calcification	●							
		Neurointervention	Peripheral vascular intervention	IAL PAD	Arteriovenous fistula treatment of hemodialysis								
				APERTO DCB aXess	Hemodialysis	●							
				LEGFLOW DCB	Peripheral vascular disease								
	Structural heart disease	Structural heart disease	Structural heart disease	Stent retriever	Ischemic stroke								
				Intracranial balloon dilatation catheter	Intracranial stenosis								
				Guiding catheter	Access								
				Microcatheter	Access								
Electrophysiology and heart failure	Electrophysiology	Heart failure	Occlusion balloon	Access	●								
			DCB	Intracranial stenosis	●								
Electrophysiology and heart failure	Electrophysiology	Heart failure	Saturn	Mitral regurgitation	●	●							
			Heartlight X3	Atrial fibrillation	●								
			CoRisma	Heart failure	●	●							

● 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 has established R&D centers in Nanjing, China and Belgium, 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; and the DNA technology platform is located at the San Diego R&D Center in the United States, focusing on tumor DNA immunotherapy.

In the segment of nuclear medicine anti-tumor diagnosis and treatment, the Group has two technology platforms, namely the tumor intervention technology platform and the RDC technology platform, consisting of two R&D centers, namely the Grand Pharmaceutical — Shandong University Radiopharmaceutical Research Institute in China.

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

## **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 (including overseas R&D teams such as Sirtex and OncoSec), of which more than 400 have master's degree and doctoral degree holders, accounting for nearly 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 2022 up to the date of this announcement, epinephrine hydrochloride injection (pre-filled), tirofiban hydrochloride injection (250ml), amiodarone hydrochloride injection, penehyclidine hydrochloride injection have been issued drug registration certificates by the NMPA.

## **Consistency Evaluation**

During 2022 up to the date of this announcement, tirofiban hydrochloride and sodium chloride injection, amiodarone hydrochloride injection, penehyclidine hydrochloride injection, haloperidol injection, succinylcholine chloride (anhydrous) injection, fluorouracil injection, moxifloxacin hydrochloride eye drop, dopamine hydrochloride injection were approved or deemed to have passed the consistency evaluation, and new applications were made for Zuo Xi Meng Dan injection, sodium hyaluronate eye drop, travoprost eye drop, carglumic acid tablet, telmisartan and hydrochlorothiazide tablet, atropine sulfate injection. At present, a total of 23 products of the Group have been approved or deemed to have passed the Consistency Evaluation, and other 11 products are under review.

## **International Registration**

During 2022 up to the date of this announcement, each of acetylcysteine (non-animal source), carbocysteine (non-animal source) and API products of xylometazoline hydrochloride has passed CEP registration of the European Union.

## **Intellectual Property Protection**

During the period under review, the Group applied for 70 new patents, including 15 core patent applications and 55 peripheral patent applications, and 136 new patents were granted, 71 of which were invention patents, accounting for 52.2%. The Group has accumulated 599 valid patents, including 333 invention patents and 266 utility model patents and design patents. The core patent applications for the project of STC3141 were granted in the United States, and the patent applications in other countries and

regions are progressing smoothly. A new PCT patent was filed for APAD, including a core patent application; 6 new PTC patent applications were filed in the biotechnological segment; 7 new patent applications around the core products were filed in the oncological segment.

### **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. In 2022, the Group had over 3,800 sales personnel and nearly 3,300 sales personnel in the pharmaceutical area, covering over 20,000 hospitals with over 1,000 OTC personnel and more than 260,000 pharmacies in China; the cerebro-cardiovascular precision interventional diagnosis and treatment segment has reached 140 sales personnel, covering more than 1,400 hospitals; the nuclear medicine anti-tumor diagnosis and treatment segment has nearly 230 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 severe disease anti-infection, 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, novel coronavirus infection 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 "self-development + 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. In 2022, the Group has carried out the following material investment, M&A and cooperation:

#### **Entering into of a product licensing agreement with Novartis AG to obtain commercialization rights for two global innovative products for the treatment of asthma**

In February 2022, the Group entered into a product licensing agreement with Novartis AG. ("Novartis", a world-renowned company) in Switzerland. The Group will pay Novartis up to US\$20 million and a certain percentage of the sales as commission, to obtain the exclusive commercialization rights of Enerzair<sup>®</sup> Breezhaler<sup>®</sup> and Ateectura<sup>®</sup> Breezhaler<sup>®</sup>, two global innovative compound preparations for the treatment of asthma from Novartis in mainland China. Enerzair<sup>®</sup> and Ateectura<sup>®</sup> products have been commercialized in Europe, Australia and Japan, and were approved by NMPA for commercialization in May 2021 and June 2021, respectively. The cooperation with Novartis is another successful attempt of the Group to join hands with internationally renowned pharmaceutical companies, which will further provide momentum for the Group's medium and long-term development.

#### **Capital injection into Wuhan Shetai Medical**

In April 2022, Grand Pharmaceutical (China) Company Limited ("Grand Pharma (China)", an indirect non-wholly owned subsidiary of the Company), Shanghai Shetai Medical Technology Limited ("Shanghai Shetai") and Wuhan Shetai Medical Technology Co., Ltd. ("Wuhan Shetai Medical", which is owned as to 33% by Grand Pharma (China) and 67% by Shanghai Shetai) entered into a capital injection agreement. Pursuant to the capital injection agreement, Grand Pharma (China) and Shanghai Shetai, as the existing shareholders of Wuhan Shetai Medical, agreed to increase the registered capital of Wuhan Shetai Medical by RMB65,000,000, where Grand Pharma (China) and Shanghai Shetai shall make additional capital contributions of RMB21,450,000 and RMB43,550,000, respectively, in proportion to their respective existing shareholdings in Wuhan Shetai Medical.

## **Reaching a strategic cooperation and signed a technology and intellectual property product transfer agreement with the Eye Hospital of Wenzhou Medical University**

In May 2022, the Group entered into a strategic cooperation agreement with the Eye Hospital of WMU. The Group will, according to the R&D progress, pay RMB70 million by phases to obtain from Eye Hospital, WMU the technology and intellectual property rights of the technology used in the prevention and treatment of myopia and the new ophthalmic preparation (GPN00884) product in the Greater China Region (Mainland China, Hong Kong Special Administrative Region of China, Macao Special Administrative Region of China and Taiwan), and subsequently may pay certain sales commission subject to the sales conditions of related products. The Group expects this strategic cooperation to leverage the resources and advantages of both sides in their respective professional fields, strengthen industry-university-research cooperation on common ophthalmic diseases, and jointly promote cutting-edge innovative research and technological achievement transformation in the ophthalmic industry.

## **Introduction of a global innovative endogenous tissue repair product**

In July 2022, the Group and XELTIS AG (“XELTIS”) have entered into a strategic cooperation agreement on equity investment and product introduction. The Group will use EUR15 million, after meeting specific terms and conditions, to acquire approximately 11% equity interests in XELTIS, and obtain exclusive development, production and commercialization rights of aXess, a global first-of-its-kind restorative device for patients with End Stage Renal Disease requiring hemodialysis access with Arteriovenous Graft, and other new products in the field of hemodialysis developed under the same technology platform in the Greater China region (Mainland China, Hong Kong Special Administrative Region of China, Macao Special Administrative Region of China, and Taiwan). According to the agreement, the Group also has the pre-emptive negotiation right for products of XELTIS developed in other indication areas, in the Greater China region. This strategic cooperation will deepen the Group’s product layout in the field of hemodialysis in peripheral vascular intervention.

## **Acquisition of 100% equity interest in Hubei Bafeng**

In July 2022, the Group entered into an equity acquisition agreement with Hubei Bafeng, pursuant to which, the Group will acquire 100% equity interest in Hubei Bafeng at an amount of not more than RMB270 million after the relevant conditions as agreed in the acquisition agreement are fulfilled. Upon completion of the acquisition, the Group will own 24 API registration certificates for amino acids, covering more than 70% of registration certificates in the same category, and become the pharmaceutical company with the largest number of API registration certificates for amino acids in China, which will further strengthen the Group’s leading position in the field of high-quality amino acids.

## **Capital injection in Sirtex**

In December 2022, the Group subscribed 29,646,627 shares of Grand Pharma Sphere Pte Ltd. (which wholly owned the equity interests of Sirtex) at the consideration of USD35 million. After the completion of the transaction the equity interests held in it increased to approximately 51.61%. The Group will be able to further increase its shareholding rights in Sirtex and its business of global innovative medical products which will further strengthen the pipeline of products available to the Group, and Sirtex may have a more stable liquidity position to support its continuous development.

Other than stated above, the Group did not have other material acquisition or disposal in 2022.

## **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 new product presentations, results announcements and investor open days, and participated in a number of summits, forums, strategy conferences and special roadshows held by large investment banks and securities companies, attracting 100 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 2022, it was awarded the "Most Valuable Pharmaceutical and Medical Company" and the "Best IR Team" in the sixth Golden Hong Kong Stocks Awards. In June 2022, it was awarded the "Best Hong Kong Listed Companies in Hubei". In July 2022, it was included in the "2021 China Pharmaceutical Industry Top 100 Series List". In September 2022, it was awarded the Golden Unicorn "Listed Company of Hong Kong and US Stocks with Most Growth Potential" Award by Sina Finance in 2022. In November 2022, it was recognized as a "National Demonstration Enterprise in Technology Innovation" and was included in the "Top 100 Private Enterprises in Hubei Province". In December 2022, it was awarded the "Most Valuable Pharmaceutical and Medical Company" and the "Best IR Team" in the seventh Golden Hong Kong Stocks Awards. In January 2023, it received the "Investment and Customs Pioneer Award" of the Royal Flush Enterprise.

### Updates on Significant Matters

With reference to the disclosure in the annual reports of the Company between 2016 to 2022, Tianjin Jingming New Technology Development Co., Ltd. (the "**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 2022, the court has concluded 72 cases, and 3 cases are 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 RMB37,222,231 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 RMB27,090,000 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 RMB5,000,000 (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 RMB10,000,000 share transfer consideration deposited in the bank account jointly controlled by the Group and the vendors. The vendors should also additionally refund approximately RMB11,200,000 share transfer consideration to the Group in according to the terms of the agreement for the acquisition of Tianjin Jingming. Up to now, the Group has followed the judgement from the court and got back the

RMB10,000,000 deposited in the bank account jointly controlled by the Group and the vendors.

### **Financial Resources and Liquidity**

As at 31 December 2022, the Group had current assets of HK\$6,886.92 million (31 December 2021: HK\$6,778.59 million) and current liabilities of HK\$6,454.60 million (31 December 2021: HK\$5,566.13 million). The current ratio was 1.07 at 31 December 2022 as compared with 1.22 at 31 December 2021.

The Group's cash and bank balances as at 31 December 2022 amounted to HK\$1,441.01 million (31 December 2021: HK\$1,752.86 million), of which approximately 10.0% were denominated in Hong Kong Dollars, United States Dollars, Australian Dollars, Euro and 90.0% in Renminbi.

As at 31 December 2022, the Group had outstanding bank loans of approximately HK\$3,741.38 million (31 December 2021: HK\$2,849.29 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 2.70% to 5.61% (31 December 2021: 2.18% to 6.89%) per annum, in which approximately HK\$33.92 million bank loans were charged at fixed interest rates. Certain bank loans were pledged by assets of the Group with a net book value of HK\$167.20 million (31 December 2021: HK\$284.35 million). The gearing ratio of the Group, measured by bank borrowings as a percentage of shareholders' equity, was approximately 26.5% as at 31 December 2022 while it was also approximately 21.3% as at 31 December 2021.

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 Renminbi and Hong Kong Dollars, the exposure to foreign exchange fluctuation 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 2022, the Group has a cross currency swap contract to offset the currency exchange risk between HKD and RMB in related to the interests payment of certain bank loans. Save as disclosed above, the Group did not have other 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 2022, the Group as lessor had operating lease commitments of HK\$0.65 million (2021: HK\$0.21 million).

As at 31 December 2022, the Group had capital commitments of HK\$140.49 million (2021: HK\$180.32 million).

### **Contingent Liabilities**

As at 31 December 2022, 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 2022 which may have a significant effect, on the assets and liabilities of future operations of the Group.

### **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.

In 2022 and 2021, the Group has paid to the trust established for the Scheme HK\$30.0 million HK\$155.0 million respectively, together with the dividend income distributed by the Shares owned, the Group applied approximately HK\$187.5 million to purchase 30,300,000 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.

Save for the aforesaid, as at the date of this announcement, the Board neither granted any awards nor caused to pay the trustee the trust fund for purchase nor subscription of Shares.

### **Purchase, Sale or Redemption of Shares**

During the year ended 31 December 2022, 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 7,869,500 Shares at a total consideration of approximately HK\$44.0 million.

### **Employees and Remuneration Policy**

As at 31 December 2022, the Group employed about 10,175 staff and workers in Hong Kong and the PRC (31 December 2021: about 10,029). 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, an executive Director, is a director of Huadong Medicine Co., Ltd., 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 2022.

### **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 2022.

### **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 2022 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 Dr. Shao Yan 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 Friday, 2 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 Tuesday, 30 May 2023 to Friday, 2 June 2023 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 Friday, 2 June 2023. 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 Monday, 29 May 2023; and
- (ii) on Tuesday, 13 June 2023, 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, 12 June 2023. The final dividend will be paid on or about Tuesday, 27 June 2023 to the shareholders whose names appear on the register of members as on Tuesday, 13 June 2023.

### **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 in accordance with Hong Kong Standards on Auditing, Hong Kong Standards on Review Engagements or Hong Kong Standards on Assurance Engagements issued by the HKICPA and consequently no assurance 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](http://www.hkexnews.hk)) and the Company ([www.grandpharm.com](http://www.grandpharm.com)) and the Company's 2022 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, 22 March 2023

*As at the date of this announcement, the Board comprises four executive directors, namely, Dr. Tang Weikun, Dr. Shao Yan, Dr. Niu Zhanqi and Dr. Shi Lin, and three independent non- executive 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 2022 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 2022*

	<i>Notes</i>	<b>2022</b> <i>HK\$'000</i>	2021 <i>HK\$'000</i>
<b>Revenue</b>	4	<b>9,562,285</b>	8,597,975
Cost of sales		<b>(3,610,806)</b>	(3,350,737)
<b>Gross profit</b>		<b>5,951,479</b>	5,247,238
Other revenue and income		<b>211,572</b>	349,016
Distribution costs		<b>(2,306,519)</b>	(2,397,848)
Administrative expenses		<b>(1,090,032)</b>	(909,617)
Reversal/(provision) of expected credit losses, net		<b>23,017</b>	(353)
Impairment loss recognized in respect of goodwill		<b>(36,442)</b>	
Net income from financial assets at fair value through profit or loss	5	<b>(94,623)</b>	484,848
Fair value change on derivative financial instruments		<b>39,720</b>	(8,350)
Share of results of associates		<b>(43,786)</b>	113,862
Finance costs	6	<b>(137,493)</b>	(92,964)
<b>Profit before tax</b>		<b>2,516,893</b>	2,785,832
Income tax expense	7	<b>(418,642)</b>	(380,800)
<b>Profit for the year</b>	8	<b>2,098,251</b>	2,405,032

	<i>Notes</i>	<b>2022</b> <b>HK\$'000</b>	2021 HK\$'000
<b>Other comprehensive income, net of income tax</b>			
<i>Items that will not be reclassified to profit or loss:</i>			
Fair value (loss)/gain on investment in equity instruments at fair value through other comprehensive income		<b>(70,706)</b>	28,641
Share of other comprehensive loss of associates		<b>(31,311)</b>	(12,047)
<i>Items that may be reclassified subsequently to profit or loss:</i>			
Exchange difference on translating foreign operations		<b>(788,439)</b>	274,095
Other comprehensive income for the year, net of income tax		<b>(890,456)</b>	290,689
<b>Total comprehensive income for the year, net of income tax</b>		<b>1,207,795</b>	2,695,721
<b>Profit for the year attributable to:</b>			
- Owners of the Company		<b>2,079,419</b>	2,402,563
- Non-controlling interests		<b>18,832</b>	2,469
		<b>2,098,251</b>	2,405,032
<b>Total comprehensive income/(loss) for the year attributable to:</b>			
- Owners of the Company		<b>1,182,143</b>	2,696,069
- Non-controlling interests		<b>25,652</b>	(348)
		<b>1,207,795</b>	2,695,721
<b>Earnings per share</b>			
	<i>10</i>		
- Basic and diluted (HK cents)		<b>58.70</b>	67.72

Details of the dividends for the year ended 31 December 2022 are disclosed in note 9.

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As at 31 December 2022

	<i>Notes</i>	<b>2022</b> <i>HK\$'000</i>	2021 <i>HK\$'000</i>
<b>Non-current assets</b>			
Property, plant and equipment		<b>3,505,138</b>	3,409,183
Right of use assets		<b>436,764</b>	392,528
Investment properties		<b>175,112</b>	167,151
Interests in associates	<i>11</i>	<b>7,704,161</b>	8,066,669
Equity instruments at fair value through other comprehensive income		<b>567,320</b>	145,685
Goodwill		<b>644,047</b>	596,746
Intangible assets		<b>1,397,992</b>	1,009,764
Deferred tax assets		<b>24,585</b>	24,608
Prepayments		<b>1,029,022</b>	466,107
		<b>15,484,141</b>	14,278,441
<b>Current assets</b>			
Financial assets at fair value through profit or loss		<b>1,038,582</b>	1,112,968
Inventories		<b>1,340,466</b>	1,117,156
Trade and other receivables	<i>12</i>	<b>2,997,384</b>	2,661,450
Loan receivables		-	113,190
Amounts due from related companies		<b>33,747</b>	13,320
Derivative financial instrument		<b>31,370</b>	-
Pledged bank deposits		<b>1,357</b>	7,645
Cash and cash equivalents		<b>1,444,014</b>	1,752,860
		<b>6,886,920</b>	6,778,589
<b>Current liabilities</b>			
Trade and other payables	<i>13</i>	<b>2,488,127</b>	2,871,759
Contract liabilities	<i>13</i>	<b>318,824</b>	202,106
Bank and other borrowings		<b>3,243,126</b>	2,116,471
Lease liabilities		<b>9,785</b>	5,728
Amounts due to related companies		<b>22,670</b>	4,831
Amount due to the immediate holding company		<b>2,331</b>	2,331
Derivative financial instrument		-	8,350
Income tax payable		<b>369,738</b>	354,549
		<b>6,454,601</b>	5,566,125
<b>Net current assets</b>		<b>432,319</b>	1,212,464
<b>Total assets less current liabilities</b>		<b>15,916,460</b>	15,490,905
<b>Non-current liabilities</b>			
Bank and other borrowings		<b>1,162,288</b>	1,510,070
Lease liabilities		<b>60,083</b>	13,306
Deferred tax liabilities		<b>220,148</b>	197,849
Deferred income		<b>265,281</b>	326,818
		<b>1,707,800</b>	2,048,043
<b>Net assets</b>		<b>14,208,660</b>	13,442,862

	<i>Notes</i>	<b>2022</b> <b>HK\$'000</b>	2021 <i>HK\$'000</i>
<b>Capital and reserves attributable to owners of the Company</b>			
Share capital	<i>14</i>	<b>35,496</b>	35,496
Reserves		<b>14,104,842</b>	13,357,135
		<hr/>	<hr/>
Equity attributable to owners of the Company		<b>14,140,338</b>	13,392,631
<b>Non-controlling interests</b>		<b>68,322</b>	50,231
		<hr/>	<hr/>
<b>Total equity</b>		<b>14,208,660</b>	13,442,862
		<hr/> <hr/>	<hr/> <hr/>

Notes:

## 1. GENERAL INFORMATION

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 Clarendon House, 2 Church Street, Hamilton HM11, Bermuda and Unit 3302, The Center, 99 Queen’s Road Central, Hong Kong, respectively.

The Group is principally engaged in the manufacture and sales of pharmaceutical preparations and medical devices, bio-technology products and health products, specialized pharmaceutical raw materials and other products, in the People’s Republic of China (the “**PRC**”).

Directors consider that Outwit Investments Limited (the “**Outwit**”) is the parent company of the Company, and China Grand Enterprises Incorporation (the “**China Grand**”) is the ultimate holding company of the Company.

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 most of the subsidiaries in Renminbi (“**RMB**”). The Board 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 2022 for the preparation of the consolidated financial statements:

Amendments to HKFRS 3	Reference to the Conceptual Framework
Amendments to HKFRS 16	Covid-19-Related Rent Concessions beyond 30 June 2021
Amendments to HKAS 16	Property, Plant and Equipment – Proceeds before Intended Use
Amendments to HKAS 37	Onerous Contracts – Cost of Fulfilling a Contract
Amendments to HKFRSs	Annual Improvements to HKFRSs 2018-2020
Accounting Guideline 5 (Revised)	Merger Accounting for Common Control Combinations

The application of the 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 in issue 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:

HKFRS 17(including the October 2020 and February 2022 Amendments to HKFRS 17)	Insurance Contracts <sup>1</sup>
Amendments to HKFRS 10 and HKAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture <sup>2</sup>
Amendments to HKFRS 16	Lease Liability in a Sale and Leaseback <sup>3</sup>
Amendments to HKAS 1	Classification of Liabilities as Current or Non- current

Amendments to HKAS 1 and HKFRS Practice Statement 2	and related amendments to Hong Kong Interpretation 5 (2020) <sup>1</sup> Disclosure of Accounting Policies <sup>1</sup>
Amendments to HKAS 8	Definition of Accounting Estimates <sup>1</sup>
Amendments to HKAS 12	Deferred Tax related to Assets and Liabilities arising from a Single Transaction <sup>1</sup>

<sup>1</sup> Effective for annual periods beginning on or after 1 January 2023.

<sup>2</sup> Effective for annual periods beginning on or after a date to be determined.

<sup>3</sup> Effective for annual periods beginning on or after 1 January 2024.

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 all applicable HKFRSs, which is a collective term that includes all applicable individual HKFRSs, Hong Kong Accounting Standards (“HKASs”), and Interpretations issued by the HKICPA and accounting principles generally accepted in Hong Kong. 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 (the “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, which are measured at fair values at the end of each reporting period.

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 *Lease* 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 year ended 31 December 2022 and 2021, 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.

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	
	2022 HK\$'000	2021 HK\$'000	2022 HK\$'000	2021 HK\$'000
The PRC	7,453,795	7,422,136	9,675,884	8,528,777
America	956,036	430,098	-	-
Europe	566,532	297,962	-	-
Asia other than the PRC	480,809	330,889	66,228	42,805
Others	105,113	116,890	-	-
Total	<b>9,562,285</b>	<b>8,597,975</b>	<b>9,742,112</b>	<b>8,571,582</b>

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 2022 and 2021, 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

	2022 HK\$'000	2021 HK\$'000
<b>Type of goods and services</b>		
Manufacture and sales of pharmaceutical preparations and medical devices	5,677,109	5,377,145
Sales of bio-technology products and health products	2,885,369	2,231,461
Sales of specialised pharmaceutical raw materials and other products	999,807	989,369
Total revenue recognised at point in time	<b>9,562,285</b>	<b>8,597,975</b>



	2022 <i>HK\$'000</i>	2021 <i>HK\$'000</i>
<b>Revenue disclosed in segment information</b>		
External customers	<u>9,562,285</u>	<u>8,597,975</u>
<b>Timing of revenue recognition</b>		
At point in time	<u>9,562,285</u>	<u>8,597,975</u>

All of the Group's revenue are recognised at point in time when carrier designated by the customer, or after the customer's acceptance or upon transfer of control of the goods to customers. 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 contracts is not disclosed.

#### 5. NET INCOME FROM FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT OR LOSS

	2022 <i>HK\$'000</i>	2021 <i>HK\$'000</i>
Changes in fair value on listed equity security in Hong Kong	(18,833)	(1,667)
Changes in fair value on listed equity security outside Hong Kong	(48,407)	485,348
Investment income at fair value, net	-	1,167
Realised gain on disposal of financial assets at fair value through profit or loss	<u>(27,383)</u>	<u>-</u>
	<u>(94,623)</u>	<u>484,848</u>

#### 6. FINANCE COSTS

	2022 <i>HK\$'000</i>	2021 <i>HK\$'000</i>
Interest on bank borrowings:		
- wholly repayable within five years	132,977	90,191
Interest on lease liabilities	<u>4,516</u>	<u>2,773</u>
	<u>137,493</u>	<u>92,964</u>

#### 7. INCOME TAX EXPENSE

	2022 <i>HK\$'000</i>	2021 <i>HK\$'000</i>
Current tax:		
The PRC Enterprise Income Tax	383,904	370,443
Deferred tax	<u>34,738</u>	<u>10,357</u>
	<u>418,642</u>	<u>380,800</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% from 1 January 2008 onwards.

According to the relevant 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

	2022 <i>HK\$'000</i>	2021 <i>HK\$'000</i>
Profit for the year is stated after charging:		
Depreciation of property, plant and equipment	328,712	305,504
Depreciation of right-of-use assets	33,859	16,991
Amortisation of intangible assets	32,341	17,024
Total depreciation and amortization	<u>394,912</u>	<u>339,519</u>
Cost of inventories recognised as an expense	3,610,806	3,350,737
Research and development expenditure	531,924	331,421
Marketing and promotion expenses	<u>498,692</u>	<u>634,985</u>

## 9. DIVIDEND

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

	2022 <i>HK\$'000</i>	2021 <i>HK\$'000</i>
Final dividend proposed after the end of report HK\$0.14 per share (2021: HK\$0.11)	<u>496,940</u>	<u>390,450</u>

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

	2022 <i>HK\$'000</i>	2021 <i>HK\$'000</i>
Final dividend in respect of the previous financial year, approved and paid during the year, of HK\$0.11 per share (2021: HK\$0.11)	<u>390,450</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.

	2022 <i>HK\$'000</i>	2021 <i>HK\$'000</i>
<b>Earnings</b>		
Earnings for the purpose of basic earnings per share calculation	<u>2,079,419</u>	<u>2,402,563</u>
	2022 '000	2021 '000
<b>Number of shares</b>		
Weighted average number of ordinary shares for the purpose of basic earnings per share calculation (Note)	<u>3,542,258</u>	<u>3,548,050</u>

Note:

As at 31 December 2022 and 2021, 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 2022 and 2021 as there were no potential dilutive ordinary shares in issue.

## 11. INTEREST IN ASSOCIATES

During the year ended 31 December 2022, the Group has subscribed 29,646,627 new shares of Grand Pharma Sphere Pte Ltd. (which wholly owned the equity interests of Sirtex) at the consideration of USD35,000,000. After the completion of the transaction the equity interests held in it increased to approximately 51.61%.

The Group's effective interest in Grand Pharma Sphere Pte. Ltd. has increased to 57.98%, with consideration of shares held by Natixis.

## 12. TRADE AND OTHER RECEIVABLES

	2022 <i>HK\$'000</i>	2021 <i>HK\$'000</i>
Trade receivables, net	1,093,854	967,703
Bills receivables	819,880	829,402
Deposits and prepayments	824,215	638,524
Other tax receivables	68,700	63,528
Other receivables, net	<u>190,735</u>	<u>162,293</u>
	<u>2,997,384</u>	<u>2,661,450</u>

Note:

The increase of deposits and prepayments and other receivables amount is mainly related to the deposit payment and milestone payment of various projects.

The Group generally allows a credit period of 30 – 180 days (2020: 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.

The bills receivables were all with maturity within 180 days from the reporting date.

	2022 <i>HK\$'000</i>	2021 <i>HK\$'000</i>
Within 90 days	788,026	738,650
91-180 days	218,252	155,539
181-365 days	87,576	73,514
	<u>1,093,854</u>	<u>967,703</u>

### 13. TRADE AND OTHER PAYABLES AND CONTRACT LIABILITIES

	2022 <i>HK\$'000</i>	2021 <i>HK\$'000</i>
Trade payables	687,731	549,963
Bills payables	185,129	184,535
Accruals and other payables	1,517,066	1,943,515
Other tax payables	98,201	193,746
	<u>2,488,127</u>	<u>2,871,759</u>
Contract liabilities (note (a))	<u>318,824</u>	<u>202,106</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 2022 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:

	2022 <i>HK\$'000</i>	2021 <i>HK\$'000</i>
Within 90 days	516,952	300,002
Over 90 days	170,779	249,961
	<u>687,731</u>	<u>549,963</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.

### 14. SHARE CAPITAL

	Number of shares at		Share capital at	
	31 December 2022 '000	31 December 2021 '000	31 December 2022 <i>HK\$'000</i>	31 December 2021 <i>HK\$'000</i>
<b>Authorized</b>				
Ordinary shares of HK\$0.01 each	<u>100,000,000</u>	<u>100,000,000</u>	<u>1,000,000</u>	<u>1,000,000</u>
<b>Issued and fully paid</b>				
At 1 January, 31 December 2021, 1 January 2022 and 31 December 2022	<u>3,549,571</u>	<u>3,549,571</u>	<u>35,496</u>	<u>35,496</u>

Notes:

- (a) As at 31 December 2022, the Company, through a trust, held 30,300,000 shares (2021: 22,430,500 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\$187.50 million (2021: HK\$143.50 million).

## 15. ACQUISITION OF A SUBSIDIARY

### Business Combination

- (a) In July 2022, the Group entered into an equity acquisition agreement with Hubei Bafeng, pursuant to which, the Group will acquire 100% equity interest in Hubei Bafeng at an amount of not more than RMB270,000,000 (equivalents to approximately HK\$305,292,000 after the relevant conditions as agreed in the acquisition agreement are fulfilled. Hubei Bafeng is principally engaged in the research and development, production and operation of amino acid APIs and preparations. The acquisition has been accounted for as acquisition of business using the acquisition method.

### Assets acquired and liabilities recognized at the date of acquisition

	<b>2022</b> <b>HK\$'000</b>
Property, plant and equipment	85,197
Right-of-use assets	17,263
Intangible assets	70,255
Prepayments	2,516
Inventories	27,805
Deposits, prepayments and other receivables	29,183
Cash and cash equivalents	44,677
Deferred Tax Liabilities	(20,159)
Other tax payables	(70,908)
Total identifiable net assets acquired	<u>185,829</u>
Goodwill	<u>128,071</u>
	<b><u>313,900</u></b>

### Net cash outflow arising on acquisition

	<b>2022</b> <b>HK\$'000</b>
Consideration paid in cash	313,900
Less: Cash and cash equivalent balances acquired	<u>(43,452)</u>
	<b><u>270,448</u></b>

Since the acquisition, Hubei Bafeng contributed approximately HK\$46,487,000 to the Group's revenue and approximately HK\$9,774,000 to the consolidated profit for the year ended 31 December 2022.