



# 2023

INTERIM REPORT



遠大醫藥集團  
GRAND PHARMACEUTICAL GROUP

## 遠大醫藥集團有限公司

GRAND PHARMACEUTICAL GROUP LIMITED

(Incorporated in Bermuda with limited liability)  
(Stock Code: 00512)



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# Corporate Profile

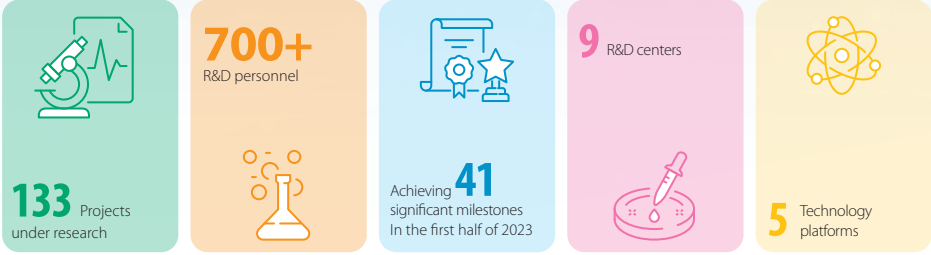
## GROUP POSITIONING

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.

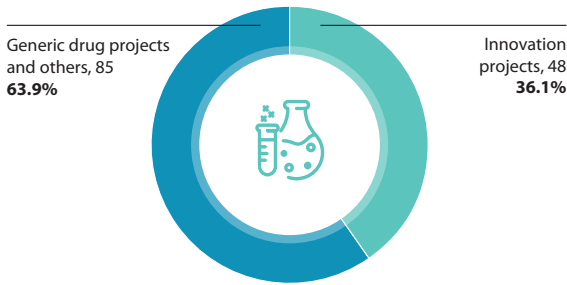
With unremitting efforts in recent years, the Group has laid a more solid foundation for development, consolidated its operation scale, gradually optimized its business structure, continued to improve its operation mode, accelerated its pace of transformation and upgrading, and made various achievements 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.

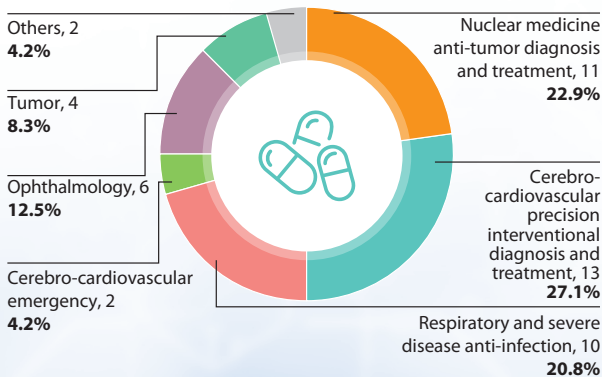
## RESEARCH AND DEVELOPMENT



### Overview of 133 R&D projects



### Overview of 48 innovative projects by areas



# Corporate Profile

## INNOVATIVE PRODUCT PIPELINE STRATEGIC PLAN:

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	GPW00136 (BRM421)	Dry eye				●	●				
			GPW00153 (CBF-001)	Pterygium					●	●			
			GPW00893	Ocular inflammation						●			
	Respiratory, severe disease and anti-infection	Respiratory	GPW00884	Myopia prevention and control	●	●							
			Ryabris*	Allergic rhinitis								●	
		Severe disease and anti-infection	STC3141	Sepsis				●					
APAD	Sepsis					●							
GPW00085	Paramfluenza	●	●										
Cerebro-cardiovascular emergency	Emergency	GPW00816	Anaphylaxis		●						●		
Anti-tumor	Immunotherapy	A002	HPV-positive head and neck cancer	●				●					
Technologies on nuclear medicine and anti-tumor diagnosis and treatment as well as cerebro-cardiovascular precision interventional diagnosis and treatment	Nuclear medicine and anti-tumor diagnosis and treatment	Interventional treatment	Y-90 microsphere injection	Primary liver cancer						●	●		
			Thrombotic/embolic agent product	Hypervascular pancreatic organ's tumor		●							
			Lava	Peripheral vascular arterial bleeding								●	
			Kona	Brain arteriovenous malformation								●	
			Avulase	Prostate cancer							●		
		Radionuclide-drug conjugate (RDC)	TLX591 (177Lu-vcapatumab)	Prostate cancer	●						●		
			TLX591-CDx (86Ga-PSMA-11)	Prostate cancer - diagnosis	●						●		
			TLX599-CDx (90Yt-EDDA)-HYMC-PSMA)	Prostate cancer - diagnosis	●						●		
			TLX250 (177Lu-girentumab)	Clear cell renal cell carcinoma - diagnosis	●			●			●		
			TLX101 (131I-IPN)	Glioblastoma	●			●			●		
	Cerebro-cardiovascular precision interventional diagnosis and treatment	Access management	Coronary artery vascular intervention	ML CAD	Moderate/severe coronary artery/peripheral arterial calcification	●							
			Peripheral vascular intervention	IAL PAD	Hemodialysis	●							
			LEGFLOW® DCB	Peripheral vascular disease			●						
		Structural heart disease	Stent retriever	DCB	Ischemic stroke	●							
			DCB	Intracranial stenosis	●								
Electrophysiology and heart failure	Structural heart disease	Satum	Mitral regurgitation	●	●								
Heart failure	Electrophysiology	HeartLight X3	Atrial fibrillation							●			
	Heart failure	CoRisma	Heart failure	●	●								

- Mainland China
- Overseas

## MAJOR EVENTS

As at the date of this report, the Group's major product development and corporate development are as follows:



The new selective mineralocorticoid receptor antagonist (MRA) eplerenone tablets cooperated by the Group and Nanjing Ka Wen Di Xu Biological Engineering Technology Co., Ltd. (南京卡文迪許生物工程技術有限公司) were granted a certificate of drug registration by the NMPA, which, as an exclusive product on the Chinese market, bridges the gap of second-generation MRA drugs in the country. At present, there are many clinical guidelines and expert consensus recommending the clinical use of MRA drugs for the treatment of cardiovascular diseases such as heart failure and hypertension.



The Group's global innovative drug STC3141 in the field of severe disease was approved by the NMPA to commence a phase II clinical study in China for the treatment of sepsis.



The Group's nuclear medicine anti-tumor diagnosis and treatment segment completed the first patient enrolment and administration in China phase I clinical trial of TLX250-CDx, a global innovative RDC drug for the diagnosis of ccRCC.

The Group's global innovative drug STC3141 in the field of severe disease has successfully reached the clinical study endpoint in its phase Ib clinical trial in Australia and Belgium for the treatment of sepsis.



Novasight Hybrid System, a global innovative intravascular dual-mode imaging device for coronary artery imaging in the Group's cerebro-cardiovascular precision interventional diagnosis and treatment segment, was granted a certificate of registration as a medical device by the NMPA.

An NDA was submitted to the FDA of the United States for GPN00833 (APP13007), hormone nano-suspension eye drops for anti-inflammatory and pain relief in the Group's ophthalmology segment.

The multicenter phase III clinical trial of Ryaltris® Compound Nasal Spray (GSP 301), a global innovative drug in the Group's respiratory and severe disease anti-infection segment, has completed full patient enrolment in China.

ITM-11, a global innovative RDC drug for the treatment of GEP-NETs in the Group's nuclear medicine anti-tumor diagnosis and treatment segment, was approved by the NMPA to commence a phase I clinical study in China.



The Group acquired 87.5% equity interest in BlackSwan from the original shareholders of BlackSwan at a consideration of no more than US\$37.5 million and it has become a non-wholly owned subsidiary of the Group. Upon completion of the acquisition, the Group will have a global interest in Lava™ and Kona™. On the one hand, these two products can form a product combination with the Group's Y-90 resin microspheres products, which is expected to expand the indications of the Y-90 resin microspheres products to other solid tumors; on the other hand, these two products can form a brand-new drug combination with other chemotherapeutic drugs or radiopharmaceuticals, which will expand the Group's product pipeline in the field of oncology intervention. In addition, the Group's existing global research and development team and sales network can help Lava™ and Kona™ to be approved and marketed globally in a speedy manner and achieve sales volume, which will strengthen our existing global business while opening up new business markets.

GPN00136 (BRM421), a small molecule peptide drug for the treatment of dry eye disease in the Group's ophthalmology segment, was approved by the NMPA to commence a phase II clinical study in China.

GPN00833 (APP13007), hormone nano-suspension eye drops for anti-inflammatory and pain relief in the Group's ophthalmology segment, was approved by the NMPA to commence a phase III clinical study in China.

APP13007, hormone nano-suspension eye drops for anti-inflammatory and pain relief in the Group's ophthalmology segment, has successfully reached clinical endpoint in a phase II clinical study and two phase III clinical studies in the United States.

TLX101, a global innovative RDC drug for the treatment of glioblastoma in the Group's nuclear medicine anti-tumor diagnosis and treatment segment, was approved by the NMPA to commence a phase I clinical study in China.

The Group's global innovative drug APAD in the field of severe disease for the treatment of sepsis was approved by the NMPA to commence a phase I clinical study in China.



HeartLight X3 laser ablation platform, a global innovative medical device for the treatment of AF in the Group's cerebro-cardiovascular precision interventional diagnosis and treatment segment, has successfully completed the first licensed clinical treatment of laser ablation of AF in China at Ruijin-Hainan Hospital.

The Group's global innovative drug STC3141 in the field of severe disease has completed full patient enrolment in its phase Ib clinical trial in Australia and Belgium for the treatment of sepsis.



The Jext® pre-filled epinephrine automatic injection pen for the treatment of severe allergic reactions in the Group's cerebro-cardiovascular emergency segment was officially approved by the Drug Administration of Guangdong Province in China, and was granted the approval for the importation of Hong Kong and Macao drugs for clinical urgency in the mainland of the Greater Bay Area.

Two global innovative compound preparations of the Group's respiratory and severe disease anti-infection segment for the treatment of asthma, Enerzair® Breezhaler® (indacaterol acetate, glycopyrronium bromide and mometasone furoate powder for inhalation II) and Ateectura® Breezhaler® (indacaterol acetate and mometasone furoate powder for inhalation II, III), with a total of three product specifications, have successfully passed the national medical insurance negotiation in China and were formally 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)》).



# Corporate Profile

## DEFINITIONS

In this report, unless the context otherwise requires, the following terms shall have the meanings set out below:

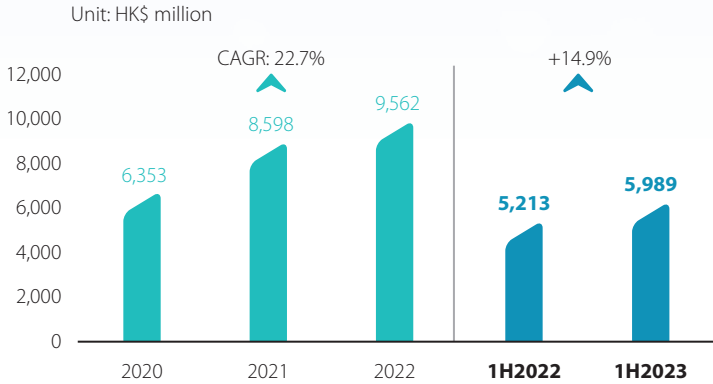
"AF" or "Atrial Fibrillation"	Atrial Fibrillation
"APERTO® OTW"	Paclitaxel Releasing Hemodialysis Shunt Balloon Dilatation Catheter
"ARDS"	Acute Respiratory Distress Syndrome
"BlackSwan"	BlackSwan Vascular, Inc.
"ccRCC"	Clear cell renal cell carcinoma
"COVID-19"	2019 novel coronavirus disease
"FDA"	United States Food and Drug Administration
"GEP-NETs"	Gastroenteropancreatic neuroendocrine tumors
"Grand Pharma Sphere"	Grand Pharma Sphere Pte Limited
"ICS"	Inhaled Glucocorticoid
"ITM"	ITM Isotope Technologies Munich SE
"LABA"	Long-acting $\beta_2$ agonist
"LAMA"	Long-acting muscarinic antagonist
"LEGFLOW® OTW"	Paclitaxel Releasing Peripheral Balloon Dilatation Catheter
"MR"	Mineralocorticoid receptor
"MRA"	Mineralocorticoid receptor antagonist
"mRNA"	messenger RNA

“Novasight”	NOVASIGHT Hybrid System
“NMPA”	National Medical Products Administration
“PCI”	Percutaneous coronary intervention
“RDC”	Radionuclide-drug conjugate
“RESTORE DEB®”	Paclitaxel Releasing Coronary Balloon Dilatation Catheter
“SARS-CoV-2”	COVID-19 virus
“Sirtex”	Sirtex Medical Pty Ltd.
“Telix”	Telix Pharmaceuticals Limited
“Greater Bay Area”	The Guangdong-Hong Kong-Macao Greater Bay Area
“Greater China Region”	Mainland China, the Hong Kong Special Administrative Region of the PRC, the Macao Special Administrative Region of the PRC, Taiwan of the PRC
“Ruijin-Hainan Hospital”	Ruijin-Hainan Hospital Shanghai Jiao Tong University School of Medicine (Boao Research Hospital) (上海交通大學醫學院附屬瑞金醫院海南醫院暨博鰲研究型醫院)
“Tianjin Jingming”	Tianjin Jingming New Technology Development Co., Ltd.
“WMU”	WenZhou Medical University
“Xudong Haipu”	Shanghai Xudong Haipu Pharmaceutical Co., Ltd.
“NMPA”	National Medical Products Administration
“Grand Pharm (China)”	Grand Pharmaceutical (China) Company Limited, a company incorporated in the PRC, being an indirect non-wholly owned subsidiary of the Company

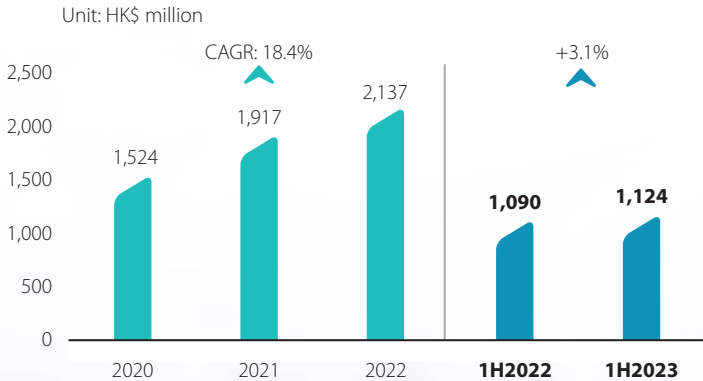
# Corporate Profile

## FINANCIAL SUMMARY

### Revenue



### Net profit attributable to the owners of the Company\*



\* Excluding the effects of fair changes and the sale of the Telix investment and the one-time administrative penalty

## GROUP POSITIONING

Grand Pharmaceutical Group Limited (the “**Company**”) and its subsidiaries (collectively, 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, with patient needs as the core and technological innovation as the driving force, the Group has adhered to 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” to fully utilize the Group’s industrial advantages and R&D strengths, forming a new pattern of domestic and international cycles that synergize with each other and being 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.

# Management Discussion and Analysis

## BUSINESS REVIEW AND PROSPECTS

During 2023 and up to the date of this report, the Group had a total of 41 significant milestones, including 26 innovative products, 10 generic products, 2 API products, 2 functional foods and 1 major merger and acquisition.

### Innovative products

#### Nuclear medicine anti-tumor diagnosis and treatment:

- The phase I clinical research for the global innovative nuclear medicine product TLX250-CDx conducted in China has completed the enrolment and dosing of the first patient;
- The global innovative nuclear medicine product TLX101 was approved to commence phase I clinical research in China;
- The global innovative nuclear medicine product ITM-11 was approved to commence phase I clinical research in China;
- Lava™, an innovative liquid embolic agent for the treatment of peripheral vascular arterial hemorrhage was approved for commercialization by the U.S. Food and Drug Administration (“FDA”);
- The application for Premarket Approval (PMA) for Kona™, a preoperative embolic agent for the treatment of cerebral arteriovenous malformations was submitted.

#### Cerebro-cardiovascular precision interventional diagnosis and treatment:

- The application for the commercialization of HeartLight X3 laser ablation platform, a global innovative medical device, has been submitted in China;
- HeartLight X3 laser ablation platform, 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**”);
- NOVASIGHT Hybrid System (“**Novasight**”), a new medical imaging system for intracavity diagnosis has been approved for commercialization in China;
- Distal access catheter Pilu® (琵琶®), a neurointerventional product, has been approved for commercialization in China;

# Management Discussion and Analysis

- Microcatheter Sheti® (蛇鵝®), a neurointerventional product, has been approved for commercialization in China.

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

- Enerzair® Breezhaler® and Ateectura® Breezhaler®, the two global innovative compound preparations for the treatment of asthma, were successfully included in the National Reimbursement Drug List (2022 edition);
- The phase III clinical trial of Ryaltris® compound nasal spray, an innovative product, conducted in China has completed the enrolment of all patients;
- The phase Ib clinical researches for STC3141, a global innovative drug, for the treatment of sepsis conducted in Australia and Belgium have successfully met the clinical endpoint;
- STC3141, a global innovative drug for the treatment of sepsis, was approved to commence phase II clinical research in China;
- APAD, a global innovative drug for the treatment of sepsis, was approved to commence phase I clinical research in China;

## **Ophthalmology:**

- BRM421, a global innovative drug for the treatment of dry eye, was approved to commence the phase II clinical research in China;
- GPN00833, an improved new drug for anti-inflammatory and pain relief after ophthalmology surgery, was approved to commence phase III clinical research 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 phase III clinical research.

## **Cerebro-cardiovascular emergency:**

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

# Management Discussion and Analysis

## Generic products

There were 10 products approved for commercialization, among which the Eplerenone Tablets is the first generic product being approved for commercialization in China, and the Chinathe ophthalmic balanced salt solution (15ml) is the first generic product of this specification being approved for commercialization in China.

## API products

There were 2 API products passed the REACH registration of the European Union.

## Functional foods:

2 functional foods that help control weight and sleep were approved for commercialization in China.

## Merger and acquisition

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

## BUSINESS INTRODUCTION

The Group has strong technological innovation strength, outstanding internationalization strength, solid industrial foundation, complete industrial chain and significant comprehensive advantages in the integration of raw materials and preparations. The Group has more than 90 products included in the National Essential Drug List (2018 version) and more than 200 products included in the National Reimbursement Drug List for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (2022 version). In June 2023, the Group ranked 19th on the list of "Top 100 Chemical Pharmaceutical Companies of China 2022" (2022 年度中國化藥企業 TOP100 排行榜).

# Management Discussion and Analysis

## 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 and the mRNA R&D Centers in Nanjing/Belgium 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(2021年)》), the Expert Consensus on Sterily Surgery in China (2020) (《中國乾眼專家共識(2020年)》), the Expert Consensus on Refractive Surgery in Laser Corneal Surgery in China (2019) (《中國激光角膜屈光手術圍手術期用專家共識(2019年)》), and the Expert Consensus on Diagnosis and Treatment of Functional Disorder of Bleacne in China (2017) (《我國臉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



# Management Discussion and Analysis

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.

# Management Discussion and Analysis

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 phase II clinical research and two phase III clinical researches for the product conducted overseas have successfully met the clinical endpoints. According to the clinical results, GPN00833 has shown remarkable effectiveness and good safety in the treatment of anti-inflammatory and pain relief after ophthalmology surgery, for which, the NDA application was submitted to the FDA in May 2023. Currently, the product was approved to commence phase III clinical research in China in April 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 research 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 research overseas, and was approved to commence phase II clinical research in April 2023 for registration in China.

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.

# Management Discussion and Analysis

## 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 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® Breezhaler® and Aectura® Breezhaler® 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, etc. Among which, the phase III clinical research of Ryaltris®, the product for the treatment of allergic rhinitis, has completed the enrolment of all patients. STC3141, a global innovative drug for the treatment of severe diseases such as sepsis, has obtained seven clinical approvals for four indications, namely sepsis, ARDS, severe novel coronavirus infections (“**COVID-19**”) and ARDS caused by COVID-19, in five countries, namely China, Australia, Belgium, the United Kingdom, Poland on three continents and completed three clinical studies on patients which have successfully met the clinical endpoints, while APAD, another global innovative product for the treatment of sepsis, was approved to commence phase I clinical research 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.

# Management Discussion and Analysis

## Respiratory products

The main products include Qie Nuo, Jinsang Series, Enerzair® Breezhaler® and Ateectura® Breezhaler®, etc.

Qie Nuo:

It is a soluble and phlegm-free drug for viscosity, and is suitable for acute and chronic rhinosinusitis as well as respiratory diseases such as acute and chronic bronchitis, pneumonia, bronchial dilation, pulmonary abscess, chronic obstructive pulmonary disease, bacterial infection in the lungs, tuberculosis, and silica lungs. It can also be used for bronchoscopic angiography to facilitate the discharge of contrast medium. It is a China 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 dozens of guidelines and expert consensus recommending the use of viscosity dissolving promoters for clinical use. Among them, about a dozen guidelines and expert consensus explicitly recommend eucalyptol, limonene and pinene enteric soft capsules or its active ingredients for clinical treatment, such as the Expert Consensus on the Diagnosis and Treatment of Adult Bronchiectasis in China (《中國成人支氣管擴張症診斷與治療專家共識》), the Guidelines for the Diagnosis and Treatment of Secretory Otitis Media in Children (2021) (《兒童分泌性中耳炎診斷和治療指南(2021)》), 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. 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.

# Management Discussion and Analysis

## 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 hoarding caused by acute pharyngitis. Several products have been included in the Guidelines for the Diagnosis and Treatment of Common Diseases in Otorhinolaryngology of China (《中國耳鼻咽喉科常見病診療指南》) issued by the Chinese Association of Traditional Chinese Medicine, the Clinical Drug Guidelines (《臨床用藥指南》) for the diagnosis and treatment of clinicians, the authoritative monographs of the Manual for Common Traditional Chinese Medicine of Otorhinolaryngology (《常見眼耳鼻咽喉科中成藥手冊》) and the Practical Otorhinolaryngology Head and Neck Surgery (《實用耳鼻咽喉頭頸外科學》), etc., and are included in a number of clinical pathways and expert diagnosis and treatment guidelines. In January 2022, the Expert Consensus on the Clinical Application of Jinsang Sanjie Capsules for the Treatment of Vocal Nodules and Polyp of Vocal Cords (《金嗓散結膠囊治療聲帶小結·聲帶息肉臨床應用專家共識》) was issued by the Chinese Association of Traditional Chinese Medicine, which has also provided new support for the evidence-based development of Jinsang Sanjie products. Jinsang Sanjie and Jinsang Kaiyin Capsules are products on the National Reimbursement Drug List. Jinsang Kaiyin and Qingyin are dual cross-over products with both prescription and over-the-counter drugs.

## Management Discussion and Analysis

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

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



# Management Discussion and Analysis

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》).

## Innovative R&D pipeline

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

Ryaltris<sup>®</sup>, a new compound nasal spray for seasonal allergic rhinitis:

Ryaltris<sup>®</sup> 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 phase III clinical trial for the treatment of allergic rhinitis and rhinoconjunctivitis symptoms in patients aged 12 and above in October 2021, in which all patients were enrolled and dosed in April 2023. At present, the clinical trial is progressing smoothly.



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

STC3141 is a small molecule compound with a novel mechanism of action independently developed by the Group, which can be used to reverse organ damage caused by excessive immune responses by neutralizing extracellular free histones and neutrophil traps and is applicable to multiple severe disease indications. The product has an innovative action mechanism. Relevant preclinical research results have been published in the top academic journal "Nature Communications" in February 2020, giving rise to profound academic influence. Currently,

## Management Discussion and Analysis

the product has obtained seven clinical approvals for four indications, namely sepsis, ARDS, COVID-19 and ARDS caused by COVID-19, in five countries, namely China, Australia, Belgium, the United Kingdom, Poland on three continents and completed three clinical studies on patients. It was approved to commence phase Ib clinical study for the treatment of sepsis in Australia and Belgium in April 2020 and January 2022, respectively, which successfully met the clinical endpoint in June 2023; it was approved by the NMPA in early March 2021 to commence phase Ib clinical study on ARDS patients in China, which was completed in October 2022 and successfully met the clinical endpoint; it was approved to commence phase IIa clinical research for the treatment of severe COVID-19 in Belgium, Poland and the United Kingdom in April, September and October 2021, respectively, which were completed in July 2022 and successfully met the clinical endpoints. All such three clinical studies have shown the good safety and potential clinical benefits in the treatment of severe diseases. Currently, the product was approved to commence phase II clinical research in China in July 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 product portfolio in the treatment of severe diseases such as sepsis. Currently, the product was approved to commence phase I clinical research by the NMPA in March 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.



# Management Discussion and Analysis

## 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 nearly 30 varieties, 14 of which are included in the national emergency drugs catalogue of China, while 16 of which are included in the shortage drugs catalogue, which has ranked the top in the industry in terms of product pipeline. The Group’s first generic product, epinephrine hydrochloride injection (pre-filled), was approved for commercialization in China in July 2022. The 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. In August 2023, Eplerenone Tablets, a domestic second-generation mineralocorticoid receptor antagonist (“**MRA**”) drug that cooperated by the Group and Nanjing Cavendish Bio-engineering Technology Co., Ltd., has been granted drug registration certificate. Currently, there are more than 20 products under research in the field of cerebro- cardiovascular emergency. Among which, Jext®, a pre-filled epinephrine auto-injector, can be used for self or family or social treatment for severe allergic reactions, filling the gap in China, and in January 2023, the product has been granted approval for Guangdong-Hong Kong-Macao Greater Bay Area Imported Pharmaceuticals for Urgent Clinical Needs in Mainland China. In the future, the Group 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), Nuo Fu Kang (methoxamine hydrochloride injection), Neng Qi Lang (coenzyme Q10 tablets), Rui An Ji (fructose sodium diphosphate oral solution) and deslanoside injection, etc.

## Management Discussion and Analysis

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 (《2016ESC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.

# Management Discussion and Analysis

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)》).

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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 Guidelines for the Diagnosis and Treatment of Migraine in China (2023 version) (《中國偏頭痛診斷與治療指南2023版》), the Expert Consensus on the Diagnosis and Treatment of Severe Fever with Thrombocytopenia Syndrome (《重症發熱伴血小板減少綜合症診治專家共識》), the Chinese Expert Consensus on the Clinical Application of Drugs to Improve Myocardial Metabolism (2021) (《改善心肌代謝藥物臨床應用中國專家共識(2021)》), the Chinese Expert Consensus on Diagnosis and Treatment of Chronic Heart Failure for the Elderly (2021) (《老年人慢性心力衰竭診治中國專家共識(2021)》), the 2020 Expert Consensus on Prevention and Treatment of Heart Failure after Myocardial Infarction (《2020心肌梗死後心力衰竭防治專家共識》) and the Diagnosis and Treatment Advice for Children's Heart Failure (《兒童心力衰竭診斷和治療建議》).

Eplerenone Tablets:

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

# Management Discussion and Analysis

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併症處置專家建議(2020)》) and the National Prescription Set in China (《中國國家處方集》).

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)》).

# Management Discussion and Analysis

## Innovative R&D pipeline

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



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

China in January 2023, and patients can purchase the product in designated medical institutions in the Guangdong-Hong Kong-Macao Greater Bay Area ("**Greater Bay Area**") of China.

## 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.

# Management Discussion and Analysis

## 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 nearly 40% of them holding master's degree and doctoral degree. The Group, together with Sirtex, cooperated with Telix Pharmaceutical Limited (“**Telix**”) and ITM Isotope Technologies Muncich SE (“**ITM**”) to establish a world-class tumor intervention technology platform and a RDC technology platform. The Group adheres to the treatment concept of integrated oncology diagnosis and treatment. Currently, the Group has 13 innovative products in the pipeline, covering six radionuclides including <sup>68</sup>Ga, <sup>177</sup>Lu, <sup>131</sup>I, <sup>90</sup>Y, <sup>89</sup>Zr and <sup>99m</sup>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, four RDC have been approved for clinical trials. 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.

# Management Discussion and Analysis

## Core products

Yttrium-90 resin microsphere injections, the global innovative product:



The Group's global blockbuster innovative product, [Yttrium-90] microsphere injections, is the only product in the world for selective internal radiation therapy (SIRT) for colorectal cancer liver metastases. It has been used by more than 150,000 people in over 50 countries and regions around the world. It is also recommended by the treatment guidelines issued by different international authoritative organizations such as Barcelona Clinic Liver Cancer Guidelines (BCLC), National Comprehensive Cancer Network (NCCN), European Society for Medical Oncology (ESMO), European Association for the Study of the Liver (EASL),

National Institute for Health and Care Excellence (NICE), etc. and has been included in several authoritative clinical practice guidelines in China, including the "2022 CSCO Guidelines for Diagnosis and Treatment of Primary Liver Cancer" (《二零二二年CSCO原发性肝癌诊疗指南》), the "Guidelines for Diagnosis and Treatment of Primary Liver Cancer (2022 edition)" (《原发性肝癌诊疗指南(2022版)》), "Chinese Guidelines for Diagnosis and Comprehensive Treatment of Colorectal Cancer Liver Metastases (2018 edition)" (《中国结直肠癌肝转移诊断和综合治疗指南(2018版)》), "Clinical Practice Guidelines for Liver Cancer and Liver Transplantation in China (2018 edition)" (《中国肝癌肝移植临床实践指南(2018版)》), etc.

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



## Management Discussion and Analysis

In May 2022, [Yttrium-90] microsphere injections was officially commercialized in China. The treatment of liver malignancies in China has entered a new “Y-90 era”. Since the official commercialization of YiGanTai®, nearly 60 hospitals have completed the nuclide transfer procedures, its official surgeries have been carried out in nearly 40 hospitals in 17 provinces and cities in China, while 7 surgery, treatment and training centers have been established. The follow-up results showed that the overall response of patients who take YiGanTai® surgery was satisfactory, and most patients achieved favorable clinical therapeutic effect and prolonged survival. As at the date of this report, more than 10 patients have successfully achieved liver cancer tumor downstaging transform and took liver cancer resection, achieving clinical cure. Among patients who could be followed up for 3 months or more, the objective response rate of YiGanTai® for liver cancer was over 50%, and more than half of the patients had achieved tumor size remission. Among them, the symptoms of over 30 patients were completely relieved with no resection required, and the disease control rate of the follow-up patients exceeded 70%, showing a remarkable therapeutic effect.

In order to speed up the implementation and popularization of YiGanTai® microsphere injections precise interventional therapy in China, the Group, based on the surgeon supervision and training system approved by China NMPA and U.S. FDA, concentrated global resources to provide comprehensive training to surgeons in China on patient screening knowledge, surgical operation skills, and prognosis assessment methods, helping doctors to master and accumulate clinical experience to ensure a wider, safe and effective applications of the product, and assisted domestic doctors in conducting multiple personalized practical trainings by well-known overseas clinical experts. At present, the Group has trained more than 400 doctors in 70 hospitals on the surgery theory or skills of YiGanTai®, nearly 20 experts have obtained the operation qualification of independent surgery through strict one-to-one training by overseas experts, and six of them have obtained the qualification of training instructor, which will further accelerate the clinical popularization of YiGanTai® radioactive interventional operation.

Since its commercialization, [Yttrium-90] microsphere injection has been included in 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.

# Management Discussion and Analysis

## 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] resin 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 the second half of 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 model inspection stage.

Lava™, a global innovative liquid embolic agent:

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

# Management Discussion and Analysis

Kona™, a global innovative liquid embolic agent:

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

# Management Discussion and Analysis

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, an application for commercialization of the product in the United Kingdom and the European Union was also under way. In October 2022, TLX591-CDx was approved by the NMPA to commence phase III clinical 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, and the enrollment and dosing of the first patient for the phase I clinical study were completed in July 2023. TLX250 is currently undergoing a phase II clinical study overseas, with registration in China actively underway.

# Management Discussion and Analysis

ITM-11/TOCscan®, a global innovative product for the treatment of gastroenteropancreatic neuroendocrine tumors ("**GEP-NETs**").

ITM-11 and TOCscan® form an integrated radiotherapy portfolio for GEP-NETs. ITM-11 has received an orphan drug status from FDA and European Medicines Agency (EMA) and is in phase III clinical studies overseas. For the registration in China, the product was approved by the NMPA to commence a phase I clinical study in May 2023. TOCscan® 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 April 2023, TLX101 was approved by the NMPA to commence a phase I clinical study.

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.

# Management Discussion and Analysis

## Cerebro-cardiovascular Precision Interventional Diagnosis and Treatment Segment

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

The Group has completed the comprehensive construction of the “active + passive” innovative device platform in this segment, 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 nearly 60 in R&D teams, with over 60% of them holding master’s degrees and doctoral degrees. With a comprehensive background in medicine, pharmacy, materials, machinery, electronics, etc., it helps to achieve stable and long-term development in R&D and innovation. The Group is committed to developing this segment into a leading “cerebro-cardiovascular precision interventional therapy platform” in China and worldwide.

# Management Discussion and Analysis

## Cerebro-cardiovascular precision intervention diagnosis and treatment products

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

RESTORE DEB®, a coronary drug-coating balloon:

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



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

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



# Management Discussion and Analysis

Novasight, an intravascular dual mode imaging system:

Novasight combines two imaging technologies, namely intravascular ultrasound (IVUS) and optical coherence tomography (OCT) and can simultaneously show the ultrasound and optical image with the same direction, axis and phase, which, on one hand, better provides doctors with histological and morphological information on intravascular plaque and vascular wall, facilitating doctors to provide patients with more accurate treatment options.

On the other hand, it also reduces the diagnosis and treatment procedures for patients and reduces their medical burden. In addition, the product is the first intravascular ultrasound and optical dual mode imaging system approved by the FDA of the United States. It has been commercialized both in Canada and Japan and approved for marketing in China during the current period with a promising prospect in the field of coronary artery imaging and intracavitary interventional surgery.



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

Cai Yu® (彩鷗®) is the first OTW-designed intracranial balloon dilatation catheter in China, which is suitable for the interventional surgery for patients with non-acute symptom intracranial atherosclerotic stenosis (非急性期症狀性顱內動脈粥樣硬化性狹窄), and can deliver the balloon to the place with distal vascular lesion through guide wire during the surgery, carry out balloon dilatation, restore blood delivery, and thus improve blood flow and perfusion in blood vessels at the lesion. Cai Yu® (彩鷗®) 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® (鵝鵝®), an occlusion balloon catheter:

Ti Hu® (鵝鵝®) 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® (鵝鵝®) 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® (鵝鵝®) 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.



# Management Discussion and Analysis

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

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

Sheti® (蛇鳎®), a microcatheter:

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

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

Access management direction:

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

LEGFLOW® OTW is a drug-coated balloon for the treatment of peripheral arterial stenosis by adopting SAFEPAX patented technology. The product has completed full patient enrollment for registered clinical study, and is expected to submit a commercial registration application in China in the second half of 2023.

# Management Discussion and Analysis

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. It is expected that an application for commercialization registration in China will be submitted in the second half of 2023.

aXess, a global innovative endogenous tissue repair product:

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

# Management Discussion and Analysis

Structural heart disease direction:

Saturn, a global innovative mitral valve replacement system:

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

Electrophysiology and heart failure direction:

HeartLight X3, a global innovative laser ablation platform:

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

# Management Discussion and Analysis

## 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. It has promoted the formulation and publication of over 40 national and industrial standards and is in the process of promoting the formulation of over 20 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 and the industrial foundation transformation project of the PRC to ensure the safety and stability of the supply chain and industrial chain of high quality amino acid in China.

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 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.

# Management Discussion and Analysis

## **New technology:**

With synthetic biology as the core and after years of R&D and innovation, we have currently 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. Currently, the Group has established long-term strategic cooperation relationship with a number of scientific research institutions such as Tsinghua University, Wuhan University, East China University of Science and Technology, Tianjin University of Science and Technology, under which, a new amino acid fermentation technology and an enzyme expression system were developed and several patented technologies in relation to strains for different chassis cells have been completed. Meanwhile, the technological development of cell culture media-level amino acid has been further deepened, providing technical support to the cell cultivation application study of amino acids, which is the key raw material of cell media required for biological drugs. 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.

## Management Discussion and Analysis

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). There are 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), the Provincial Hidden Champion Enterprises and the 15th China Crop Protection Industry Association First Prize for Technological Innovation (第十五屆中國農藥工業協會技術創新一等獎).

### High quality:

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

# Management Discussion and Analysis

## 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 Group have obtained the U.S. FDA approval and was officially commercialized in the United States for sales in 2021. In the first half of this year, two functional foods that help control weight and sleep developed by the Group were approved for commercialization in China.

## Internationalization:

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

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

# Management Discussion and Analysis

## FINANCIAL REVIEW

### Revenue and profit

For the six months ended 30 June 2023, the business of the Group recorded steady growth. For the six months ended 30 June 2023 it recorded revenue of approximately HK\$5,989.49 million (for the six months ended 30 June 2022: HK\$5,212.58 million), representing an increase of approximately 14.9% as compared to the corresponding period of last year. If disregarding the exchange rate fluctuation between RMB and HK\$, it was increased by approximately 22.6% as compared with the same period of 2022. During the current review period, the net profit for the period attributable to owners of the Company amounted to approximately HK\$1,029.35 million. If disregarding the effect from fair value change of investment in Telix amounted to approximately HK\$229.15 million and an one-off penalty amount to approximately HK\$323.39 million, the net profit for the period attributable to owners of the Company amounted to approximately HK\$1,123.60 million, with an increment of approximately 3.1% as compared with the corresponding period of last year. If disregarding the exchange rate fluctuation between RMB and HK\$, it was increased by approximately 10.0% as compared with the same period of 2022. The Group's gross profit margin during the current period was approximately 64.6%, while it was approximately 62.5% in the same period of 2022.

### Distribution costs and administrative expenses

For the six months ended 30 June 2023, the Group's distribution costs and administrative expenses were approximately HK\$1,637.68 million and HK\$695.89 million respectively as compared to approximately HK\$1,373.12 million and HK\$550.76 million respectively for the corresponding period in 2022. The distribution costs during the current period increased by approximately 19.3% was mainly due to the substantial increment of revenue recorded during the current period. The overall administrative expenses also increased by approximately 26.4% as compared to the corresponding period of last year since the Group continuously increased the contribution in research and development.

### Finance costs

For the six months ended 30 June 2023, the Group's finance costs were approximately HK\$113.23 million as compared to approximately HK\$63.21 million for the corresponding period in 2022. The increase in finance costs was due to certain financing arrangements in response to business expansion and higher finance costs due to US dollar interest rate hike.



# Management Discussion and Analysis

## R&D and project investment

For the six months ended 30 June 2023, the Group continuously invested resources in the stages of research project and introduction of innovative projects. If including the R&D expenses and also the capitalized R&D expenses, prepayments for new projects and other investments, the Group's investment in R&D and various projects throughout the first six months of 2023 is approximately HK\$497 million.

## Receivables and payables

For the six months ended 30 June 2023, trade and other receivables of the Group amounted to approximately HK\$3,551.42 million, representing an increase of approximately HK\$554.04 million as compared to the balance in 2022, mainly due to the increase in trade receivables of approximately HK\$984.56 million as compared to the closing balance of last year. This is mainly a result of the increase in business during the current period, and also as general market practise it will put more force to collect receivables at the year end and thus the trade receivable year-end balances always recorded comparatively lower.

For the six months ended 30 June 2023, the Group's trade and other payables amounted to approximately HK\$2,886.29 million, representing an increase of approximately HK\$398.17 million as compared to the balance in 2022, mainly due to the increase in trade and bills payables of approximately HK\$161.59 million as a result of the increase in business during the period. Furthermore, in order to cope with the expansion of business scope, we accrued additional selling and operating expenses such as salaries, marketing and promotion expenses and R&D expenses amounted to approximately HK\$166.33 million.

# Management Discussion and Analysis

## Significant Investments

The Group's investments with value over 5% of value of its total assets are considered as significant investments. In respect of the Group's significant investments as at 30 June 2023, set out below are certain information on those investments and the comparative figures as at 31 December 2022 and 2021:

Name	Carrying value of interests in associates as at:			Size relative to the Group's total assets as at:		
	30 June 2023 (HK\$, million)	31 December 2022 (HK\$, million)	31 December 2021 (HK\$, million)	30 June 2023	31 December 2022	31 December 2021
Grand Pharma Sphere Pte Limited ("Grand Pharma Sphere") (Note A)	5,263	5,074	4,873	23.4%	22.7%	23.2%
Shanghai Xudong Haipu Pharmaceutical Company Limited ("Xudong Haipu") (Note B)	2,196	2,136	2,217	9.8%	9.5%	10.5%
Others (Note C)	418	494	977	1.9%	2.2%	4.6%
<b>Total interests in associates</b>	<b>7,877</b>	<b>7,704</b>	<b>8,067</b>	<b>35.1%</b>	<b>34.4%</b>	<b>38.3%</b>

Note A: Grand Pharma Sphere is the holding company of a group of companies principally engaged in the manufacturing and sales of interventional oncology products. The Group effectively owned approximately 57.98% equity interests of it. For the six months ended 30 June 2023, the Group's share of loss in Grand Pharma Sphere was approximately HK\$57.2 million (for the year ended 31 December 2022 and 2021: approximately HK\$41.0 million and HK\$9.8 million respectively).

Note B: Xudong Haipu and its subsidiaries is a group of companies principally engaged in the manufacturing and sales of pharmaceutical injections of various volumes. The Group effectively owned 55% equity interests of it. For the six months ended 30 June 2023, the Group's share of profit in Xudong Haipu was approximately HK\$54.8 million (for the year ended 31 December 2022 and 2021: approximately: HK\$110.3 million and HK\$279.4 million respectively).

Note C: Others represents the aggregate of carrying value of interests in various associates, in which none of these investments individually accounted for over 5% of the total assets of the Group as at 30 June 2023, and 31 December 2022 and 2021.

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

# Management Discussion and Analysis

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

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

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

## Research and development

The Group has sufficient innovation pipeline. During the Period, there were accumulatively 133 projects under research and 48 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 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.

# Management Discussion and Analysis

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

In the cerebro-cardiovascular precision interventional diagnosis and treatment 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 nearly 700 R&D personnel, of which more than 400 are master's degree and doctoral degree holders, accounting for over 60%. All professional leaders and core team members of each segment have academic background in clinical medicine or pharmacy, while some of whom also have overseas education or working experience.

## Development of Generic Drugs

During 2023 up to the date of this report, Eplerenone Tablets, digoxin injection, warfarin sodium tablets, ophthalmic balanced salt solution (15ml), moxifloxacin hydrochloride eye drops and sodium hyaluronate eye drops have been issued drug registration certificates by the NMPA, among which the Eplerenone Tablets is the first generic product being approved for commercialization in China, and the ophthalmic balanced salt solution (15ml) is the first generic product of such specification being approved for commercialization in China.

## Consistency Evaluation

During 2023 up to the date of this report, digoxin injection, warfarin sodium tablets, ophthalmic balanced salt solution (15ml), moxifloxacin hydrochloride eye drops, sodium hyaluronate eye drops, tramadol hydrochloride injection and fluorouracil injection were approved or deemed to have passed the consistency evaluation, and new applications were made for vigabatrin powder, compound tropicamide eye drops, hydroxychloroquine sulfate tablets, olopatadine hydrochloride eye drops, levofloxacin eye drops, minoxidil topical solution, metaraminol bitartrate injection, nicorandil for injection, atropine sulfate injection. At present, a total of 27 products of the Group have been approved or deemed to have passed the consistency evaluation, and other 19 products are under review.

# Management Discussion and Analysis

## Intellectual Property Protection

During the period under review, the Group added 7 new core patents, 27 new peripheral patents, and 52 new patents were granted, 31 of which were invention patents, accounting for 59.6%, and 4 new overseas patents were granted. The Group has accumulated 660 valid patents, including 371 valid invention patents. In respect of innovative medicine: the STC3141 project has filed four PCT international applications, with a total of 37 applications for patents in the same family. The core patents have been granted in the U.S., Israel and Singapore, and patent applications in other countries or regions are in progress.

## Commercialization Capability

The Group's performance continued to improve, and the continuous commercialization of innovative products and profit contribution cannot be separated from the continuous improvement of commercialization capabilities. As at 30 June 2023, the Group had nearly 3,700 sales personnel and nearly 3,300 sales personnel in the pharmaceutical area, covering over 22,000 hospitals with over 1,000 OTC sales personnel and nearly 250,000 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 220 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 and sepsis. Currently, the Group has 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 2023 up to the date of this report, the Group has carried out the following material investment, M&A and cooperation:

# Management Discussion and Analysis

- **Acquisition of equity interest in BlackSwan**

In April 2023, the Group entered into an equity acquisition agreement to acquire 87.5% equity interest in BlackSwan from its original shareholders at a consideration of not more than US\$37.5 million and BlackSwan has become a non-wholly owned subsidiary of the Group. Upon completion of this acquisition, the Group will own the global rights and interests of Lava™ and Kona™. On the one hand, these two products can form a product combination with the Group's [Yttrium-90] microspheres product, which is expected to expand the indications of the [Yttrium-90] microspheres product to other solid tumors; on the other hand, these two products can form a brand-new combination of drugs and devices with other chemical drugs or radiopharmaceuticals, which will expand the Group's product pipeline in the field of tumor intervention. In addition, the Group's existing global R&D team and sales network can facilitate Lava™ and Kona™ to be approved for commercialization globally and achieve high sales volume, which will develop new business markets while strengthening its existing global business.

## INVESTOR RELATIONS

The Group has been committing to improving its corporate governance to ensure the long-term development. During the period, 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.

# Management Discussion and Analysis

The Group's investor relations management is conducive to establishing a high-quality corporate image and delivering the core strategy of technological innovation. It has been highly recognized in the industry in multiple dimensions. In January 2023, it received the "Investment and Customs Pioneer Award" of the Royal Flush Enterprise.

## Other Significant Matters

### (I) Litigations

With reference to the disclosure in the annual reports of the Company between 2016 to 2022, 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 30 June 2023, the court has concluded 74 cases, and 1 case is under hearing processes at the people's court. Among the final and effective judgements, Tianjin Jingming has paid the compensation and the related legal charges of approximately RMB39,015,000 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.

# Management Discussion and Analysis

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 (recovered) 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 case has been applied to the People’s Court for enforcement and has been accepted. The Group has followed the judgement from the court and got back the RMB10,000,000 deposited in the bank account jointly controlled by the Group and the vendors.

## (II) Penalties

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



# Management Discussion and Analysis

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

The above fine amount accounted for approximately 3.4% and 15.6% of the audited consolidated operating income and profit attributable to the Company's holders in the most recent fiscal year of the Group respectively. The Company considers that this administrative fine will not have any material adverse impact on the business operations and financial position of the Group.

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

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

The Group made a loss provision of approximately HK\$59.65 million, representing approximately 2.9% of the profit attributable to the holder of the Company for the most recent financial year, as a result of the bankruptcy and liquidation of OncoSec, and the products of OncoSec are still in the research and development stage and have not yet hit the market, therefore, the Company considers that this matter will not have any material adverse impact on the business operation and financial position of the Group.

# Management Discussion and Analysis

## SHARE OPTION SCHEME

As at 30 June 2023 and 2022, the Company did not adopt any share option scheme and no outstanding share options.

No share options were granted or exercised under any share option scheme, and there were no outstanding share options as at 30 June 2023 and 2022.

## Share Award Scheme

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

The Group has paid to the trust established for the Scheme approximately HK\$263.37 million, and including the dividend belongs to the shares acquired previously, the trustee used approximately HK\$266.54 million to purchase 47,257,500 shares of the Company ("**Shares**") as part of the trust fund, and such Shares are held by the trustee for the benefit of the eligible participants under the trust and are the total number of award shares available for grant under the Scheme as at 30 June 2023, representing approximately 1.3% of the issued Shares of the Company. As at 31 December 2022 and 2021, the total number of award shares available for grant under the Scheme are 30,300,000 and 22,430,500 respectively, representing 0.85% and 0.63% of the issued Shares respectively. Where the trustee has received instructions from the Group to acquire Shares and necessary funds, the trustee shall acquire such number of Shares on-market at the prevailing market price as soon as reasonably practicable.

Save for the aforesaid, as at 30 June 2023, the Group did not grant any awards nor caused to pay the trustee the trust fund for purchase nor subscription of Shares. When any awards were granted later, the number of Shares to be awarded, award price, vesting criteria and vesting schedule of awards of each participant will be subject to the applicable Listing Rules and other applicable regulations by that time, and will inform the participants in the form of an award letter. The Board shall not make any award of Shares which will result in the aggregate number of the Shares awarded by the Board under the Scheme exceeding 5% of the number of issued Shares of the Company as at the adoption date of the Scheme (i.e. 177,478,557 Shares), and the maximum entitlement of each participant under the Scheme in every 12-months in aggregate shall not exceed 1% of the issued Shares as at the adoption date of the Scheme (i.e. 35,495,711 Shares).

# Management Discussion and Analysis

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

Save for the aforesaid, during the six months ended 30 June 2023, neither the Company nor any of its subsidiaries has purchased, sold or redeemed any of the Shares.

## **Employees and Remuneration Policy**

As at 30 June 2023, the Group employed 10,124 staff and workers (31 December 2022: 10,172). 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.

## **Events after the Reporting Period**

Save as disclosed above, no subsequent events occurred after 30 June 2023, which may have a significant effect, on the assets and liabilities of future operations of the Group.

### DIRECTORS' AND CHIEF EXECUTIVE'S INTERESTS AND SHORT POSITIONS IN SHARES AND UNDERLYING SHARES

As at 30 June 2023, the Directors and the chief executives of the Company, and their respective associates had the following interests in the shares and underlying shares of the Company and its associated corporations (within the meaning of Part XV of the Securities and Future Ordinance (the "SFO")) which were required to be notified to the Company and the Stock Exchange of Hong Kong Limited (the "**Stock Exchange**") pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which they are taken or deemed to have under such provisions of the SFO) or which were required, pursuant to section 352 of the SFO, to be entered in the register referred to therein or as otherwise notified to the Company and the Stock Exchange pursuant to the Model Code for Securities Transactions by Directors of Listed Issuers (the "**Model Code**"):

#### Long positions in the shares of the Company:

Name of Directors and chief executive of the Company	Capacity	Number of Ordinary shares held	Approximate percentage of the Company's issued share capital
Tang Weikun	Beneficial owner	60,000	0.00%
Zhou Chao	Beneficial owner	56,000	0.00%

Apart from the foregoing, none of the directors and chief executive of the Company or any of their spouses or children under eighteen years of age has interests or short positions in shares, underlying shares or debentures of the Company, any of its holding company, subsidiaries or fellow subsidiaries, as recorded in the register required to be kept under section 352 of the SFO or pursuant to the Model Code for Securities Transactions by Directors of Listed Issuers contained in the Listing Rules or required to be notified to the Company and the Stock Exchange pursuant to Divisions 7 and 8 of the SFO.

### SUBSTANTIAL SHAREHOLDERS

As at 30 June 2023, the following persons (other than the directors or chief executive of the Company) had an interest or short position in the shares and underlying shares of the Company which are required to be disclosed to the Company and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO, or required to be entered in the register maintained by the Company pursuant to Section 336 of the SFO.

## Other Information

### Long and short positions in the shares of the Company:

Name of Shareholders	Notes	Number of the shares interested	Nature of interests	Approximate percentage or attributable percentage of shareholding (%)
Outwit Investments Limited ("Outwit")	1	1,671,671,149 (L)	Beneficial owner	47.09 (L)
Grand (Hongkong) International Investments Holdings Limited ("Grand Investment")	1	1,671,671,149 (L)	Interest of controlled corporation	47.09 (L)
China Grand Enterprises Incorporation ("China Grand")	1	1,671,671,149 (L)	Interest of controlled corporation	47.09 (L)
Shanghai China Grand Asset Finance Investment Management Co., Limited ("Shanghai Finance")	2	286,039,153 (L)	Beneficial owner/ Interest of controlled corporation	8.06 (L)
Mr. Hu Kaijun ("Mr. Hu")	1 & 2 & 3	1,999,230,302 (L)	Interest of controlled corporation	56.32 (L)
Ms. Chau Tung	1 & 2 & 3	1,999,230,302 (L)	Beneficial owner/ Interest in spouse	56.32 (L)
CDH Giant Health I Limited ("CDH Giant")	4	356,648,142 (L)	Beneficial owner	10.05 (L)
CDH Fund V, L.P. ("CDH Fund")	4	356,648,142 (L)	Interest of controlled corporation	10.05 (L)
CDH V Holdings Company Limited ("CDH V")	4	356,648,142 (L)	Interest of controlled corporation	10.05 (L)
China Diamond Holdings V Limited ("China Diamond V")	4	356,648,142 (L)	Interest of controlled corporation	10.05 (L)
China Diamond Holdings Company Limited ("China Diamond")	4	356,648,142 (L)	Interest of controlled corporation	10.05 (L)
CNCB (Hong Kong) Investment Limited	5	208,750,000 (L)	Owned security interests in shares	5.88 (L)

## Other Information

Name of Shareholders	Notes	Number of the shares interested	Nature of interests	Approximate percentage or attributable percentage of shareholding (%)
China CITIC Bank Corporation Limited	5	208,750,000 (L)	Interest of controlled corporation	5.88 (L)
CITIC Limited	5	208,750,000 (L)	Interest of controlled corporation	5.88 (L)
CITIC Group Corporation	5	208,750,000 (L)	Interest of controlled corporation	5.88 (L)
Assicurazioni Generali S.p.A	6	179,173,959 (L)	Interest of controlled corporation	5.05 (L)
Li Zhenfu	6	179,173,959 (L)	Interest of controlled corporation	5.05 (L)
Lion River I N.V.	6	179,173,959 (L)	Interest of controlled corporation	5.05 (L)
GL Partners Capital Management Ltd.	6	179,173,959 (L)	Interest of controlled corporation	5.05 (L)

(L) denotes long position

Note:

1. Outwit is the beneficial owner of 1,671,671,149 Shares. Grand Investment, being wholly-owned by China Grand, held 99.85% equity interests of Outwit, and Ms. Chau Tung, spouse of Mr. Hu, held the remaining 0.15% equity interests. Grand Investment and China Grand are therefore deemed to be interested in 1,671,671,149 Shares pursuant to the SFO.
2. Beijing Yuanda Huachuang Investment Co., Ltd. (北京遠大華創投資有限公司), a company wholly owned by Mr. Hu, owned 70% of the equity interests of Shanghai Finance. Shanghai Finance is the beneficial owner of 255,142,148 Shares. East Ocean Capital (Hong Kong) Limited, a wholly owned subsidiary of Shanghai Finance, also holds 30,897,005 Shares. Shanghai Finance is therefore deemed to be interested in 286,039,153 Shares pursuant to the SFO.
3. China Grand is controlled and ultimately and beneficially owned by Mr. Hu. Ms. Chau Tung, spouse of Mr. Hu, is also the beneficial owner of 41,520,000 Shares. Mr. Hu and Ms. Chau Tung are therefore deemed to be interested in 1,999,230,302 Shares pursuant to the SFO.
4. CDH Giant is the beneficial owner of 356,648,142 Shares. CDH Giant is wholly-owned by CDH Fund, and pursuant to the SFO CDH Fund is therefore deemed to be interested in the 356,648,142 Shares. CDH Fund is controlled by CDH V, which in turn held as to 80% by China Diamond V. China Diamond V is in held as to 100% by China Diamond.

## Other Information

5. CNCB (Hong Kong) Investment Limited owns a security interest in 208,750,000 Shares.

China CITIC Bank Corporation Limited owns 99.05% interests in CNCB (Hong Kong) Investment Limited. China CITIC Bank Corporation Limited is owned by CITIC Limited by approximately 65.97%. CITIC Limited is owned by CITIC Group Corporation by approximately 58.13%. Pursuant to the SFO these three companies are therefore deemed to be interested in the 208,750,000 Shares.

6. GL Trade Investment Limited owns 99,438,959 Shares, and GL China Long Equity Opportunities Fund SPV LP owns 79,735,000 Shares.

Lion River I N.V. owns 49% interests of GL Trade Investment Limited and approximately 80.13% interests in GL China Long Equity Opportunities Fund SPV LP. Assicurazioni Generali S.p.A owns 100% interests of Lion River I N.V.. Pursuant to the SFO these two companies are therefore deemed to be interested in the 179,173,959 Shares. GL Partners Capital Management Limited and Li Zhenfu also declare to have the same interests in Shares through the control and/or interests in the above companies.

Save as disclosed above, as at 30 June 2023, the directors or chief executive of the Company were not aware of any other person (other than the directors or chief executive of the Company) who had an interest or short position in the shares or underlying shares of the Company which would fall to be disclosed to the Company under the provisions of Divisions 2 and 3 of Part XV of the SFO or, who is, directly or indirectly, interested in 5% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any other members of the Group, or any other substantial shareholders whose interests or short positions were recorded in the register required to be kept by the Company under Section 336 of the SFO.

### 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 Directors, all Directors have confirmed their compliance with all the relevant requirements as set out in the Model Code during the six months ended 30 June 2023.

### CODE OF CORPORATE GOVERNANCE PRACTICES

During the six months ended 30 June 2023, saved as provisions addressed below, the Company has complied with all the applicable 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 six months ended 30 June 2023.

Under the code provision F.2.2 of Part 2 of the CG Code, the chairman of the board should attend the annual general meeting. In addition, under the code provision C.1.6 of Part 2 of the CG Code, independent non-executive directors in general should attend general meeting.

The chairman of the board of the Company and each independent non-executive directors did not attend the annual general meeting of the Company held on 2 June 2023 due to other business engagements, but they had appointed the chief executive officer of the Company and also being a director appointed during the annual general meeting, Mr. Zhou Chao, attended the annual general meeting.

### **AUDIT COMMITTEE**

The Company has established the audit committee for the purpose of monitoring the integrity of the financial statements and reports, and overseeing the financial controls, risk management and 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 including the independent non-executive Directors Dr. Pei Geng and Mr. Hu Yebi.

The Group's condensed consolidated interim financial statements for the six months ended 30 June 2023 are unaudited but have 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 including the executive Director Dr. Tang Weikun and 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 including the executive Director Mr. Zhou Chao and independent non-executive Director Mr. Hu Yebi.

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

Hong Kong, 10 August 2023



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## Interim Results

The board (the “**Board**”) of directors (the “**Directors**”) of Grand Pharmaceutical Group Limited (the “**Company**”) is pleased to announce the unaudited consolidated interim results for the six months ended 30 June 2023 of the Company and its subsidiaries (collectively the “**Group**”), together with comparative figures for the previous period.

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

For the six months ended 30 June 2023

	Note	Six months ended 30 June	
		2023 HK\$'000 (Unaudited)	2022 HK\$'000 (Unaudited)
<b>Revenue</b>	3	<b>5,989,486</b>	5,212,581
Cost of sales		<b>(2,121,049)</b>	(1,952,487)
<b>Gross profit</b>		<b>3,868,437</b>	3,260,094
Other revenue and losses, net		<b>(259,137)</b>	83,644
Distribution costs		<b>(1,637,675)</b>	(1,373,124)
Administrative expenses		<b>(695,890)</b>	(550,759)
Net income from financial assets at fair value through profit or loss		<b>229,658</b>	(392,560)
Impairment provision on interests in associates		<b>(59,652)</b>	–
Share of results of associates		<b>(6,811)</b>	(48,382)
Finance costs		<b>(113,233)</b>	(63,213)
<b>Profit before tax</b>		<b>1,325,697</b>	915,700
Income tax expense	4	<b>(268,926)</b>	(217,777)
<b>Profit for the period</b>	5	<b>1,056,771</b>	697,923

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

Note	Six months ended 30 June	
	2023 HK\$'000 (Unaudited)	2022 HK\$'000 (Unaudited)
<b>Other comprehensive income/(loss), net of income tax</b>		
<i>Items that will not be reclassified to profit or loss:</i>		
Fair value gain on investment in equity instruments at fair value through other comprehensive income	12,769	4,263
Share of other comprehensive income of associates	(30,877)	1,689
<i>Items that may be reclassified subsequently to profit or loss:</i>		
Exchange difference on translation of foreign operations	(119,732)	(89,076)
Other comprehensive loss for the period, net of income tax	(137,840)	(83,124)
<b>Total comprehensive income for the period, net of income tax</b>	<b>918,931</b>	614,799
<b>Profit/(loss) for the period attributable to:</b>		
— Owners of the Company	1,029,354	710,411
— Non-controlling interests	27,417	(12,488)
	<b>1,056,771</b>	697,923

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

		<b>Six months ended 30 June</b>	
<i>Note</i>	<b>2023</b>	2022	
	<b>HK\$'000</b>	HK\$'000	
	<b>(Unaudited)</b>	(Unaudited)	
<b>Total comprehensive income/(loss) for the period attributable to:</b>			
— Owners of the Company	<b>887,173</b>	623,304	
— Non-controlling interests	<b>31,758</b>	(8,505)	
	<b>918,931</b>	614,799	
<b>Dividend</b>	6	—	
<b>Earnings per share</b>	7	—	
— Basic and diluted (HK cents)	<b>29.12</b>	20.16	

# Condensed Consolidated Statement of Financial Position

As at 30 June 2023

	Note	30 June 2023 HK\$'000 (Unaudited)	31 December 2022 HK\$'000 (Audited)
<b>Non-current assets</b>			
Property, plant and equipment	8	3,376,291	3,505,138
Right-of-use assets		447,282	436,764
Investment properties		167,316	175,112
Interests in associates		7,876,712	7,704,161
Equity instruments at fair value through other comprehensive income		584,167	567,320
Goodwill		617,114	644,047
Intangible assets		1,551,300	1,397,992
Deferred tax assets		21,685	24,585
Prepayments		806,690	1,029,022
		<b>15,448,557</b>	15,484,141
<b>Current assets</b>			
Inventories		1,107,562	1,340,466
Trade and other receivables	9	3,551,420	2,997,384
Amounts due from related companies		111,057	33,747
Financial assets at fair value through profit or loss	10	1,502,523	1,038,582
Derivative financial instrument		31,370	31,370
Pledged bank deposits		3,106	1,357
Cash and cash equivalents		693,612	1,444,014
		<b>7,000,650</b>	6,886,920

# Condensed Consolidated Statement of Financial Position

As at 30 June 2023

	Note	30 June 2023 HK\$'000 (Unaudited)	31 December 2022 HK\$'000 (Audited)
<b>Current liabilities</b>			
Trade and other payables	11	2,886,292	2,488,127
Contract liabilities	11	54,111	318,824
Bank and other borrowings		3,294,168	3,243,126
Lease liabilities		9,033	9,785
Amounts due to related companies		20,299	22,670
Amounts due to immediate holding company		2,331	2,331
Income tax payable		229,042	369,738
		<b>6,495,276</b>	6,454,601
<b>Net current assets</b>		<b>505,374</b>	432,319
<b>Total assets less current liabilities</b>		<b>15,953,931</b>	15,916,460
<b>Non-current liabilities</b>			
Bank and other borrowings		881,270	1,162,288
Lease liabilities		54,726	60,083
Deferred tax liabilities		216,494	220,148
Deferred income		228,547	265,281
		<b>1,381,037</b>	1,707,800
<b>Net assets</b>		<b>14,572,894</b>	14,208,660

# Condensed Consolidated Statement of Financial Position

As at 30 June 2023

	Note	<b>30 June 2023 HK\$'000 (Unaudited)</b>	31 December 2022 HK\$'000 (Audited)
<b>Capital and reserves attributable to owners of the Company</b>			
Share capital	12	<b>35,496</b>	35,496
Reserves		<b>14,416,026</b>	14,104,842
<b>Equity attributable to owners of the Company</b>			
		<b>14,451,522</b>	14,140,338
<b>Non-controlling interests</b>			
		<b>121,372</b>	68,322
<b>Total equity</b>		<b>14,572,894</b>	14,208,660

# Condensed Consolidated Statement of Changes in Equity

For the six months ended 30 June 2023

	Share capital	Share premium	Contribution	Statutory reserve	Safety	Translation reserve	Other reserve	FVTOCI reserve	Treasury shares	Retained profits	Equity	Non-controlling interests	Total
			Share surplus premium reserve		fund reserve						attributable to owners of the Company		
	HK\$'000	HK\$'000	HK\$'000	HK\$'000	HK\$'000	HK\$'000	HK\$'000	HK\$'000	HK\$'000	HK\$'000	HK\$'000	HK\$'000	HK\$'000
At 1 January 2022 (audited)	35,496	6,523,049	121,273	545,074	28,825	438,956	(81,686)	3,046	(143,503)	5,921,101	13,392,631	50,231	13,442,862
Profit for the period	-	-	-	-	-	-	-	-	-	710,411	710,411	(12,488)	697,923
Other comprehensive income for the period:													
Change in fair value of financial assets through other comprehensive income	-	-	-	-	-	-	-	4,263	-	-	4,263	-	4,263
Share of other comprehensive income of associates	-	-	-	-	-	-	-	1,689	-	-	1,689	-	1,689
Exchange difference on translation of foreign operations	-	-	-	-	-	(93,059)	-	-	-	-	(93,059)	3,983	(89,076)
Total comprehensive income for the period	-	-	-	-	-	(93,059)	-	5,952	-	710,411	623,304	(8,505)	614,799
Purchase of treasury shares	-	-	-	-	-	-	-	-	(41,251)	-	(41,251)	-	(41,251)
Dividend paid	-	-	-	-	-	-	-	-	-	(390,453)	(390,453)	-	(390,453)
At 30 June 2022 (unaudited)	35,496	6,523,049	121,273	545,074	28,825	346,897	(81,686)	8,998	(184,754)	6,241,059	13,584,231	41,726	13,625,957
At 1 January 2023 (audited)	<b>35,496</b>	<b>6,523,049</b>	<b>121,273</b>	<b>611,369</b>	<b>28,825</b>	<b>(355,303)</b>	<b>(81,686)</b>	<b>(98,971)</b>	<b>(187,489)</b>	<b>7,543,775</b>	<b>14,140,338</b>	<b>68,322</b>	<b>14,208,660</b>
Profit for the period	-	-	-	-	-	-	-	-	-	1,029,354	1,029,354	27,417	1,056,771
Other comprehensive income for the period:													
Change in fair value of financial assets through other comprehensive income	-	-	-	-	-	-	-	12,769	-	-	12,769	-	12,769
Share of other comprehensive income of associates	-	-	-	-	-	-	-	(30,877)	-	-	(30,877)	-	(30,877)
Exchange difference on translation of foreign operations	-	-	-	-	-	(124,073)	-	-	-	-	(124,073)	4,341	(119,732)
Total comprehensive income for the period	-	-	-	-	-	(124,073)	-	(18,108)	-	1,029,354	887,173	31,758	918,931
Purchase of treasury shares	-	-	-	-	-	-	-	-	(79,049)	-	(79,049)	-	(79,049)
Acquisition of a subsidiary	-	-	-	-	-	-	-	-	-	-	-	40,712	40,712
Dividend paid	-	-	-	-	-	-	-	-	-	(496,940)	(496,940)	(19,420)	(516,360)
Transfer	-	-	-	3,826	-	-	-	-	-	(3,826)	-	-	-
At 30 June 2023 (unaudited)	<b>35,496</b>	<b>6,523,049</b>	<b>121,273</b>	<b>615,195</b>	<b>28,825</b>	<b>(479,376)</b>	<b>(81,686)</b>	<b>(117,079)</b>	<b>(266,538)</b>	<b>8,072,363</b>	<b>14,451,522</b>	<b>121,372</b>	<b>14,572,894</b>



# Condensed Consolidated Statement of Cash Flows

For the six months ended 30 June 2023

	<b>Six months ended 30 June</b>	
	<b>2023</b> <b>HK\$'000</b> <b>(Unaudited)</b>	2022 HK\$'000 (Unaudited)
<b>Net cash generated from operating activities</b>	<b>749,142</b>	787,958
<b>Investing activities</b>		
Purchase of property, plant and equipment	<b>(227,776)</b>	(86,392)
Purchase of intangible assets	<b>(759)</b>	(156,948)
Net cash outflow from acquisition of a subsidiary	<b>(146,861)</b>	–
Addition of investments in associates	<b>(70,263)</b>	(197,165)
Acquisition of financial assets at fair value through profit or loss	<b>(136,740)</b>	(2,495)
Acquisition of financial assets at fair value through other comprehensive income	–	(437,983)
Increase in non-current prepayments	–	(129,831)
Other cash flows arising from investing activities	<b>6,862</b>	28,095
<b>Net cash used in investing activities</b>	<b>(575,537)</b>	(982,719)
<b>Financing activities</b>		
Repayments of bank loans	<b>(1,012,696)</b>	(791,832)
Proceeds from new borrowings	<b>1,067,793</b>	767,234
Dividend paid	<b>(496,940)</b>	(390,453)
Purchase of shares for share award scheme	<b>(79,049)</b>	(41,251)
Interest paid	<b>(113,233)</b>	(63,213)
Other cash flows used in financing activities	<b>(26,512)</b>	(9,621)
<b>Net cash used in financing activities</b>	<b>(660,637)</b>	(529,136)
<b>Net decrease in cash and cash equivalents</b>	<b>(625,940)</b>	(723,897)
<b>Cash and cash equivalents at 1 January</b>	<b>1,444,014</b>	1,752,860
Effect of foreign exchange rate changes	<b>(263,370)</b>	5,922
<b>Cash and cash equivalents at 30 June</b>	<b>693,612</b>	1,034,885

# Notes to the Condensed Consolidated Financial Statements

## 1. BASIS OF PREPARATION

This consolidated interim financial results has been prepared in accordance with the applicable disclosure requirements of the Rules Governing the Listing of Securities on the Main Board of The Stock Exchange of Hong Kong Limited (the “**Listing Rules**”).

This consolidated interim financial result contains consolidated financial results and selected explanatory notes. The notes include an explanation of events and transactions that are significant to an understanding of the changes in financial position and performance of the Group since the 2022 annual financial statements. This consolidated interim financial results and notes thereon do not include all of the information required for full set of financial statements prepared in accordance with Hong Kong Financial Report Standards (“**HKFRSs**”) issued by the Hong Kong Institute of Certified Public Accountants (“**HKICPA**”).

The financial information relating to the financial year ended 31 December 2022 included in this consolidated interim financial results as being previously reported information does not constitute the Company’s statutory financial statements for that financial year but is derived from those financial statements. Statutory financial statements for the year ended 31 December 2022 are available from the Company’s registered office. The auditors have expressed an unqualified opinion on those financial statements in their report dated 22 March 2023.

The accounting policies and methods of computation used in the preparation of this interim results announcement are consistent with those adopted by the Group in the 2022 annual accounts, except for the adoption of new and revised standards with effect from 1 January 2023 as detailed in note 2 below.

# Notes to the Condensed Consolidated Financial Statements

## 2. CHANGES IN ACCOUNTING POLICIES

The Group has applied the following amendments to HKFRSs issued by the HKICPA to its interim financial results for the current accounting period:

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

The application of the amendments to HKFRSs in the current period has had no material impact on the Group's financial positions and performance for the current and prior years and/or on the disclosures set out in these condensed consolidated financial statements.

# Notes to the Condensed Consolidated Financial Statements

## 3. REVENUE AND SEGMENT INFORMATION

For the six months ended 30 June 2023, the Group is principally engaged in manufacture and sales of pharmaceutical products and medical devices, bio- technology products, health products, specialized pharmaceutical ingredients and other products. The Board, 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 People's Republic of China (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	
	Six months ended 30 June		As at 30 June 2023	As at 31 December 2022
	2023 HK\$'000 (Unaudited)	2022 HK\$'000 (Unaudited)	2023 HK\$'000 (Unaudited)	2022 HK\$'000 (Audited)
The PRC	4,978,716	4,183,944	9,501,011	9,675,884
America	346,090	572,425	-	-
Europe	279,345	234,925	-	-
Asia other than the PRC	207,392	201,001	69,059	66,228
Others	177,943	20,286	-	-
<b>Total</b>	<b>5,989,486</b>	<b>5,212,581</b>	<b>9,570,070</b>	<b>9,742,112</b>

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

# Notes to the Condensed Consolidated Financial Statements

## 3. REVENUE AND SEGMENT INFORMATION *(Continued)*

### Information about major customers

For the six months ended 30 June 2023 and 2022, none of the Group's sales to a single customer amounted to 10% or more of the Group's total revenue.

## 4. INCOME TAX EXPENSES

Taxation in the condensed consolidated statement of profit or loss and other comprehensive income represents:

	<b>Six months ended 30 June</b>	
	<b>2023</b> HK\$'000 (Unaudited)	2022 HK\$'000 (Unaudited)
Current tax:		
PRC Enterprise Income Tax	<b>266,147</b>	215,974
Deferred tax	<b>2,779</b>	1,803
	<b>268,926</b>	217,777

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 periods. 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 People's Republic of China 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") being assessed by relevant government authorities 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.

# Notes to the Condensed Consolidated Financial Statements

## 5. PROFIT FOR THE PERIOD

	<b>Six months ended 30 June</b>	
	<b>2023</b>	2022
	<b>HK\$'000</b>	HK\$'000
	<b>(Unaudited)</b>	(Unaudited)
Profit before tax is stated after charging/(crediting):		
Staff costs comprises:		
— Wages and salaries	<b>817,473</b>	789,304
— Retirement benefits schemes contributions	<b>62,651</b>	57,366
	<b>880,124</b>	846,670
Depreciation of property, plant and equipment	<b>165,093</b>	153,262
Depreciation of right-of-use assets	<b>5,491</b>	6,286
Amortisation of intangible assets	<b>20,971</b>	12,991
Total depreciation and amortisation	<b>191,555</b>	172,539
Cost of inventories recognised as an expense	<b>2,121,049</b>	1,952,487
Operating leases rentals in respect of land and buildings	<b>4,988</b>	7,554
Gain on disposal of property, plant and equipment	<b>(1,115)</b>	(90)
Research and development costs	<b>355,976</b>	252,862
Written off of property, plant and equipment	<b>–</b>	1,680

# Notes to the Condensed Consolidated Financial Statements

## 6. INTERIM DIVIDEND

During the six months ended 30 June 2023, the Board declared HK\$0.14 per share or approximately HK\$496.94 million in aggregate as final dividend for the year ended 31 December 2022 (2022: HK\$0.11 per share or approximately HK\$390.45 million in aggregate).

No interim dividend has been paid or declared by the Company for the six months ended 30 June 2023 (six months ended 30 June 2022: Nil).

## 7. 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.

	Six months ended 30 June	
	2023 HK\$'000 (Unaudited)	2022 HK\$'000 (Unaudited)
<b>Earnings</b>		
Earnings for the purpose of basic earnings per share calculation	<b>1,029,354</b>	710,411

	Six months ended 30 June	
	2023 '000 (Unaudited)	2022 '000 (Unaudited)
<b>Number of shares</b>		
Weighted average number of ordinary shares for the purpose of basic earnings per share calculation ( <i>Note</i> )	<b>3,534,580</b>	3,523,037

# Notes to the Condensed Consolidated Financial Statements

## 7. EARNINGS PER SHARE *(Continued)*

Note:

As at 30 June 2023, 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 six months ended 30 June 2023 and 2022 as there were no potential dilutive ordinary shares in issue.

## 8. PROPERTY, PLANT AND EQUIPMENT

During the reporting period, the Group incurred approximately HK\$227,776,000 (for the six months ended 30 June 2022: HK\$86,392,000) on additions to property, plant and equipment.

## 9. TRADE AND OTHER RECEIVABLES

	<b>30 June 2023 HK\$'000 (Unaudited)</b>	31 December 2022 HK\$'000 (Audited)
Trade receivables, net	<b>2,078,413</b>	1,093,854
Bills receivables	<b>535,316</b>	819,880
Prepayments	<b>594,474</b>	824,215
Other tax receivables	<b>56,307</b>	68,700
Other receivables, net	<b>286,910</b>	190,735
	<b>3,551,420</b>	2,997,384



# Notes to the Condensed Consolidated Financial Statements

## 9. TRADE AND OTHER RECEIVABLES *(Continued)*

The Group generally allows a credit period of 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.

	<b>30 June 2023 HK\$'000 (Unaudited)</b>	31 December 2022 HK\$'000 (Audited)
Trade receivables	<b>2,136,734</b>	1,155,195
Less: Allowance for credit loss	<b>(58,321)</b>	(61,341)
	<b>2,078,413</b>	1,093,854

The ageing analysis of the trade receivables is as follows:

	<b>30 June 2023 HK\$'000 (Unaudited)</b>	31 December 2022 HK\$'000 (Audited)
Within 90 days	<b>1,705,012</b>	788,026
91–180 days	<b>292,091</b>	218,252
181–365 days	<b>81,310</b>	87,576
	<b>2,078,413</b>	1,093,854

# Notes to the Condensed Consolidated Financial Statements

## 10. FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT OR LOSS

	30 June 2023 HK\$'000 (Unaudited)	31 December 2022 HK\$'000 (Audited)
Equity securities listed in Hong Kong ( <i>note (a)</i> )	16,499	14,499
Listed equity security outside Hong Kong ( <i>note (a)</i> )	642,858	423,596
Investment at fair value ( <i>note (b)</i> )	843,166	600,487
	<b>1,502,523</b>	1,038,582

Notes:

- (a) Fair value was determined with reference to quoted market bid prices.
- (b) The Group's investment in wealth management products were designed at financial assets at fair value through profit or loss of which fair values are determined by reference to the quoted market bid prices available on the relevant PRC market.

## 11. TRADE AND OTHER PAYABLES AND CONTRACT LIABILITIES

	30 June 2023 HK\$'000 (Unaudited)	31 December 2022 HK\$'000 (Audited)
Trade payables	683,987	687,731
Bills payables	350,461	185,129
Accruals and other payables	1,742,951	1,517,066
Other tax payables	108,893	98,201
Total	<b>2,886,292</b>	2,488,127
Contract liabilities ( <i>note a</i> )	<b>54,111</b>	318,824

Note:

- (a) Contract liabilities in relation to sales of finished goods are expected to be settled within one year.

# Notes to the Condensed Consolidated Financial Statements

## 11. TRADE AND OTHER PAYABLES AND CONTRACT LIABILITIES *(Continued)*

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

	<b>30 June 2023 HK\$'000 (Unaudited)</b>	31 December 2022 HK\$'000 (Audited)
Within 90 days	<b>455,623</b>	516,952
Over 90 days	<b>228,364</b>	170,779
	<b>683,987</b>	687,731

## 12. SHARE CAPITAL

### Ordinary shares of HK\$0.01 each

	<b>30 June 2023</b>		31 December 2022	
	Number of shares '000 (Unaudited)	Amount HK\$'000 (Unaudited)	Number of shares '000 (Audited)	Amount HK\$'000 (Audited)
<b>Authorised:</b> Ordinary shares of HK\$0.01 each	<b>100,000,000</b>	<b>1,000,000</b>	100,000,000	1,000,000
<b>Issued and fully paid:</b> At the beginning and the end of the period/year	<b>3,549,571</b>	<b>35,496</b>	3,549,571	35,496

# Notes to the Condensed Consolidated Financial Statements

## 13. COMMITMENTS

### (a) Operating lease commitment

#### The Group as lessor

The Group sub-leases certain of its office premises under operating lease arrangement. The rental income earned during the period was approximately HK\$269,000 (2022: HK\$766,000). The Group had future minimum lease receipts from tenants under non- cancellable operating lease which fall due as follows:

	<b>30 June 2023 HK\$'000 (Unaudited)</b>	31 December 2022 HK\$'000 (Audited)
Within one year	<b>582</b>	570
In the second to fifth year inclusive	<b>74</b>	77
	<b>656</b>	647

### (b) Capital commitment

	<b>30 June 2023 HK\$'000 (Unaudited)</b>	31 December 2022 HK\$'000 (Audited)
Capital expenditure contracted but not provided for: Acquisition of property, plant and equipment	<b>204,061</b>	140,487

## 14. CONTINGENT LIABILITIES

The Group had no significant contingent liabilities as at 30 June 2023 (2022: Nil).

# Corporate Information

## EXECUTIVE DIRECTORS

Dr. Tang Weikun (*Chairman*)  
Mr. Zhou Chao (*Chief Executive Officer*)  
Dr. Shi Lin  
Mr. Yang Guang

## INDEPENDENT NON-EXECUTIVE DIRECTORS

Ms. So Tosi Wan, Winnie  
Dr. Pei Geng  
Mr. Hu Yebi

## COMPANY SECRETARY

Mr. Foo Tin Chung, Victor

## AUTHORISED REPRESENTATIVES

Dr. Tang Weikun  
Mr. Foo Tin Chung, Victor

## AUDIT COMMITTEE

Ms. So Tosi Wan, Winnie (*Chairwoman*)  
Dr. Pei Geng  
Mr. Hu Yebi

## REMUNERATION COMMITTEE

Ms. So Tosi Wan, Winnie (*Chairwoman*)  
Dr. Tang Weikun  
Mr. Hu Yebi

## NOMINATION COMMITTEE

Ms. So Tosi Wan, Winnie (*Chairwoman*)  
Mr. Zhou Chao  
Mr. Hu Yebi

## WEBSITE

[www.grandpharma.cn](http://www.grandpharma.cn)

## AUDITORS

HLB Hodgson Impey Cheng Limited Certified  
Public Accountants

## LEGAL ADVISERS

*As to Bermuda Law:*  
Conyers Dill & Pearman

*As to Hong Kong Law:*  
Loeb & Loeb LLP

## PRINCIPAL SHARE REGISTRAR

MUFG Fund Services (Bermuda) Limited  
The Belvedere Building  
69 Pitts Bay Road  
Pembroke HM08  
Bermuda

## HONG KONG BRANCH SHARE REGISTRAR

Computershare Hong Kong Investor  
Services Limited  
Shops 1712–1716, Hopewell Centre  
183 Queen's Road East, Hong Kong

## PRINCIPAL BANKERS

HSBC  
Bank of China  
Bank of Communications

## REGISTERED OFFICE

Clarendon House, 2 Church Street  
Hamilton HM 11, Bermuda

## PRINCIPAL OFFICE

Units 3302, The Center  
99 Queen's Road Central, Hong Kong