

2022

Interim Report

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

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", upon the principles of meeting the needs of patients, adapting to market development and insisting on technological innovation as well as 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.

As of the date of this report, the core products of the Group are as follows:

Ophthalmic products:

Rui Zhu® (polyvinyl alcohol eye drops)

He Xue Ming Mu tablets



Corporate Profile

Respiratory and severe disease anti-infection segment:

Qie Nuo (Eucalyptol, Limonene and Pinene Enteric Soft Capsules)

Jinsang Series (Jinsang Kaiyin, Jinsang Qingyin, Jinsang Liyan, Jinsang Sanjie)



Antiviral Oral-Liquid

Atectura®, Enerzair®



Cerebro-cardiovascular emergency segment:

Li Shu An[®] (norepinephrine bitartrate injection, epinephrine hydrochloride injection), Xin Wei Ning (tirofiban hydrochloride and sodium chloride injection), Nuo Fu Kang[®] (methoxamine hydrochloride injection), Rui An Ji (fructose sodium diphosphate oral solution), Neng Qi Lang (coenzyme Q10 tablets)



Nuclear medicine anti-tumor diagnosis and treatment segment:

Yttrium-90 microsphere injections



Cerebro-cardiovascular precision interventional diagnosis and treatment segment:

RESTORE DEB[®] (a coronary drug-coating balloon), APERTO[®] OTW (a drug coated balloon for dialysis access), Cai Yu[®]



Biotechnology:

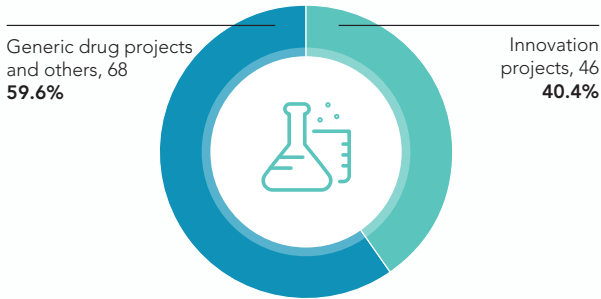
High-quality amino acids and their derivatives

Corporate Profile

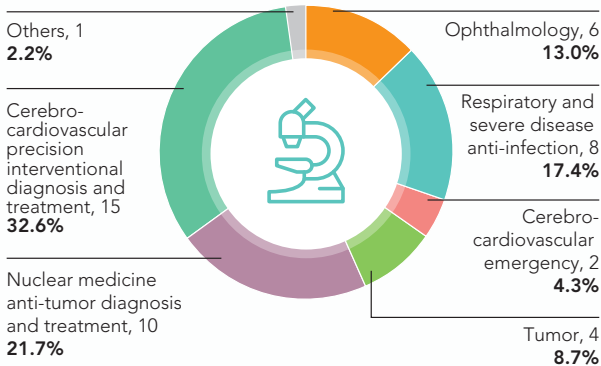
RESEARCH AND DEVELOPMENT



Overview of 114 R&D projects



Overview of 46 innovative projects by therapeutic areas



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	GNP00136 (BRM421)	Dry eye	●					●				
			GNP00153 (CBT-001)	Pterygium	●					●				
			GNP00833	Ocular inflammation	●					●				
			GNP00884	Myopia prevention and control	●●									
	Respiratory, severe disease and anti-infection	Respiratory	Severe disease and anti-infection	Ryaltris	Allergic rhinitis					●				
				STC3141	Sepsis COVID-19 ARDS		●		●					
		Emergency	Emergency	APAD	Sepsis									
				GNP00085	Parainfluenza	●●	●							
				GNP00816	Anaphylaxis	●	●				●			
	Anti-tumor	Immunotherapy	TAVO	REV-001	Colorectal cancer Metastatic melanoma Triple-negative breast cancer					●				
				A002	Squamous cell carcinoma 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	Malignant liver tumor						●●
							Thermosensitive embolic agent product	Hypervascular parenchymal organs tumor	●					
	Lava	Cerebral aneurysm									●			
AuroLase*	Prostate cancer	●												
TLX591 (177Lu-rosapatumab)	Prostate cancer	●							●					
TLX591-CDx (68Ga-PSMA-11)	Prostate cancer - diagnosis		●						●					
TLX599-CDx (90mTc-EDDA/HYNIC-IP-SMA)	Prostate cancer - diagnosis	●						●						
TLX250 (177Lu-girentuximab)	Clear cell renal cell carcinoma	●					●							
TLX250-CDx (89Zr-girentuximab)	Clear cell renal cell carcinoma - diagnosis	●	●					●						
TLX101 (131I-IPA)	Glioblastoma	●					●							
TOCscan®	Gastroenteropancreatic neuroendocrine tumor - diagnosis	●						●						
ITM-11	Gastroenteropancreatic neuroendocrine tumor	●					●							
ITM-41	Malignant tumor bone metastases	●			●									
Cerebro-cardiovascular precision interventional diagnosis and treatment	Coronary artery vascular intervention	Restore DCB*	De novo coronary artery lesions and in-stent restenosis							●●				
			Novasight	Coronary artery imaging and intracavitary interventional surgery					●					
		Access management	Peripheral vascular intervention	IVL CAD	Moderate/ severe coronary artery/ peripheral arterial calcification	●								
				IVL PAD		●								
	Neurointervention	APERT® DCB	Arteriovenous fistula treatment of hemodialysis	●					●●					
			aXess	Hemodialysis	●		●							
		LEGFLOW® DCB	Peripheral vascular disease					●						
		Stent retriever	Ischemic stroke					●						
		Intracranial balloon dilatation catheter	Intracranial stenosis											
		Guiding catheter	Access					●						
		Microcatheter	Access					●						
		Occlusion balloon	Access					●						
	DCB	Intracranial stenosis	●											
	Structural heart disease	Structural heart disease	Satum	Mitral regurgitation	●●									
Electrophysiology and heart failure	Electrophysiology/Heart failure	HeartLight X3	Atrial fibrillation		●				●					
		CoRISMA	Heart failure	●●										

● Mainland China

● Overseas

* AuroLase: The Group owns the right of first negotiation for that product

Corporate Profile

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

August

The Group entered into an equity acquisition agreement with Hubei Bafeng to acquire 100% equity interests of Hubei Bafeng with no more than RMB270 million. After the completion of the acquisition, the Group would have 24 registration numbers of amino acid APIs, accounting for more than 70% of the registration numbers in the same segment, making it the pharmaceutical company with the most registration numbers for amino acid APIs in China. This further reinforced the Group's leading position in the high-quality amino acid segment.

The application for the Group's RDC drug TLX591-CDx for the diagnosis of prostate cancer and the drug TLX250-CDx for the diagnosis of ccRCC have been officially accepted by the NMPA.

July

The Group's global innovative drug STC3141 in the field of severe disease completed the enrollment and dosing of all patients in the phase Ib clinical trial for the treatment of ARDS in China. The research report was expected to be completed within the next 6 months; and successfully achieved the primary clinical study endpoint in the Phase IIa clinical trial for the treatment of severe COVID-19 conducted in Europe.

The Group and XELTIS entered into a strategic cooperation agreement on equity investment and product introduction, pursuant to which, the Group acquired approximately 11% equity interests in XELTIS with EUR15 million in total, in order to obtain aXess, a global first-of-its-kind restorative device, and relevant rights regarding other new products in the field of hemodialysis developed under the same technology platform in the Greater China region. Pursuant to the agreement, the Group had the pre-emptive negotiation right for products of XELTIS developed in other indication areas in the Greater China region.

June

Beijing Purevalley (an indirect non wholly-owned subsidiary of the Company) and Sirtex Medical entered into a distribution agreement, pursuant to which Sirtex Medical has appointed Beijing Purevalley as Sirtex Medical's exclusive distributor for the resale of the products in the PRC.

May

The Group has reached a strategic cooperation agreement with Eye Hospital, WMU. The Group would, according to the R&D progress, pay RMB70 million by phases to obtain from Eye Hospital, WMU relevant rights regarding the technology used in the prevention and treatment of myopia and the new ophthalmic preparation (GPN00884) product in the Greater China Region, and subsequently may pay certain sales commission subject to the sales conditions of related products.

April

Grand Pharma (China), Shanghai Shetai and Wuhan Shetai entered into a capital injection agreement. Grand Pharma (China) and Shanghai Shetai, as the existing shareholders of Wuhan Shetai, agreed to increase the registered capital of Wuhan Shetai by RMB65,000,000, where Grand Pharma (China) and Shanghai Shetai shall make additional capital contributions of RMB21,450,000 and RMB43,550,000, respectively, in proportion to their respective existing shareholdings in Wuhan Shetai.

The Group's global innovative drug STC3141 in the field of severe disease had been approved in Belgium to conduct a phase Ib clinical study for the treatment of sepsis.

The multicenter Phase III clinical trial of Ryaltris Compound Nasal Spray, the Group's global innovation drug for the treatment of seasonal allergic rhinitis and rhinoconjunctivitis in patients aged 12 years and above, completed the first patient enrollment in China.

February

The Group entered into a product licensing agreement with Novartis, a world-renowned company in Switzerland. The Group would pay Novartis not more than US\$20 million and a certain percentage of the sales commission, to obtain the exclusive commercialization rights of Enerzair® and Atecura®, two global innovative compound preparations for the treatment of asthma from Novartis in mainland China.

The Group entered an equity investment agreement with ITM, whereby the Group would subscribe approximately 1.31% shares of ITM at the consideration of EUR25 million.

January

The Group received the approval from the NMPA for commercialization its global blockbuster innovative product, Yttrium-90 microsphere injections, for the treatment of patients with unresectable colorectal liver metastases who have failed standard of care. The product would 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.

Corporate Profile

DEFINITIONS

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

“APERTO® OTW”	Paclitaxel Releasing Hemodialysis Shunt Balloon Dilatation Catheter
“ARDS”	Acute Respiratory Distress Syndrome
“Beijing Purevalley”	Beijing Purevalley Biotechnology Co., Ltd (北京普爾偉業生物科技股份有限公司), a limited liability company established in the PRC and an indirect non wholly-owned subsidiary of the Company
“ccRCC”	Clear cell renal cell carcinoma
“COVID-19”	2019 novel coronavirus disease
“FDA”	United States Food and Drug Administration
“Grand Pharm (China)”	Grand Pharmaceutical (China) Company Limited, a company incorporated in the PRC, being a subsidiary of the Company owned as to 99.84%
“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
“Hubei Bafeng”	Hubei Provincial Bafeng Pharmaceuticals and Chemicals Share Co., Ltd.
“ICS”	Inhaled Glucocorticoid
“IND”	Investigational New Drug Applications
“ITM”	ITM Isotope Technologies Munich SE

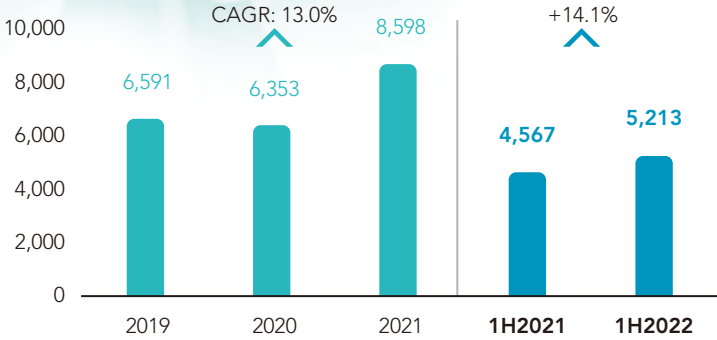
"LABA"	Long-acting β 2 agonist
"LAMA"	Long-acting muscarinic antagonist
"LEGFLOW® OTW"	Paclitaxel Releasing Peripheral Balloon Dilatation Catheter
"mRNA"	messenger RNA
"NMPA"	National Medical Products Administration
"Novartis"	Novartis AG.
"RDC"	Radionuclide-drug conjugate
"RESTORE DEB®"	Paclitaxel Releasing Coronary Balloon Dilatation Catheter
"Shanghai Shetai"	Shanghai Shetai Medical Technology Limited, a company established in the PRC with limited liability
"Sirtex"	Sirtex Medical Pty Ltd
"Sirtex Medical"	Sirtex Medical Singapore Pte Ltd.
"TAVO™"	Tavokinogene Telseplasmid
"Telix"	Telix Pharmaceuticals Limited
"Tianjin Jingming "	Tianjin Jingming New Technology Development Co., Ltd.
"WMU"	WenZhou Medical University
"Wuhan Shetai"	Wuhan Shetai Medical Technology Co., Ltd, a company established in the PRC with limited liability and owned as to 33% by Grand Pharma (China) and 67% by Shanghai Shetai
"XELTIS"	XELTIS AG

Corporate Profile

FINANCIAL SUMMARY

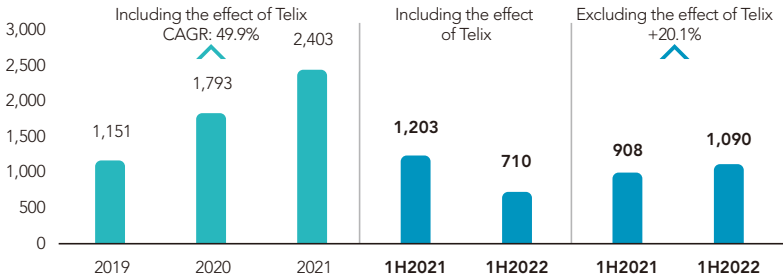
Revenue

Unit: HK\$ million



Net profit attributable to the owners of the Company

Unit: HK\$ million



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

INDUSTRY REVIEW

In the first half of 2022, with the further rapid spread of the Omicron variant, it posed certain challenges to the global pandemic prevention and control. The war, coupled with the global inflation brought by the pandemic, hindered the process of economic recovery. In the first half of the year, the domestic pandemic in China was scattered, especially in Shanghai, Beijing and other major economic cities which are among the largest pharmaceutical markets, gathering places for pharmaceutical companies or important ports in China. The production and operation of enterprises and international trade activities were affected to varying degrees in the second quarter of the year. The economic growth in China slowed down in the first half of the year, with an increase in GDP of approximately 2.5% as compared to the corresponding period of last year, while the added value of the pharmaceutical manufacturing industry increased by approximately 0.9% year-on-year. The capacity utilization rate of the pharmaceutical manufacturing industry showed a downward trend as compared to the corresponding period of last year. On the demand side, the total retail sales of Chinese and Western medicines in the first half of the year increased by approximately 9.7% year-on-year, which was significantly higher than the growth rate of the total retail sales of consumer goods in the Chinese Society and highlighted the rigid demand of the pharmaceutical industry. With the acceleration of aging population and the continuous growth of residents' medical expenditure, there is a clear long-term demand in the pharmaceutical industry.

Since the beginning of the year, China has successively issued a number of programmatic policy documents, including the "14th Five-Year Plan", the government work reports, the revision of the implementation regulations of drug management, and the key tasks of deepening medical reform, which fully reflected the government's emphasis on the pharmaceutical industry and indicated the direction for the development of the industry. At present, for Chinese pharmaceutical companies, severe challenges and innovation opportunities coexist. Centralized and volume-based procurement becomes normalized, with a gradual increase in its coverage batch by batch. As generic drug enterprises are facing downward pressure, innovation and internationalization are the core driving forces for the development of the pharmaceutical industry. With the improvement of the drug evaluation and approval system, the full implementation of the Marketing Authorization Holder (MAH) system, the accelerated integration of the drug registration management system with international standards, the dynamic adjustment of the medical insurance catalogue and the implementation of a series of encouraging policies and reforms on the R&D of innovative drugs, the innovation and R&D of China's pharmaceutical industry ushered in a benign development pattern. Recently, pharmaceutical innovation policies have

Management Discussion and Analysis

become more scientific, and many R&D guiding principles have contributed to technological innovation. The mechanism for negotiating the medical insurance catalogue access is becoming more mature, which highlights the innovation orientation and accelerates the market entry process of drugs with high clinical value. Commercial health insurance represented by the inclusive insurance also plays a role in promoting the use of innovative drugs.

BUSINESS REVIEW

Facing various pressures and challenges such as the complex and changeable external environment, frequent outbreaks of pandemic in China, and declining market demand, the Group concentrated its efforts, focused on implement, firming its confidence and overcome difficulties, striving to achieve its annual operating goals. During the period, the Group recorded revenue of approximately HK\$5,212.58 million representing an increase of approximately 14.1% as compared to the corresponding period in 2021, while the gross profit margin amounted to approximately 62.5%, representing a decrease of approximately 0.8 percentage points as compared to the gross profit margin of 63.3% for the corresponding period in 2021, but representing an increase of approximately 1.5 percentage point as compared to the year 2021. The total profit for the period attributable to owners of the Company was approximately HK\$710.41 million, representing a decrease of approximately 40.92% as compared to the corresponding period in 2021. The decrease was mainly due to the loss on fair value changes of the investment in Telix of approximately HK\$379.56 million. Excluding the loss on fair value changes of the investment in Telix, the profit for the period attributable to owners of the Company was approximately HK\$1,089.97 million, representing an increase of approximately 20.07% as compared to approximately HK\$907.75 million for the corresponding period in 2021.

During 2022 up to the date of this report, the Group had a total of 19 R&D milestones, including 14 innovative products and 5 generic drugs.

Innovative products

Nuclear medicine anti-tumor diagnosis and treatment:

- Yttrium-90 microsphere injections, a blockbuster product of the nuclear medicine anti-tumor segment, was approved for commercialization in China;
- The Investigational New Drug (“IND”) application for the global innovative nuclear medicine product TLX591-CDx was submitted and accepted in China;
- The IND application for the global innovative nuclear medicine product TLX250-CDx was submitted and accepted in China;

Management Discussion and Analysis

Cerebro-cardiovascular precision interventional diagnosis and treatment:

- OTW intracranial balloon dilatation catheter Cai Yu® (彩鹞®), a neurointerventional product, was approved for commercialization in China;
- The application for NOVASIGHT Hybrid, a new medical imaging device for intracavity diagnosis, was accepted for commercialization in China;
- aXess, a global innovative endogenous tissue repair product for hemodialysis, was introduced to expand the R&D product pipeline;

Respiratory and severe disease anti-infection:

- Enerzair® and Ateectura®, the two global innovative compound preparations for the treatment of asthma, were introduced to expand the existing product pipeline;
- The first patient was dosed in the phase III clinical trial of Ryaltris compound nasal spray, an innovative product, in China;
- The phase IIa clinical trial of STC3141, a global innovative drug, for the treatment of severe novel coronavirus (“**COVID-19**”) in Europe successfully met the primary clinical trial endpoint;
- The phase Ib clinical trial of STC314, a global innovative drug, for the treatment of acute respiratory distress syndrome (“**ARDS**”) in China has completed the enrolment of all patients;
- STC314, a global innovative drug, was approved to commence the phase Ib clinical trial for the treatment of sepsis in Belgium;

Ophthalmology:

- GPN00884, a new ophthalmic preparation for myopia control, was introduced to expand the R&D product pipeline;

Emergency drug:

- The IND application for a pre-filled epinephrine automatic injection pen used for the treatment of severe allergic reactions was submitted and accepted in China.

Management Discussion and Analysis

Generic drugs

The Group has 5 products approved for commercialization, among which, the epinephrine hydrochloride injection (pre-filled) is the first type 3 generic products being approved for commercialization in China.

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

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

R&D centers:

The International R&D Center in Optics Valley, Wuhan, the mRNA R&D Center in Nanjing and the Innovative Device R&D and Production Base in Wuhan were officially put into operation, which further enhanced the Group’s R&D capabilities in innovative drugs and mRNA technology, as well as the capability to localize innovative medical devices and the independent R&D and production capacity.

Production bases:

The amino acid production base of the Group in Xiantao City, Hubei Province, China, has officially started construction, and will be officially put into production in 2023. The operation of the production base will further expand the production capacity of a number of high-quality amino acid varieties of the Group and provide sustainable momentum for the Group’s amino acid segment to grow profitably in the future.

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 (2021 version). In July 2022, the Group ranked 24 in the “Top 100 Chinese Chemical Pharmaceutical Companies of the Year” list (「年度中國化藥企業TOP100」榜單).

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 mRNA R&D Centers in Nanjing/Belgium, the DNA R&D Center in the United States and the Glycomics R&D Center in Australia 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.

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

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

Management Discussion and Analysis



The DNA R&D Center in the United States focuses on the development of DNA immuno-antitumor drugs, establishing the TAVOTM cytokine therapy platform and the electro transfer drug delivery platform, which expresses immune stimulating factor locally in tumors through electro transfer, enabling patients who are resistant or unresponsive to immunotherapeutic drugs can respond to immunotherapy drugs again and achieve long-term therapeutic effects. As a highly scalable platform, TAVOTM can be expanded to treat a wide range of tumors in the future.

The Glycomics R&D Center in Australia is based at the Australian National University and Griffith University for the development of glycomics-based anti-infection drugs. Griffith University is one of the few research institutions in the world focusing on glycomics and one of the world's largest in this field, with a focus on the discovery and development of drugs, vaccines and diagnostics for infectious diseases worldwide, and a staff of over 200 clinical and basic science researchers and internationally renowned professors.

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.

Management Discussion and Analysis

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) (《我國驗板腺功能障礙診斷與治療專家共識(2017年)》). Rui Zhu has good brand recognition and was awarded the China Well-known Trademark in 2017; and was awarded the CPEO Gold Award for five consecutive years from 2016 to 2020, namely the “Healthy China Brand List” and the “China Pharmaceutical Brand List” by Menet in 2021. 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 (2021 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.

Management Discussion and Analysis



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 registration work is undergoing steadily in China. It is expected that the IND application will be submitted in the second half of 2022.

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

It is a potent glucocorticoid and has efficient local anti-inflammatory and strong capillary contraction effect. Its unique nanopreparation technique effectively eliminates the risk of low bioavailability and safety due to the low water solubility of hormones products. The completed phase II clinical trial in the United States showed that the product has good effectiveness and safety at lower concentrations. Currently, the registration work of the product is undergoing steadily in China. It is expected that the IND application will be submitted in the second half of 2022.

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

It is small molecule peptide eye drops that can accelerate the division and proliferation of limbal stem cells, and in turn stimulate the repair of ocular surface. According to the phase II clinical study data completed in the United States, compared to cyclosporine eye drops currently commercialized for the treatment of dry eye, BRM421 has high safety and low irritation, as well as the potential to quickly alleviate the signs and symptoms of dry eye within two weeks. Currently, the registration work of the product is undergoing steadily in China. It is expected that the IND application will be submitted at the end of 2022.

Management Discussion and Analysis

GPN00884, a new eye preparation for myopia control:

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

Respiratory and Severe Disease Anti-infection Segment

The Group has nearly 10 products on sale in the respiratory and severe disease anti-infection segment, covering a wide range of indications such as rhinitis, pharyngitis, bronchitis and pneumonia. 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) are both exclusive products nationwide, and a number of products are in the leading position in their respective segments. Antiviral Oral-Liquid* (抗病毒口服液) is also the Group’s key product, which can play an important role in the prevention and treatment of influenza and COVID-19.

It is expected that in the second half of 2022, the Group will have two global innovative inhalers for the treatment of asthma to step into commercialization stage, of which are dual combination and triple combination respectively. The innovative strategic plan in this field focuses on the unmet significant clinical needs, with a number of products under research, covering allergic rhinitis, sepsis, ARDS, parainfluenza and COVID-19, etc. Among which, the product for the treatment of allergic rhinitis has entered the registration clinical stage. STC3141, a global innovative drug for severe diseases such as sepsis, has received seven clinical approvals in five countries and is progressing smoothly in the international global multi-center clinical trial, while the world’s first new parainfluenza drug has completed compound screening and entered the pre-clinical stage. 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, Antiviral Oral-Liquid, Nuo Tong, Atectura® and Enerzair®, etc.

Qie Nuo:

It is a soluble and phlegm-free drug for viscosity, and is suitable for acute and chronic rhinosinusitis as well as respiratory diseases such as acute and chronic bronchitis, pneumonia, bronchial dilation, pulmonary abscess, chronic obstructive pulmonary disease, bacterial infection in the lungs, tuberculosis, and silica lungs. It can also be used for bronchoscopic angiography to facilitate the discharge of contrast medium. It is a national exclusive product independently developed by the Group with two separate types of drugs for adult and children's use and was included in the National Reimbursement Drug List in 2017 and the National Essential Drug List in 2018 respectively. Currently, there are 11 guidelines and 12 expert consensus recommending the use of viscosity dissolving promoters for clinical use. Among them, 9 guidelines and 5 expert consensus explicitly recommend eucalyptol, limonene and pinene enteric soft capsules or its active ingredients for clinical treatment, such as the Diagnosis and Treatment Guidelines for Cough (2021) (《咳嗽的診斷與治療指南(2021)》), the Guidelines for Rational Use of Drugs for Chronic COPD in Primary Care 2020 (《慢性阻塞性肺疾病基層合理用藥指南(2020)》), the Chinese Expert Consensus — Chinese (2015) on High-secretion Management of Gastrointestinal Adhesion for Chronic Gastric Diseases (《慢性氣道炎症性疾病氣道黏液高分泌管理中國專家共識 — 中文版(2015)》), etc. The clinical status is prominent, and the level of recognition among doctors and patients is high, continuing to lead the market of oral cough relieving and phlegm relieving drugs.

Jinsang Series Products:

They are exclusive products nationwide, covering all the diseases of the throat, among which, Jinsang Sanjie Capsule is used for the treatment of chronic hoarseness disease caused by heat and poisoning storage and airtight blood stasis (vocal nodules, polyp of vocal cords, thickening of mucosa of vocal cords) and the resulting hoarseness. Jinsang Sanjie Capsule has been widely used in clinical application for more than 30 years since its commercialization. Jinsang Liyan Capsule is the only Chinese patent medicine for the treatment of throat diseases caused by intraocular obstruction of liver depression and phlegm and humidification. It is also an ideal medicine for the treatment of pharyngeal symptoms in clinical operation, gastroesophageal reflux pharyngitis, and chronic and thick pharyngitis. Jinsang Kaiyin Capsule is designed for the rapid effect of acute pharyngitis as well as throat redness, swelling, heat, pain and hoarseness caused by acute pharyngitis. Several products have been included in the Guidelines for the Diagnosis

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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 were included in the National Reimbursement Drug List in 2021, and Jinsang Kaiyin and Qingyin are dual cross-over products with both prescription and over-the-counter drugs.

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

Ateectura® (indacaterol acetate and mometasone furoate powder for inhalation) is a global innovative dual combination of inhaled glucocorticoid (“ICS”) mometasone furoate and long-acting $\beta 2$ agonist (“LABA”) indatrol acetate for maintenance treatment of adults and adolescents over 12 years of age with asthma who are not adequately controlled with inhaled glucocorticoids or long-acting $\beta 2$ agonists and low-dose inhaled corticosteroids. Enerzair® (indacaterol acetate, glycopyrronium bromide and mometasone furoate powder for inhalation) is a global innovative triple combination of ICS mometasone furoate, LABA indatrol acetate and the long-acting muscarinic antagonists (“LAMA”) for the maintenance treatment of adult asthma patients who are not adequately controlled with a combination of long-acting $\beta 2$ agonists and inhaled glucocorticoids. These two innovative products have been approved for commercialization by the National Medical Products Administration of the People’s Republic of China (the “NMPA”) in the second quarter of 2021, which are both new-generation compound inhalation preparations with once-daily dosing to further improve patient compliance. As the first combination of ICS+LABA+LAMA for asthma treatment in China, Enerzair® filled the gap in clinical trials. The combination of Ateectura®+Enerzair® can widely cover the population undergoing long-term asthma treatment. The two innovative products will be officially commercialized to the market by the Group in the second half of 2022.

Management Discussion and Analysis

Antiviral Oral-Liquid:

Antiviral Oral-Liquid, used for wind-heat colds, influenza, is the only product which has sugar free specification that is produced and sold among the TOP10 brands of antiviral oral-liquid market share in retail channels. The product was included in 2017, 2019 and 2021 Edition of the National Reimbursement Drug List. It was recommended in the Guidelines for the diagnosis and treatment of hand, foot, and mouth disease (2018 Edition) of Ministry of Health, was included in the Expert Consensus on Clinical Application of Antiviral Oral-Liquid in the Treatment of Influenza* (《抗病毒口服液治療流感臨床應用專家共識》) formulated by the expert group related to traditional Chinese medicines in 2020; and was included in the Expert Consensus on the Prevention and Treatment of COVID-19 with Proprietary Chinese Medicines* (《中成藥防治新型冠狀病毒肺炎專家共識》) recommending treating mild/common patients with Proprietary Chinese Medicines in 2022.

Innovative R&D pipeline

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

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

Ryaltris is a new compound nasal spray for glucocorticoid and antihistamine drugs. Currently, the product has been approved for commercialization in the United States, Australia, South Korea, Russia, the United Kingdom, the European Union as well as other countries and regions. In terms of registration in China, it was approved to commence a phase III clinical trial for the treatment of allergic rhinitis and nasal conjunctivitis in patients aged 12 and above in October 2021, in which the first patient was enrolled in April 2022. Currently, the clinical trial is progressing smoothly.

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

STC3141 is a small molecule compound with a novel mechanism of action independently developed by the Group, which can be used to reverse organ damage caused by excessive immune responses by neutralizing extracellular free histones and neutrophil traps and is applicable to multiple severe disease indications. STC3141 is currently in three clinical studies worldwide. Among which, the phase Ib clinical study for the treatment of patients with ARDS was clinically approved in China in early March 2021. All patients have been currently enrolled and the clinical study is expected to be completed by the end of 2022. The phase IIa clinical trial for the treatment of severe COVID-19 was clinically approved in Belgium, Poland and the United Kingdom from April to October 2021, and all clinical studies have been currently completed. The results of the study showed that the study of STC3141 for the treatment of severe COVID-19 has achieved the primary endpoint pre-set by the clinical program, with no serious drug-related adverse reactions and the patients being well tolerated. The phase Ib clinical study for the treatment of sepsis was clinically approved in Australia and Belgium in May 2020 and April 2022 respectively, and the study is expected to be completed by the end of 2023.

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

APAD is a small molecule compound with a novel mechanism of action independently developed by the Group, which can antagonize a variety of pathogen-related molecules. The preclinical trial data showed that it can play a therapeutic role in sepsis caused by both bacterial and viral infections, and it is complementary to STC3141's mechanism of antagonizing the body's excessive immune response to treat sepsis, which can form a good synergy in the treatment of severe diseases such as sepsis. Currently, the compounds have been screened and are in the preclinical development stage.

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, the compounds have been screened and entered the preclinical development stage.

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Cerebro-cardiovascular Emergency Segment

The Group is listed as a “national essential drug production base”, an “emergency medicines manufacturer for national ready reserve” and a “national centralized production base and construction unit for minority-variety medicines (drugs in short supply)”, etc. with a total of 24 varieties, 14 of which are included in the national emergency drugs catalogue covering 6 major categories, while 16 of which are included in the shortage drugs catalogue covering 6 major categories, which has ranked the top in the industry in terms of product pipeline. The Group’s first generic product, epinephrine hydrochloride injection (pre-filled), was approved for commercialization in July 2022. Compared with the epinephrine products packaged in ampoules commercialized in China, the Group’s pre-filled product has various features including convenient for operation, accurate medication, avoiding glass chips, and reducing secondary pollution. While optimizing the quality of the product, it can save valuable rescue time for the patients to a great extent. Currently, there are more than 20 products under research in the field of cerebro-cardiovascular emergency. Among which, the 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 the IND application of such product was accepted by NMPA in July 2022. In the future, the Group will continue to focus on the three major emergency scenarios, namely in-hospital emergency, pre-hospital emergency and social emergency, and allocate and develop emergency products that are in urgent clinical need.

Cerebro-cardiovascular emergency products

The products mainly cover the fields of platelet inhibitors, blood pressure control, and vascular active drugs. The main products include Li Shu An (norepinephrine bitartrate injection, epinephrine hydrochloride injection), Xin Wei Ning (tirofiban hydrochloride and sodium chloride injection), Nuo Fu Kang (methoxamine hydrochloride injection), Neng Qi Lang (coenzyme Q10 tablets), Rui An Ji (fructose sodium diphosphate oral solution) and deslanoside injection, etc.

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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征診斷和治療中國急診專家共識(2021)》), the Guidelines for the Treatment of Sepsis/Septic Shock in Emergency in China (2018) (《中國膿毒症/膿毒性休克急診治療指南(2018)》), the Expert Consensus on Diagnosis and Treatment of Cardiogenic Shock in China (2018) (《心源性休克診斷和治療中國專家共識(2018)》), the Consensus of Chinese Emergency Medicine Experts on Diagnosis and Treatment of Traumatic Hemorrhagic Shock in China (2017) (《創傷失血性休克診治中國急診專家共識(2017)》), the Guidelines for Diagnosis and Treatment of ESC Urgent and Chronic Heart Failure in 2016 (《2016 ESC急、慢性心力衰竭診斷和治療指南》), and the Guidelines for Rational Use of Medication for Heart Failure (2nd Edition) (《心力衰竭合理用藥指南(第2版)》), and the clinical status of the products is remarkable.

Epinephrine hydrochloride injection (pre-filled):

In July 2022, the “epinephrine hydrochloride injection (pre-filled)” independently developed by the Group was approved for commercialization. As a Class 3 chemical drug, this product is currently the first epinephrine pre-filled preparation being commercialized in China. At present, all the epinephrine products for commercialization in China are packaged in ampoule bottles and are required to be prepared on site for use, resulting in wastage of drug solution and inevitable generation of glass chips and causing the risk of secondary contamination. The Group’s pre-filled packaging products do not need to be prepared and can be used directly, with the characteristics of convenient operation, accurate medication, avoiding the generation of glass chips, and reducing secondary contamination. While optimizing the quality of the products, it can maximize the precious rescue time for patients and provide a more efficient product portfolio for doctors and patients to cope with more complex clinical emergency scenarios.

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

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

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 of the Group in China and has been commercialized for more than 30 years. It has been recommended and used by guidelines and expert consensus, including the Guiding Opinions on the Management of Peripheral Anesthesia in Chinese Geriatric Patients (2014/2017/2020) (《中國老年患者圍術期麻醉管理指導意見(2014/2017/2020)》), the Expert Consensus on Anesthesia Management for Cranial Brain Disease Intervention in China (2016) (《中國顱腦疾病介入治療麻醉管理專家共識(2016)》), the Expert Consensus on Perioperative Use of $\alpha 1$ Adrenergic Receptor Agonists (2017 Edition) (《 $\alpha 1$ 腎上腺素能受體激動劑圍術期應用專家共識(2017版)》), the Expert Consensus on Obstetric Anesthesia in China (2018/2020) (《中國產科麻醉專家共識(2018/2020)》), and the Consensus on the Clinical Management of Chinese Experts in the Peripheral Anesthesia Period of Non-cardiac Surgery in Patients with Cardiac Disease (2020) (《心臟病患者非心臟手術圍麻醉期中國專家臨床管理共識(2020年)》).

Neng Qi Lang, the coenzyme Q10 tablets:

It is used to improve myocardial metabolism and energy supply, with the function of promoting oxidization phosphorylation reaction and protecting structural integrity of biological membranes. For patients with chronic cardiac insufficiency, it can significantly improve the symptoms of shortness of breath and fatigue, effectively combine with regular treatment to accelerate the prognosis of patients, and improve their quality of life. For the reduction of coenzyme Q10 synthesis caused by patients with statin, exogenous and effective supplementation can be achieved to relieve side effects such as muscle pain, and bring better compliance to patients with statin. For the high incidence of cardiotoxicity caused by cancer radiotherapy drugs, Neng Qi Lang can effectively carry out anti-oxidation, relieve the damage and protect the heart. The product has been commercialized for more than 30 years and has been successively included in 20 guidelines and expert consensus, including the Chinese Expert Consensus on the Clinical Application of Drugs to Improve Myocardial Metabolism (2021) (《改善心肌代謝藥物臨床應用中國專家共識(2021)》), the Chinese Expert Consensus on Diagnosis and Treatment of Chronic Heart Failure for the Elderly (2021) (《老年人慢性心力衰竭診治中國專家共識(2021)》), the 2020 Expert Consensus on

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Prevention and Treatment of Heart Failure after Myocardial Infarction (《2020心肌梗死後心力衰竭防治專家共識》), the Diagnosis and Treatment Advice for Children's Heart Failure (《兒童心力衰竭診斷和治療建議》) and the Expert Advice on the Clinical Management of Myocardial Injury in relation to COVID-19 (《新型冠狀病毒肺炎相關心肌損傷的臨床管理專家建議》).

Rui An Ji, the fructose sodium diphosphate oral solution:

It is mainly used for the treatment of angina pectoris of coronary heart disease, acute myocardial infarction, arrhythmia and myocardial ischemia in heart failure, and viral myocarditis. It is also used for brain ischemic symptoms caused by cerebral infarction and cerebral hemorrhage, and was included in a number of guidelines and expert consensus, such as the Diagnosis and Treatment Suggestions for Children's Heart Failure (2020 Revision) (《兒童心力衰竭診斷和治療建議(2020年修訂版)》), 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)》) 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 the China Heart Failure Diagnosis and Treatment Guidelines 2018 (《中國心力衰竭診斷和治療指南2018》), the 2020 China Heart Failure Medical Quality Control Report (《2020中國心力衰竭醫療品質控制報告》), the 2021 European Society of Cardiology Guidelines for Acute Heart Failure (《2021歐洲心臟病學會急性心力衰竭指南》) and the Heart Failure Rational Drug Use Guidelines (2nd Edition) (《心力衰竭合理用藥指南(第2版)》).

Innovative R&D pipeline

GPN00816, a 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. At present, the product has been commercialized in Europe, Korea and Hong Kong, China, and the IND application submitted in mainland China was accepted by the NMPA in July 2022.

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Tumor Segment

The Group mainly focuses on immunotherapy and creates a brand-new tumor immunotherapy product offering, such as mRNA immunotherapy, DNA immunotherapy, oncolytic virus, etc., to solve the problem of ineffective and drug resistance of tumor immunotherapy. At present, the Group has three global innovative products covering five cancer types, including HPV-positive head and neck cancer, triple-negative breast cancer and colorectal cancer, so as to achieve multi-cancer coverage in this therapeutic area and the development pattern of multi-treatment combination, so that the products of tumor treatment can serve patients in multiple dimensions.

Innovative R&D pipeline

A002, a global innovative mRNA immunotherapy drug:

A002 is an mRNA immunotherapeutic product for HPV-positive head and neck cancer, and is expected to increase response rates and improve clinical prognosis for tumor patients by triggering an adoptive immune response in the body in combination with existing tumor immune checkpoint inhibitor. The product is currently in preclinical study in China and the IND application is expected to be submitted to the NMPA in the first half of 2023.

TAVO™, the world's first genetic immunotherapy product:

TAVO™, the world's first DNA immunotherapy product, realizes the expression of tumor local interleukin-12 ("**IL-12**") through the electrophorus delivery system, and converts the "cold tumor" that does not respond to immunotherapy into "hot tumor" that responds to immunotherapy through the immune stimulatory function of IL-12. TAVO™ was granted a Fast Track Designation and an Orphan Drug Designation for the treatment of unresectable or metastatic melanoma by the Food and Drug Administration ("**FDA**") in the United States in 2017. The phase IIb clinical trial currently conducted for anti-PD-1 checkpoint resistant metastatic melanoma in combination with anti-PD-1 drug KEYTRUDA® (Keytruda, generic name: pembrolizumab) is expected to be completed by the end of 2022. The clinical research of TAVO™ on indications such as triple-negative breast cancer and squamous cell carcinoma is also progressing steadily.

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REV-001, a global innovative oncolytic virus drug:

REV-001 is a global innovative Vesicular Stomatitis Oncolytic Virus product (VSV-GPM) for the treatment of colorectal cancer. The product is the only oncolytic virus that does not insert exogenous genes, where the genetically modified virus enhances the selectivity of tumor cells, but is less toxic to normal cells. In addition, the virus genes will not be integrated into the human cell genomes and has no risk of genotoxicity with higher safety. REV-001 targets the RAS protein of refractory tumors. Refractory tumors with this target have the characteristics of high incidence rate, high malignancy and high fatality rate. Currently, there is no effective treatment method for the targeted refractory tumors. The product is currently in the pre-clinical development stage.

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 interventional diagnosis and treatment technology platform with international cutting-edge technologies.

Nuclear Medicine Anti-tumor Diagnosis and Treatment Segment

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

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The nuclear medicine anti-tumor diagnosis and treatment platform is the Group's high-end technology platform in the field of anti-tumor. It has more than 400 employees, with approximately 35% of them holding master's degrees and doctoral degrees, and is one of the most globalized segments of the Group. The Group, together with Sirtex Medical Pty Limited ("Sirtex"), cooperated with Telix Pharmaceutical Limited ("Telix") and ITM Isotope Technologies Muncich SE ("ITM") to establish a world-class tumor intervention R&D platform and a radionuclide-drug conjugate ("RDC") R&D platform. By adhering to the treatment concept of integrated oncology diagnosis and treatment, the Group aims to achieve early diagnosis and precise treatment of tumors. Currently, the Group has 13 innovative products in the pipeline, covering six nuclides including 68Ga, 177Lu, 131I, 90Y, 89Zr and 99mTc as well as eight cancers including liver cancer, prostate cancer and brain cancer. 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 and plan to commence the early development of four types of diagnostic and therapeutic RDC drugs in the institute.

With the continuous expansion of the product pipeline, the registration and application of innovative products in China is also progressing smoothly. During the period, Yttrium-90 microsphere injections has been commercialized successfully, and two RDC clinical application has been accepted, and products are expected to achieve milestone progress in the second half of this year. In the next 1 to 2 years, 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, establish at least one production platform with Grade A qualification in China, 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. The Group has been a leading enterprise in China's nuclear medicine anti-tumor diagnosis and treatment, and this segment will be a significant performance growth point of the Group in the future.

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Core products

Yttrium-90 microsphere injections, the global innovative product:

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

Based on the huge number of patients with liver cancer, the clinical demand in the field of liver cancer in China is strong, and the commercialization of Yttrium-90 microsphere injections provides an effective weapon for the multi-disciplinary treatment of liver cancer patients in China. Given that the barriers and innovation of this product, the understanding of the management procedures of this product by the clinical regulatory administration in China is gradually thorough. With a highly responsible attitude toward patients, and based on the surgeon supervision and training system approved by the NMPA and the FDA, the Group concentrated global resources to provide comprehensive training to surgeons in China on patient screening knowledge, surgical operation skills, and prognosis assessment methods, helping doctors to master and accumulate clinical experience to ensure a wider, safe and effective applications of the product. With the gradual increase in the number of doctors who have obtained the independent surgical qualifications for Yttrium-90 microsphere injections, the Group is confident to build up such product to be a blockbuster product in the field of liver cancer in China.

In September 2021, relying on the overseas commercialized medical device pilot policy of Boao Lecheng International Medical Tourism Pilot Zone of Hainan Free Trade Port, the Group has successfully carried out the clinical treatment of patients with liver cancer with the licensed access of Yttrium-90 microsphere injections in Boao Super Hospital in Hainan. As at the date of this report, two patients have successfully undergone down-stage transformation of liver tumor and liver cancer resection to achieve clinical cure.

Management Discussion and Analysis

In May 2022, Yttrium-90 microsphere injections was officially commercialized in China. A number of hospitals, including the Zhongda Hospital of Southeast University, Tianjin Medical University Cancer Hospital, Hunan Provincial People's Hospital and the First Affiliated Hospital of Medical School, Xi'an Jiaotong University, performed and successfully completed the precise interventional clinical surgeries by using Yttrium-90 microsphere injections. The treatment of liver malignancies in China has entered a new "Y-90 era".

In June 2022, the Group held a commercialization conference for Yttrium-90 microsphere injections in China, gathering a total of 7 academicians from the Chinese Academy of Engineering and the Chinese Academy of Sciences, 30 experts at committee chairperson level to participate 9 conference venues in person, and 500 professors of oncology medicine, interventional medicine, nuclear medicine, surgery and imaging from leading tertiary hospitals in China to attend the meeting. The experts and scholars highly anticipated that Yttrium-90 microsphere injections can be widely used in liver cancer patients in China and achieve clear and significant efficacy. After its commercialization, nearly 15 well-known hospitals in China completed the hospital admission and team training within an extremely fast time. Most hospitals are led by the dean or the deputy dean in charge to set up a Y-90 precision interventional diagnosis and treatment multi-disciplinary treatment (MDT) team and start training as soon as the Yttrium-90 microsphere injections was approved. It fully reflects the attention and support of experts in the fields of hepatobiliary, interventional and nuclear medicine for Yttrium-90 microsphere injections, also reflects the domestic experts' recognition of the technological innovation, safety and effectiveness of Yttrium-90 microsphere injections, and it prominently reflects that domestic clinicians' attention to the clinical needs of liver cancer patients in China and the urgent need for advanced therapy. Since June 2022, Yttrium-90 microsphere injections has been included in the inclusive insurance such as Shanghai Hu Hui Bao (上海滬惠保) and Nanjing Ning Hui Bao (南京甯惠保). At present, the Group has trained more than 300 doctors in 70 hospitals on the surgery theory or skills of Yttrium-90 microsphere injections. The Group will continue to strengthen the academic promotion and training of doctors so that more patients with liver cancer in China can benefit from it as soon as possible.

Management Discussion and Analysis

Yttrium-90 microsphere injections is a key product of the Group's nuclear medicine anti-tumor diagnosis and treatment segment and is the only product in the world for the selective internal radiotherapy "SIRT" for colorectal liver metastases, which has been used by more than 150,000 people in more than 60 countries and regions around the world. It has been recommended by the treatment guidelines of various international authoritative institutions such as the National Comprehensive Cancer Network (NCCN), the European Society for Medical Oncology (ESMO), the European Association for the Study of the Liver (EASL) and the National Institute for Health and Care Excellence (NICE), and has been included in a number of the authoritative clinical practice guidelines in China, including the Guidelines for the Diagnosis and Treatment of Primary Liver Cancer (2022 Edition) (《原發性肝癌診療指南(2022版)》), the Guidelines for the Diagnosis and Comprehensive Treatment of Colorectal Liver Metastases in China (2018 Edition) (《中國結直腸癌肝轉移診斷和綜合治療指南(2018版)》) and the Guidelines for the Clinical Practice of Liver Transplant for Liver Cancer (2018 Edition) (《中國肝癌肝移植臨床實踐指南(2018版)》).

Innovative R&D pipeline

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

Interventional therapy:

Yttrium-90 microsphere injections:

The IND application of Yttrium-90 microsphere injections for the indication of primary liver cancer is expected to be submitted at the end of 2022.

GPN00289, a global innovative temperature sensitive embolic agent:

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

Management Discussion and Analysis



Lava™, a global innovative liquid embolic agent:

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

Management Discussion and Analysis

RDC drugs:

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

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

TLX591 is a therapeutic RDC drug targeting prostate-specific membrane antigen (PSMA), while TLX591-CDx and TLX599-CDx are companion diagnostic agents to TLX591, forming an integrated radiotherapy portfolio for prostate cancer. TLX591-CDx was approved for commercialization in Australia in November 2021 and in the United States in December of the same year, and was granted a special license in Brazil for pre-approval sales. At the same time, the applications for the commercialization of TLX591-CDx have also been submitted in 17 countries. In clinical studies, a phase I trial of TLX591-CDx was completed in Japan in February 2022 with 10 subjects. The results of the study showed that TLX591-CDx was safe and well tolerated, with no serious adverse events observed in any of the subjects, and systemic and organ-specific radiation dose measurements and pharmacokinetic data showed no significant differences between Japanese and Western populations. In July 2022, The IND application for TLX591-CDx was submitted and accepted by the NMPA, and it is expected to initiate clinical trials this year. The overseas clinical studies of other products are also progressing smoothly, while the implementation in China is also progressing as planned. It is expected that the IND application for TLX591 will be submitted by the end of this year.

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 all 300 subjects have been enrolled in the overseas phase III clinical study in July 2022. It is expected to complete the study and report results in the second half of the year. TLX250 is currently undergoing a phase II clinical study overseas. In July 2002, The IND application for TLX250-CDx was submitted to the NMPA and it is expected to initial clinical trials this year. It is expected that the IND application for TLX250 will be submitted by the end of this year.

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. 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 an RDC drug for the treatment of glioblastoma multiforme, which takes advantage of the difference in the nutritional requirements of cancer cells in a tumor to target the radiated cancer cells and promote their apoptosis to achieve therapeutic effects. The product has been approved by the FDA as an orphan drug and is currently in phase I/II clinical trials in Europe and Australia, with registration in China actively underway.

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 ¹⁷⁷Lu with zoledronic acid. The product can precisely target hydroxyapatite at the metastasis site, inhibiting bone metastasis from malignant tumors while minimizing radiation to normal tissues, greatly improving patient survival and potentially further reducing skeletal-related events in patients with severe bone metastases. The product is currently in clinical phase I studies overseas and the registration in China is actively underway.

Cerebro-cardiovascular Precision Interventional Diagnosis and Treatment Segment

The Group adheres to the treatment concept of “interventional without implantation” and conducts comprehensive layout in three directions, namely channel management, structural heart disease, electrophysiology and heart failure, to build a high-end medical device product cluster. At present, the segment has reserved 16 products, of which 3 products in vascular intervention have been approved for commercialization in China and the NDA application for NOVASIGHT Hybrid was submitted and accepted in June 2022, while other products are also being actively promoted for China’s clinical registration 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.

Management Discussion and Analysis

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 nearly 300 employees and more than 50 R&D teams, with over 50% of them holding master’s degrees and doctoral degrees. With a comprehensive background in medicine, pharmacy, materials, machinery, electronics, etc., it helps to achieve stable and long-term development in R&D and innovation. The Group is committed to developing this segment into a leading “cerebro-cardiovascular precision interventional therapy platform” in China and worldwide.

Cerebro-cardiovascular precision intervention diagnosis and treatment products

In October 2019 and April 2020, the Group commercialized two drug-coating balloons RESTORE DEB® and APERTO® OTW in China respectively, which adopt the unique patented SAFEPAX technology. Both drug coating products are stable with small decay rate. After more than two years of clinical use, the product has been recognized by clinical doctors and patients and good market reputation. In July 2022, the commercialization of the Group’s first self-developed and self-produced innovative global neurointerventional product, the OTW (Over The Wire) intracranial balloon dilatation catheter Cai Yu® (彩鹬®), was approved for commercialization in China.

Management Discussion and Analysis

RESTORE DEB®, a coronary drug-coating balloon:

RESTORE DEB® is currently the only 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.

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

Cai Yu® (彩鵲®) 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® (彩鵲®) 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.

Management Discussion and Analysis

Innovative and R&D pipeline

Access management direction:

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

LEGFLOW® 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 is currently in the clinical research stage and is expected to be commercialized in China in 2024.

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

IVL CAD/IVL 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 is expected to be clinically enrolled by the end of 2022. Several other products, such as catheters and blocking balloons, are already in the clinical and registration stage.

Management Discussion and Analysis

aXess, a global innovative endogenous tissue repair product:

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

Structural heart disease direction:

Saturn, a global innovative mitral valve replacement system:

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

Electrophysiology and heart failure direction:

HeartLight X3, a global innovative laser ablation platform:

HeartLight X3 is a global innovative laser ablation product for the treatment of atrial fibrillation (“AF”) approved by the FDA for commercialization in May 2020, and is the only product in the world that can achieve circumferential ablation of AF through laser. HeartLight X3 adopts direct tissue visualization, adjustable laser energy and compliant balloon technology to achieve precise and continuous energy delivery, taking into account the adjustable energy point-to-point precision ablation characteristics of traditional radiofrequency catheter ablation and the simplicity of cryoablation with short operation time and significantly reduced dependence on the operator, making it the latest generation of AF ablation technology platform. The product is in preclinical development stage in China.

CoRISMA, a global innovative ventricular assisted device:

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

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 95 invention patents and has promoted the formulation of nearly 40 national industry standards. It has a complete domestic and international quality system certification, and has won many honors such as the National and Provincial Specialized New Enterprise (國家和省級專精特新企業), the National Intellectual Property Advantage Enterprise (國家級知識產權優勢企業) and the Provincial Hidden Champion Enterprise (省級隱形冠軍企業). The Group has also undertaken the "one-stop" application demonstration project for national industrial strong foundation engineering and high-end amino acid products.

The Group has been cultivating in the field of amino acids for more than 20 years and has always adhered to the spirit of technological innovation, taking synthetic biology as the core, it pioneered a world's leading innovative technology in China based on biotechnology method to produce various amino acids by biological method, which filled the gap in the industry. The Group's core product, Cysteine series, ranks first in the world in terms of market position and production capacity, while Taurine ranks second in the world in terms of production capacity. Benefiting from the continuous expansion of the international business and the general health business, the Group's amino acid segment has continued to maintain a high growth rate in recent years.

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

Management Discussion and Analysis



New technology:

With synthetic biology as the core and after years of scientific research, with significant cost and quality advantages. At present, we have built eight technology platforms, including enzyme engineering, fermentation engineering, process engineering, quality research and application transformation, which have formed unique technology leadership in strain construction optimization, metabolic pathway regulation, fermentation control, separation and purification, and product application development, etc. Some of the processes fill the domestic gaps in China. Through the innovation and integration of several sub technology areas, we have built an integrated synergistic system with new product development, new technology engineering, industrialization and application solutions, which provides strong support for continuous technological innovation and industrialization transfer. Among them, the fermentation production process with strain construction optimization as the core and the enzyme conversion production process with immobilized enzymes as the core can not only replace the traditional synthesis process, but also significantly reduce the emission of carbon dioxide during the production process, which fully proves the development concept of energy saving, emission reduction and green environment protection of emission peak and carbon neutrality, showing great economic and environmental benefits. By continuously optimizing the fermentation and isolation purification process, we have achieved the leading position in the industry in terms of key indicators such as production volume and yield. The integrated technology of fermentation and enzymatic process, i.e. industrial microbial fermentation for the production of industrial enzymes, and the patented technology of immobilized enzymes can significantly shorten the time of enzyme conversion, significantly improve the yield and reduce the unit cost of products. Replacing dangerous processes in traditional synthesis routes by bio-enzymatic methods can also significantly reduce synthesis costs and significantly improve production safety. The industrial technology highway built by the Group in the amino acid segment is beginning to take shape and is entering its best harvesting period, which has laid a solid foundation for technological innovation at source and product industrialization.

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), and has established long-term strategic cooperation with many research institutes, including Tsinghua University, Wuhan University and Tianjin University of Science and Technology. There are over 300 R&D and technical 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 64 invention patents, ranking at the leading level in the same industry. The core subsidiaries in the segment have won many honors, such as the National and Provincial Specialized New Enterprises (專精特新企業), the National Intellectual Property Advantage Enterprises (國家級知識產權優勢企業), the China Light Industry Green Manufacturing Engineering Technology Research Centers for Sulfur-containing Amino Acids (中國輕工業含硫氨基酸綠色製造工程技術研究中心), the China Foreign Trade Export Leading Indicator (ELI) Sample Enterprises (中國外貿出口先導指數(ELI)樣本企業) and the Provincial Hidden Champion Enterprises.

High quality:

The Group's amino acid products have a complete quality certification system at home and abroad. Many products have passed the drug/food system certification and registration in Europe, the United States, Japan, Southeast Asia, China and other countries and regions, including European Union GMP certification, the Accreditation certificate of foreign drug manufacturer in Japan, KFDA Registration in Korea, MAPA certification in Brazil, Free Sale Certificate Attestation in Argentina; as well as the ISO quality control 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. After the completion of acquiring Hubei Bafeng, it will have 24 registered amino acid APIs, covering more than 70% of the registration certificates in the same category, and is the pharmaceutical company with the largest number of registered amino acid APIs in China. The rich amino acid product cluster can better meet the customized needs of the downstream market, provide one-stop services of multiple varieties and specifications, and enhance customer adhesion in high-end application scenarios. In addition to raw material products, the Group is also actively expanding its pharmaceutical products. Two functional dietary supplements, namely the U.S. patented citrulline and taurine preparations (which is used to enhance exercise endurance) and the acetylcysteine preparations (which protects respiratory health and enhances immunity) independently developed by the Company have obtained the U.S. FDA approval and was officially commercialized in the United States for sales in 2021.

Internationalization:

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

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

Management Discussion and Analysis

FINANCIAL REVIEW

Revenue and profit

For the six months ended 30 June 2022 (the “**Period**” or the “**1H**”), the Group recorded revenue of approximately HK\$5,212.58 million, representing an increase of approximately 14.1% as compared to the corresponding period in 2021. The Group’s gross profit margin for the Period was approximately 62.5%.

For the six months ended 30 June 2022, total profit for the Period attributable to owners of the Company was approximately HK\$710.41 million, representing a decrease of approximately 40.92% as compared to the corresponding period in 2021. The decrease was mainly due to the loss on fair value change in the investment in Telix of approximately HK\$379.56 million. If the loss on fair value change in the investment in Telix is excluded, the profit for the Period attributable to owners of the Company would be approximately HK\$1,089.97 million, representing an increase of approximately 20.07% as compared to approximately HK\$907.75 million over the corresponding period in 2021.

During the Period, for pharmaceutical technology, the Group recorded revenue of approximately HK\$3,598.61 million, representing an increase of approximately 7.5% as compared to the corresponding period in 2021, which was mainly due to gradually commercialization of new products. For the ophthalmology sector, a revenue of approximately HK\$660.88 million, representing an increase of approximately 14.7% as compared to the corresponding period in 2021, was recorded, mainly as a result of stable growth in market promotion for core products “Rui Zhu” and “He Xue Ming Mu tablets”. For the respiratory, severe and disease and anti-infection sector, a revenue of approximately HK\$1,051.39 million which was 10.7% higher than that of the corresponding period in 2021, was recorded. The increase was mainly due to mainly as a result of expansion for clinical usage resulted a stable growth in the products of the respiratory, severe and disease and anti-infection sector. For the cerebro-cardiovascular emergency sector, a revenue of approximately HK\$997.35 million was recorded, representing a slightly decrease of 7.7% as compared to the same period in 2021.

During the Period, the Group recorded revenue of approximately HK\$125.80 million from its nuclear medicine anti-tumor diagnosis and treatment as well as cerebro-cardiovascular precision interventional diagnosis and treatment technology products, representing an increase of approximately 36.2% as compared to the corresponding period in 2021. The increment is due to our cerebro-cardiovascular precision interventional products are further recognized by doctors and patients and step into growing stage, and Yttrium-90 microspheres injections were approved for commercialization during the current period.

Management Discussion and Analysis

During the Period, the Group's biotechnology products recorded revenue of approximately HK\$1,488.17 million, representing an increase of approximately 32.0% as compared to the corresponding period in 2021, among which the amino acid segment recorded revenue of approximately HK\$1,251.43 million and is approximately 40.3% increased as compared with the same period of 2021. The increment is mainly due to the stable support from the supply chain and the increase in demand from international high-end markets.

Distribution costs and administrative expenses

For the six months ended 30 June 2022, the Group's distribution costs and administrative expenses were approximately HK\$1,373.12 million and HK\$550.76 million respectively as compared to approximately HK\$1,414.79 million and HK\$429.15 million respectively for the corresponding period in 2021. The decrease in distribution costs of approximately HK\$41.67 million during the Period was mainly due to the sales staffs' targeted deployment and work during the Period, to promote new product in a more efficient way. With the expansion of the Group's business, the overall administrative expenses also increased by approximately 28.3% as compared to the corresponding period in 2021.

Finance costs

For the six months ended 30 June 2022, the Group's finance costs were approximately HK\$63.21 million as compared to approximately HK\$23.67 million for the corresponding period in 2021. The increase was due to certain financing arrangements in response to business expansion.

R&D and project investment

The Group has invested a large amount of capital in the stages of research project such as research, testing, commercialization and registration. For the six months ended 30 June 2022, the total research and development expenses amounted to HK\$252.86 million. In addition to the prepayments for new projects and other investments, the Group's investment in R&D and various projects was approximately HK\$1.60 billion in the first half of the year.

Management Discussion and Analysis

Receivables and payables

For the six months ended 30 June 2022, trade and other receivables of the Group amounted to approximately HK\$3,737.99 million, representing an increase of approximately HK\$1,076.54 million as compared to the balance in 2021, mainly due to the increase in trade receivables of approximately HK\$628.42 million as a result of the increase in business during the Period. Prepayments have increased by approximately HK\$297.91 million, and was mainly related to the prepayment for the procurement of raw materials and projects investment for coping with business expansion.

For the six months ended 30 June 2022, the Group's trade and other payables amounted to approximately HK\$3,621.19 million, representing an increase of approximately HK\$749.43 million as compared to the balance in 2021, mainly due to the increase in trade payables of approximately HK\$714.93 million as a result of the increase in business during the Period.

Research and development

The Group has sufficient innovation pipeline. During the Period, there were accumulatively 114 projects under research and 46 innovation projects, which were in different stages from preclinical to new drug commercialization application. The pipeline layout was reasonable, forming a good echelon effect.

In terms of R&D progress, during 2022 up to the date of this report, the Group has obtained 7 production approvals, including 2 for innovative products and 5 for generic drugs (including consistency evaluation). Also one application for product commercialization and two clinical approvals are obtained. The clinical-stage projects have been progressing smoothly.

Management Discussion and Analysis



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 Group's 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; the DNA technology platform is located at the San Diego R&D Center in the United States, focusing on tumor DNA immunotherapy; the Glycomics technology platform is located at the R&D center in Australia, focusing on the development of antiviral drugs; 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.

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

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

R&D Team

As a technology-based innovative pharmaceutical company, the Group has long been committed to building a high-end innovative R&D talent system to promote the global development of innovative projects. At present, the Group, together with its associates, has a total of 630 R&D personnel (including overseas R&D teams such as Sirtex and OncoSec Medical Incorporated), of which nearly 400 have master's degree and doctoral degree holders, accounting for nearly 60%. All professional leaders and core team members of each segment have academic background in clinical medicine or pharmacy, while some of whom also have overseas education or working experience.

Management Discussion and Analysis

Development of Generic Drugs

As of the date of this report, epinephrine hydrochloride injection (pre-filled), tirofiban hydrochloride injection (250ml), amiodarone hydrochloride injection, fluorouracil injection and haloperidol injection have been issued drug registration certificates by NMPA.

Consistency Evaluation

During the period under review, tirofiban hydrochloride and sodium chloride injection and amiodarone hydrochloride injection were approved or deemed to have passed the consistency evaluation, and new applications were made for sodium hyaluronate eye drop, travoprost eye drop and carglumic acid tablet. At present, a total of 17 products of the Group have been approved or deemed to have passed the Consistency Evaluation, and another 15 products are under review.

Intellectual Property Protection

During the period under review, the Group applied for 4 core patents and 11 peripheral patents, and was granted 59 patents, including 25 invention patents, accounting for 42%. The Group has accumulated 539 valid patents, including 286 invention patents, 253 utility model patents and design patents. In terms of innovative drugs, STC3141 has filed new patent applications for COVID-19 relevant indications. The core patent applications are currently under review in the United States, Europe and China. Other innovative drug projects are all under patent layout in the United States, Europe, China and other countries around the world.

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. During the Period, the Group had over 3,800 sales personnel and nearly 3,300 sales personnel in the pharmaceutical area, covering over 20,000 hospitals with over 1,000 OTC personnel and more than 200,000 pharmacies in China; the cerebro-cardiovascular precision interventional diagnosis and treatment segment has more than 130 sales personnel, covering more than 1,000 hospitals; the nuclear medicine anti-tumor diagnosis and treatment segment has more than 230 sales personnel worldwide, with its global sales network covering more than 60 countries and regions. It has also actively carried out the hospital admission and academic promotion of Yttrium-90 microsphere injections in China.

Management Discussion and Analysis



International Standard

The Group continues to accelerate the pace of globalization and has five 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, triple negative breast cancer and sepsis. Currently, the Group has over 320 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. As of the date of this report, the Group has carried out the following material investment, M&A and cooperation:

- ***Entering into of an equity investment agreement with ITM***

In February 2022, the Group entered an equity investment agreement with ITM Company, whereby the Group will subscribe newly issued shares of ITM Company equivalent to approximately 1.31% of its enlarged share capital at the consideration of EUR25 million. The equity investment this time will further deepen the cooperation between the Group and ITM and lay a solid foundation for the Group’s global deployment of the entire industrial chain of radionuclide production, research and sales.

Management Discussion and Analysis

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

In February 2022, the Group entered into a product licensing agreement with Novartis AG. (“**Novartis**”, a world-renowned company) in Switzerland. The Group will pay Novartis no more than US\$20 million and a certain percentage of the sales commission, to obtain the exclusive commercialization rights of Enerzair® and Ateectura®, two global innovative compound preparations for the treatment of asthma from Novartis in mainland China. Enerzair® and Ateectura® products have been commercialized in Europe, Australia and Japan, and were approved by NMPA for commercialization in May 2021 and June 2021, respectively. The cooperation with Novartis is another successful attempt of the Group to join hands with internationally renowned pharmaceutical companies, which will further provide momentum for the Group’s medium and long-term development.

- ***Capital injection into Wuhan Shetai Medical***

In April 2022, Grand Pharmaceutical (China) Company Limited (“**Grand Pharma (China)**”, an indirect non-wholly owned subsidiary of the Company), Shanghai Shetai Medical Technology Limited (“**Shanghai Shetai**”) and Wuhan Shetai Medical Technology Co., Ltd. (“**Wuhan Shetai Medical**”, which is owned as to 33% by Grand Pharma (China) and 67% by Shanghai Shetai) entered into a capital injection agreement. Pursuant to the capital injection agreement, Grand Pharma (China) and Shanghai Shetai, as the existing shareholders of Wuhan Shetai Medical, agreed to increase the registered capital of Wuhan Shetai Medical by RMB65 million, where Grand Pharma (China) and Shanghai Shetai shall make additional capital contributions of RMB21.45 million and RMB43.55 million, respectively, in proportion to their respective existing shareholdings in Wuhan Shetai Medical.

Management Discussion and Analysis

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

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

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

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

Management Discussion and Analysis

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

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

Other than stated above, the Group did not have other material acquisition or disposal from 1 January 2022 to the date of this report.

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 Period, 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 2022, it was awarded the "Most Valuable Pharmaceutical and Medical Company" and the "Best IR Team" in the sixth Golden Hong Kong Stocks Awards. In June 2022, it was awarded the "Best Hong Kong Listed Companies in Hubei".

PROSPECTS

During the "14th Five-Year" period, China's pharmaceutical industry will enter a new stage of development, promoting high-end, intelligent and green industries, and building new advantages in international competition. In May, the National Development and Reform Commission issued the first top-level design of China's biological economy, the "14th Five-Year Development Plan for Biological Economy", focusing on the higher-level needs of the people in areas such as medical health, food consumption, green and low-carbon, and biological safety. China's biological economy will usher in an important period of opportunities. Facing the development of the industry, the Group will seize the opportunities arising from the high-quality development of the pharmaceutical industry in the future. Driven by technological innovation, the Group will continue to deploy global innovative products and advanced technologies in a differentiated manner, continuously enrich and improve product pipelines, strengthen the layout and construction of the industrial chain, promote cutting-edge synthetic biological technology innovation, make breakthroughs in key technologies such as biological bacterial construction and metabolic channel control.

In the first half of the year, with the global innovative products like Yttrium-90 microsphere injections been commercialized in the China, and the Group will continue to put full effort in different core aspects, continuously contribute new profit growing points and persistently consolidate its position as an industry leader in advantageous fields for building solid foundation for the continuous growth of the Group.

Management Discussion and Analysis

Deploying the production of medical isotopes and promoting the construction of innovative nuclear medicine anti-tumor diagnosis and treatment platform

In recent years, China's radiopharmaceuticals market has developed rapidly, and the supporting policy and guidance have also accelerated the development of China's nuclear medicine. In 2021, the state issued the first framework document for nuclear technology in the field of medical and health applications, namely the Medium and Long-term Development Plan for Medical Isotope (2021–2035) (醫用同位素中長期發展規劃(2021–2035年)) and the Technical Guidelines for Non-clinical Research of Radioactive In-vivo Diagnostic Drugs (放射性體內診斷藥物非臨床研究技術指導原則) and other regulatory policies, which are of great significance to China's strategy of improving the capability of medical isotope-related industries, promoting and regulating the research and development of radioactive in-vivo diagnostic drugs in China, and ensuring health. The Group closely followed the policy direction, deeply deployed and built a nuclear medicine diagnosis and treatment platform, and improved the industrial chain links such as the supervision, registration, R&D, raw materials, transportation, and admission to hospitals of nuclear medicine, laying a solid foundation for the implementation of the Group's radionuclide drugs.

In early 2022, in the 14th Five-Year Plan, new mechanism innovative drugs such as microsphere injections and drug-device combinations are taken as the focus of future development in the future. In June of the same year, the first clinical expert consensus on selective internal radiotherapy of Yttrium-90 resin microsphere injections in Asia was released, which is of great significance to the standardized clinical diagnosis and treatment of the Group's blockbuster product, Yttrium-90 microsphere injections. At the same time, the coverage of inclusive insurance such as "Hu Hui Bao" for the coverage for therapeutic use of the product will significantly increase the accessibility of patients. The recent release of DRG excluded payment method for innovative drugs and devices by Beijing Municipal Medical Insurance Bureau may also accelerate the marketing process of the product.

Management Discussion and Analysis

Deploying global cutting-edge innovative medical device product clusters and promoting the localization of high-end medical devices

With the advancement of the new medical reform, China's medical device industry is looking for certainty and prosperous development opportunities amid crises and opportunities. In 2021, the medical device industry accelerated regulation, unified consumable codes, centralized procurement of consumables and medical insurance payment by DRG/DIP have a profound impact on the future regulation and operation of the industry, which clarified the new development direction of the industry in the future. According to the 14th Five-Year Plan, innovative medical devices such as high-end interventional implants, new medical imaging equipment and biomedical materials will be the focus of future development.

The Group deeply grasped the current situation of global disease diagnosis and treatment, and deeply understood the trend of key technology fields. In the cerebro-cardiovascular precision interventional diagnosis and treatment segment, the Group established the layout for channel management, structural heart disease, electrophysiology and heart failure. With the core idea of international layout, differentiated innovation and professional development, the Group focused on scientific and technological innovation, loyalty to clinical needs, and optimization of product portfolio.

With the commercialization of the two drug-coated balloons and the advancement of their localization, the segment is expected to enter into harvest period gradually. In the future, the Group will continue to strategically plan the global cutting-edge high-end medical devices, focus on the improvement of innovative R&D capabilities, and accelerate the construction and industrial localization of R&D centers, to create a high-end medical device platform that integrates research, production, supply and sales in the field of cerebro-cardiovascular precision intervention diagnosis and treatment.

Management Discussion and Analysis

Taking advantage of the industrial chain to ensure the supply of emergency drugs and drugs in short supply

Ensuring the stability and controllability of the pharmaceutical industry chain is the key development goal set out in the 14th Five-Year Plan, and strengthening the supply guarantee capability of emergency drugs and drugs in short supply and improving the relevant system construction is once again designated as a key task. As the “National essential drug production base”, “Emergency medicines manufacturer for national ready reserve” and “National centralized production base construction unit for minority-variety medicines (drugs in short supply)”, the Group has 24 varieties, among which, 14 varieties are included in the national emergency rescue drug list covering 6 major categories, and 16 varieties are included in the shortage drugs catalog covering 6 major categories, which has ranked the top in the industry in terms of product pipeline. In the future, the Group will continue to leverage the strengths of its industry chain to meet the clinical demand for emergency drugs and drugs in short supply.

Practicing green, low-carbon and sustainable development, and promote high-quality industrial development with biological manufacturing technology

The 14th Five-Year Plan for the Development of Biological Economy clearly states the trend of shifting from “pursuing production capacity and efficiency” to “adhering to ecological priority”, developing green and low-carbon biomass alternative applications. The issue of the 14th Five-Year Plan for the Development of Biological Economy will promote the robust development of China’s biological economy, and enterprises with cutting-edge biological technology innovation and capability to achieve large-scale production are expected to fully benefit from the rapid expansion of market scale. Amino acid industry has always been the dominant area of the Group. After years of intensive cultivation, the Group has accumulated profound experience in biotechnology application, industrial chain layout, large-scale production, establishment of product quality system and international sales, and is equipped with international competitiveness.

Management Discussion and Analysis

The Group's development in the field of biotechnology is highly in line with the national development plan for biological economy. The Group will fully grasp the development opportunities of the industry, consolidate the industrial chain and strengthen the construction of the value chain. In the future, the Group will further integrate the resources of the amino acid industry, strengthen the development of biological technology, optimize the production process and increase the production capacity. While enriching the product clusters, the Group will promote the development of high value-added products business, and actively expand the preparation products and bio-cell culture media business, which will benefit from the broad market demand for health products and the rapid development of the biopharmaceutical sector and the trend of domestic substitution.

Updates on Significant Matters

With reference to the disclosure in the annual reports of the Company between 2016 to 2021, Tianjin Jingming New Technology Development Co., Ltd. (the "**Tianjin Jingming**"), an indirect non-wholly owned subsidiary of the Company, is undertaking certain litigations related to a product quality incident, and it is also claiming the original shareholders of the Tianjin Jingming for the indemnification of those possible loss suffered by the Company. Up to 30 June 2022, the court has concluded 64 cases, and 11 cases are under hearing processes at the people's court. Among the final and effective judgements, Tianjin Jingming has paid the compensation and the related legal charges of approximately RMB32.06 million in according to the court orders. The other related litigations of the product quality incident have not yet been concluded. Given that (1) such product is not the core product of the Group, and (2) according to the terms of the agreement for the acquisition of Tianjin Jingming, the original shareholders of Tianjin Jingming should be responsible for the compensation of such product incident until 30 June 2015, and in April 2021 Grand Pharm (China) had claimed the original shareholders of the Tianjin Jingming for the indemnification of those possible loss suffered. According to the final judgment by the court, the original shareholders of Tianjin Jingming should compensate to us approximately RMB27.09 million as the existing compensate and liquidated damages at the point of raising litigation. As the execution of the enforcement order from the people's court, Grand Pharm (China) has got properties and cash at approximately RMB6.60 million in aggregate from the original shareholders of the Tianjin Jingming, and the outstanding amount is still under enforcement processes. Also Grand Pharm (China) has rights to raise litigation claiming the original shareholders of the Tianjin Jingming for the losses of approximately from 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 (灌溉液)) of Tianjin Jingming for the period commencing on 1 January 2015 and ending on 30 June 2015 shall not be less than RMB5 million (the “**Performance Guarantee**”). If the above Performance Guarantee cannot be met, the Group can claim for a refund of part of the consideration in according to the formula set out in the announcement of the Company dated 22 December 2014. The Group raised a litigation against those vendors in related to the said Performance Guarantee, and after the first trial, second trial and retrial from the court, the court granted the final judgement in December 2020. It was concluded that the Group can get back the RMB10 million share transfer consideration deposited in the bank account jointly controlled by the Group and the vendors. The vendors should also additionally refund approximately RMB11.2 million share transfer consideration to the Group in according to the terms of the agreement for the acquisition of Tianjin Jingming. Up to now, the Group has followed the judgement from the court and get back the RMB10 million deposited in the bank account jointly controlled by the Group and the vendors.

FINANCIAL RESOURCES AND LIQUIDITY

As at 30 June 2022, the Group had current assets of HK\$6,725.44 million (31 December 2021: HK\$6,778.59 million) and current liabilities of HK\$5,940.80 million (31 December 2021: HK\$5,566.13 million). The current ratio was 1.13 at 30 June 2022 as compared with 1.22 at 31 December 2021.

The Group’s cash and bank balances as at 30 June 2022 amounted to HK\$1,034.89 million (31 December 2021: HK\$1,752.86 million), of which approximately 6.5% were denominated in Hong Kong Dollars, United States Dollars, Australian Dollars, Euro and 93.5% in Renminbi.

As at 30 June 2022, the Group had outstanding bank loans of approximately HK\$2,775.52 million (31 December 2021: HK\$2,849.29 million) were granted by banks in the PRC and Hong Kong. All bank loans were denominated in RMB, USD and HK\$. The interest rates charged by banks ranged from 2.70% to 5.66% (31 December 2021: 2.18% to 6.89%) per annum, in which approximately HK\$840.84 million bank loans were charged at fixed interest rates. Certain bank loans were pledged by assets of the Group with a net book value of HK\$272.12 million (31 December 2021: HK\$284.35 million). The gearing ratio of the Group, measured by bank borrowings as a percentage of shareholders’ equity, was reduced to approximately 20.4% as at 30 June 2022 as compared with approximately 21.3% as at 31 December 2021.

Management Discussion and Analysis

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

The Group intends to principally finance its operations and investing activities with its operating revenue, internal resources and bank facilities. The Directors believe that the Group has a healthy financial position and has sufficient resources to satisfy its capital expenditure and working capital requirement. The Group adopted a conservative treasury policy with most of the bank deposits being kept in Hong Kong dollars, or in the local currencies of the operating subsidiaries to minimize exposure to foreign exchange risks. As at 30 June 2022, the Group did not have foreign exchange contracts, interest or currency swaps or other financial derivatives for hedging purposes.

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\$185.0 million, and approximately HK\$184.76 million of which was used to purchase 29,500,000 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.

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

Material Acquisitions and Disposals

Save as disclosed above, the Group did not have material acquisitions and disposals for the six months ended 30 June 2022.

Significant Investment

Save as disclosed above, the Group did not have other significant investment for the six months ended 30 June 2022.

Management Discussion and Analysis

EMPLOYEES AND REMUNERATION POLICY

As at 30 June 2022, the Group employed 9,649 staff and workers (31 December 2021: 10,029). The Group remunerates its employees based on their performance and experience and their remuneration package will be reviewed periodically by the management. Other employee benefits include medical insurance, retirement scheme, appropriate training program and share option scheme.

EVENTS AFTER THE REPORTING PERIOD

Save as disclosed above, no subsequent events occurred after 30 June 2022, 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 2022, 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%
Niu Zhanqi	Interests in spouse (Note 1)	173,500	0.00%
Shao Yan	Interests in spouse (Note 2)	6,019,600	0.17%
Zhou Chao	Beneficial owner	56,000	0.00%

Note:

1. Dr. Niu Zhanqi, a director of the Company, is the spouse of Ms. Shang Yan Yan who is the holder of the above shares. By virtue of the SFO, Dr. Niu Zhanqi shall be deemed to be interested in such 173,500 Shares.
2. Dr. Shao Yan, a director of the Company, is the spouse of Ms. Tian Wen Hong who is the holder of the above shares. By virtue of the SFO, Dr. Shao Yan shall be deemed to be interested in such 6,019,600 Shares.

Other Information

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 2022, 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.

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)

Other Information

Name of Shareholders	Notes	Number of the shares interested	Nature of interests	Approximate percentage or attributable percentage of shareholding (%)
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)

(L) denotes long position

Note:

- 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.
- 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.
- 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.
- 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

Save as disclosed above, as at 30 June 2022, 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.

PURCHASE, SALE OR REDEMPTION OF SHARES

During the six months ended 30 June 2022, neither the Company nor any of its subsidiaries has purchased, sold or redeemed any of the Shares.

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 2022.

CODE OF CORPORATE GOVERNANCE PRACTICES

The Company has complied with the code provisions of the Corporate Governance Code and Corporate Governance Report (the “**CG Code**”) as set out in Appendix 14 of the Listing Rules during the six months ended 30 June 2022.

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 Director Dr. Pei Geng and Mr. Hu Yebi.

The Group’s condensed consolidated interim financial statements for the six months ended 30 June 2022 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 Dr. Shao Yan 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 2022

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Interim Results

The board (the “**Board**”) of directors (the “**Directors**”) of China Grand Pharmaceutical and Healthcare Holdings Limited (the “**Company**”) is pleased to announce the unaudited consolidated interim results for the six months ended 30 June 2022 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 2022

	Note	Six months ended 30 June	
		2022 HK\$'000 (Unaudited)	2021 HK\$'000 (Unaudited)
Revenue	3	5,212,581	4,566,530
Cost of sales		(1,952,487)	(1,673,689)
Gross profit		3,260,094	2,892,841
Other revenue and income		83,644	61,202
Distribution costs		(1,373,124)	(1,414,786)
Administrative expenses		(550,759)	(429,151)
Net income from financial assets at fair value through profit or loss		(392,560)	298,892
Share of results of associates		(48,382)	23,209
Finance costs		(63,213)	(23,671)
Profit before tax		915,700	1,408,536
Income tax expense	4	(217,777)	(204,299)
Profit for the period	5	697,923	1,204,237

Condensed Consolidated Statement of Profit or Loss and Other Comprehensive Income

Note	Six months ended 30 June	
	2022 HK\$'000 (Unaudited)	2021 HK\$'000 (Unaudited)
Other comprehensive income/(loss), net of income tax		
<i>Items that will not be reclassified to profit or loss:</i>		
Fair value gain/(loss) on investment in equity instruments at fair value through other comprehensive income	4,263	(1,590)
Share of other comprehensive income of associates	1,689	(1,529)
<i>Items that may be reclassified subsequently to profit or loss:</i>		
Exchange difference on translation of foreign operations	(89,076)	91,561
Other comprehensive (loss)/income for the period, net of income tax	(83,124)	88,442
Total comprehensive income for the period, net of income tax	614,799	1,292,679
Profit/(loss) for the period attributable to:		
— Owners of the Company	710,411	1,202,543
— Non-controlling interests	(12,488)	1,694
	697,923	1,204,237

Condensed Consolidated Statement of Profit or Loss and Other Comprehensive Income

Six months ended 30 June

	Note	2022 HK\$'000 (Unaudited)	2021 HK\$'000 (Unaudited)
Total comprehensive income/(loss) for the period attributable to:			
— Owners of the Company		623,304	1,294,332
— Non-controlling interests		(8,505)	(1,653)
		614,799	1,292,679
Dividend	6	—	—
Earnings per share	7		
— Basic and diluted (HK cents)		20.16	33.88

Condensed Consolidated Statement of Financial Position

As at 30 June 2022

Note	30 June 2022 HK\$'000 (Unaudited)	31 December 2021 HK\$'000 (Audited)
Non-current assets		
	3,383,675	3,409,183
Property, plant and equipment		
	395,213	392,528
Right-of-use assets		
	159,924	167,151
Investment properties		
	8,122,235	8,066,669
Interests in associates		
Equity instruments at fair value through other comprehensive income	601,200	145,685
Goodwill	573,321	596,746
Intangible assets	1,069,090	1,009,764
Deferred tax assets	26,899	24,608
Prepayments	616,581	466,107
	14,948,138	14,278,441
Current assets		
Financial asset at fair value through profit or loss	705,244	1,112,968
11		
Inventories	1,109,102	1,117,156
Trade and other receivables	3,737,993	2,661,450
9		
Loan receivables	114,610	113,190
Amounts due from related companies	20,083	13,320
Pledged bank deposits	3,524	7,645
Cash and cash equivalents	1,034,885	1,752,860
	6,725,441	6,778,589

Condensed Consolidated Statement of Financial Position

As at 30 June 2022

	Note	30 June 2022 HK\$'000 (Unaudited)	31 December 2021 HK\$'000 (Audited)
Current liabilities			
Trade and other payables	10	3,621,189	2,871,759
Contract liabilities	10	87,265	202,106
Bank and other borrowings		1,951,739	2,116,471
Lease liabilities		6,874	5,728
Amounts due to related companies		1,000	4,831
Amounts due to immediate holding company		2,331	2,331
Derivative financial instrument		8,399	8,350
Income tax payable		262,002	354,549
		5,940,799	5,566,125
Net current assets			
		784,642	1,212,464
Total assets less current liabilities			
		15,732,780	15,490,905
Non-current liabilities			
Bank and other borrowings		1,606,302	1,510,070
Lease liabilities		20,686	13,306
Deferred tax liabilities		191,733	197,849
Deferred income		288,102	326,818
		2,106,823	2,048,043
Net assets			
		13,625,957	13,442,862

Condensed Consolidated Statement of Financial Position

As at 30 June 2022

	Note	30 June 2022 HK\$'000 (Unaudited)	31 December 2021 HK\$'000 (Audited)
Capital and reserves attributable to owners of the Company			
Share capital	12	35,496	35,496
Reserves		13,548,735	13,357,135
Equity attributable to owners of the Company		13,584,231	13,392,631
Non-controlling interests		41,726	50,231
Total equity		13,625,957	13,442,862

Condensed Consolidated Statement of Changes in Equity

For the six months ended 30 June 2022

	Share capital HK\$'000	Share premium HK\$'000	Contribution Share surplus premium reserve HK\$'000	Statutory reserve HK\$'000	Safety fund reserve HK\$'000	Translation reserve HK\$'000	Other reserve HK\$'000	FVTOCI reserve HK\$'000	Treasury shares HK\$'000	Retained profits HK\$'000	Equity attributable to owners of the Company HK\$'000	Non- controlling interests HK\$'000	Total HK\$'000
At 1 January 2021 (audited)	35,496	6,523,049	121,273	479,682	28,825	163,044	(98,116)	11,871	-	3,974,380	11,239,504	104,705	11,344,209
Profit for the period	-	-	-	-	-	-	-	-	-	1,202,543	1,202,543	1,694	1,204,237
Other comprehensive income for the period:													
Change in fair value of financial assets through other comprehensive income	-	-	-	-	-	-	-	(1,590)	-	-	(1,590)	-	(1,590)
Share of other comprehensive income of associates	-	-	-	-	-	-	-	(1,529)	-	-	(1,529)	-	(1,529)
Exchange difference on translation of foreign operations	-	-	-	-	-	94,908	-	-	-	-	94,908	(3,347)	91,561
Total comprehensive income for the period	-	-	-	-	-	94,908	-	(3,119)	-	1,202,543	1,294,332	(1,653)	1,292,679
Dividend paid	-	-	-	-	-	-	-	-	-	(390,453)	(390,453)	(1,372)	(391,825)
At 30 June 2021 (unaudited)	35,496	6,523,049	121,273	479,682	28,825	257,952	(98,116)	8,752	-	4,786,470	12,143,383	101,680	12,245,063
At 1 January 2022 (audited)	35,496	6,523,049	121,273	545,074	28,825	439,956	(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

Condensed Consolidated Statement of Cash Flows

For the six months ended 30 June 2022

	Six months ended 30 June	
	2022 HK\$'000 (Unaudited)	2021 HK\$'000 (Unaudited)
Net cash generated from operating activities	787,958	978,227
Investing activities		
Purchase of property, plant and equipment	(86,392)	(275,658)
Purchase of intangible assets	(156,948)	(38,802)
Net cash outflow from acquisition of subsidiaries	–	(125,575)
Addition of investments in associates	(197,165)	(182,014)
Acquisition of financial assets at fair value through other comprehensive income	(437,983)	(54,847)
Increase in non-current prepayments	(129,831)	(3,524)
Other cash flows arising from investing activities	25,600	73,013
Net cash used in investing activities	(982,719)	(607,407)
Financing activities		
Repayments of bank loans	(791,832)	(1,166,193)
Proceeds from new borrowings	767,234	1,631,047
Dividend paid	(390,453)	(391,825)
Purchase of shares for share award scheme	(41,251)	–
Interest paid	(63,213)	(23,671)
Other cash flows (used in)/arising from financing activities	(9,621)	5,716
Net cash (used in)/generated from financing activities	(529,136)	55,074
Net (decrease)/increase in cash and cash equivalents	(723,897)	425,894
Cash and cash equivalents at 1 January	1,752,860	1,836,695
Effect of foreign exchange rate changes	5,922	74,934
Cash and cash equivalents at 30 June	1,034,885	2,337,523

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 2021 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 2021 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 2021 are available from the Company’s registered office. The auditors have expressed an unqualified opinion on those financial statements in their report dated 17 March 2022.

The accounting policies and methods of computation used in the preparation of this interim report are consistent with those adopted by the Group in the 2021 annual accounts, except for the adoption of new and revised standards with effect from 1 January 2022 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:

Amendments to HKAS 16	Property, plant and equipment: Proceeds before intended use
Amendments to HKAS 37	Provisions, contingent liabilities and contingent assets: Onerous contracts — cost of fulfilling a contract

The Group has not applied any new standard or interpretation that is not yet effective for the current accounting period. Impacts of the adoption of the amended HKFRSs are discussed below:

Amendments to HKAS 16 “Property, plant and equipment: Proceeds before intended use”

The amendments prohibit an entity from deducting the proceeds from selling items produced before that asset is available for use from the cost of an item of property, plant and equipment. Instead, the sales proceeds and the related costs should be included in profit and loss. The amendments do not have a material impact on these financial statements as the Group does not sell items produced before an item of property, plant and equipment is available for use.

Amendments to HKAS 37 “Provisions, contingent liabilities and contingent assets: Onerous contracts — cost of fulfilling a contract”

The amendments clarify that for the purpose of assessing whether a contract is onerous, the cost of fulfilling the contract includes both the incremental costs of fulfilling that contract and an allocation of other costs that relate directly to fulfilling contracts.

Previously, the Group included only incremental costs when determining whether a contract was onerous. In accordance with the transitional provisions, the Group has applied the new accounting policy to contracts for which it has not yet fulfilled all its obligations at 1 January 2022, and has concluded that none of them is onerous.

Notes to the Condensed Consolidated Financial Statements

3. REVENUE AND SEGMENT INFORMATION

For the six months ended 30 June 2022, the Group is principally engaged in manufacture and sales of pharmaceutical products and medical devices, biotechnology 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 2022	As at 31 December 2021
	2022 HK\$'000 (Unaudited)	2021 HK\$'000 (Unaudited)	HK\$'000 (Unaudited)	HK\$'000 (Audited)
The PRC	4,183,944	3,769,554	8,708,728	8,528,777
America	572,425	329,934	–	–
Europe	234,925	235,044	–	–
Asia other than the PRC	201,001	186,517	53,631	42,805
Others	20,286	45,481	–	–
Total	5,212,581	4,566,530	8,762,359	8,571,582

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 2022 and 2021, 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:

	Six months ended 30 June	
	2022 HK\$'000 (Unaudited)	2021 HK\$'000 (Unaudited)
Current tax:		
PRC Enterprise Income Tax	215,974	205,966
Deferred tax	1,803	(1,667)
	217,777	204,299

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

	Six months ended 30 June	
	2022 HK\$'000 (Unaudited)	2021 HK\$'000 (Unaudited)
Profit before tax is stated after charging:		
Staff costs comprises:		
— Wages and salaries	789,304	565,750
— Retirement benefits schemes contributions	57,366	40,954
	846,670	606,704
Depreciation of property, plant and equipment	153,262	139,450
Depreciation of right-of-use assets	6,286	8,589
Amortisation of intangible assets	12,991	10,263
Total depreciation and amortisation	172,539	158,302
Cost of inventories recognised as an expense	1,952,487	1,673,689
Operating leases rentals in respect of land and buildings	7,554	6,162
Gain on disposal of property, plant and equipment	(90)	(679)
Research and development costs	252,862	171,370
Written off of property, plant and equipment	1,680	253

6. INTERIM DIVIDEND

During the six months ended 30 June 2022, the Board declared HK\$0.11 per share or approximately HK\$390.45 million in aggregate as final dividend for the year ended 31 December 2021 (2021: 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 2022 (six months ended 30 June 2021: Nil).

Notes to the Condensed Consolidated Financial Statements

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	
	2022 HK\$'000 (Unaudited)	2021 HK\$'000 (Unaudited)
Earnings Earnings for the purpose of basic earnings per share calculation	710,411	1,202,543

	Six months ended 30 June	
	2022 '000 (Unaudited)	2021 '000 (Unaudited)
Number of shares Weighted average number of ordinary shares for the purpose of basic earnings per share calculation (Note)	3,523,037	3,549,571

Note:

As at 30 June 2022, treasury shares are deducted from total shares in issue for the purpose of calculating earnings per share.

Diluted earnings per share is the same as the basic earnings per share for the six months ended 30 June 2022 and 2021 as there were no potential dilutive ordinary shares in issue.

8. PROPERTY, PLANT AND EQUIPMENT

During the reporting period, the Group incurred approximately HK86,392,000 (for the six months ended 30 June 2021: HK\$275,658,000) on additions to property, plant and equipment.

Notes to the Condensed Consolidated Financial Statements

9. TRADE AND OTHER RECEIVABLES

	30 June 2022 HK\$'000 (Unaudited)	31 December 2021 HK\$'000 (Audited)
Trade receivables, net	1,979,173	967,703
Bills receivables	446,355	829,402
Prepayments	936,437	638,524
Other tax receivables	42,014	63,528
Other receivables, net	334,014	162,293
	3,737,993	2,661,450

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.

	30 June 2022 HK\$'000 (Unaudited)	31 December 2021 HK\$'000 (Audited)
Trade receivables	2,079,825	1,070,634
Less: Allowance for credit loss	(100,652)	(102,931)
	1,979,173	967,703

Notes to the Condensed Consolidated Financial Statements

9. TRADE AND OTHER RECEIVABLES (Continued)

The ageing analysis of the trade receivables is as follows:

	30 June 2022 HK\$'000 (Unaudited)	31 December 2021 HK\$'000 (Audited)
Within 90 days	1,687,505	738,650
91–180 days	270,161	155,539
181–365 days	21,507	73,514
	1,979,173	967,703

10. TRADE AND OTHER PAYABLES AND CONTRACT LIABILITIES

	30 June 2022 HK\$'000 (Unaudited)	31 December 2021 HK\$'000 (Audited)
Trade payables	619,547	549,963
Bills payables	829,885	184,535
Accruals and other payables	2,014,808	1,943,515
Other tax payables	156,949	193,746
Total	3,621,189	2,871,759
Contract liabilities (note a)	87,265	202,106

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

10. 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:

	30 June 2022 HK\$'000 (Unaudited)	31 December 2021 HK\$'000 (Audited)
Within 90 days	412,669	300,002
Over 90 days	206,878	249,961
	619,547	549,963

11. FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT OR LOSS

	30 June 2022 HK\$'000 (Unaudited)	31 December 2021 HK\$'000 (Audited)
Equity securities listed in Hong Kong (note (a))	20,333	33,332
Listed equity security in Australia (note (a))	514,118	905,156
Investment at fair value (note (b))	170,793	174,480
	705,244	1,112,968

Note:

- (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.

Notes to the Condensed Consolidated Financial Statements

12. SHARE CAPITAL

Ordinary shares of HK\$0.01 each

	30 June 2022		31 December 2021	
	Number of shares '000 (Unaudited)	Amount HK\$'000 (Unaudited)	Number of shares '000 (Audited)	Amount HK\$'000 (Audited)
Authorised: Ordinary shares of HK\$0.01 each	100,000,000	1,000,000	100,000,000	1,000,000
Issued and fully paid: At the beginning and the end of the period/year	3,549,571	35,496	3,549,571	35,496

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\$766,000 (2021: HK\$262,000). The Group had future minimum lease receipts from tenants under non- cancellable operating lease which fall due as follows:

	30 June 2022 HK\$'000 (Unaudited)	31 December 2021 HK\$'000 (Audited)
Within one year	677	212
In the second to fifth year inclusive	2,344	–
	3,021	212

Notes to the Condensed Consolidated Financial Statements

13. COMMITMENTS (Continued)

(b) Capital commitment

	30 June 2022 HK\$'000 (Unaudited)	31 December 2021 HK\$'000 (Audited)
Capital expenditure contracted but not provided for: Acquisition of property, plant and equipment	185,939	180,322

14. CONTINGENT LIABILITIES

The Group had no significant contingent liabilities as at 30 June 2022 (2021: Nil).

Corporate Information

Executive directors

Dr. Tang Weikun (*Chairman*)
Dr. Shao Yan
Dr. Niu Zhanqi
Dr. Shi Lin

Independent non-executive directors

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

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*)
Mr. Hu Yebi
Dr. Pei Geng

REMUNERATION COMMITTEE

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

NOMINATION COMMITTEE

Ms. So Tosi Wan, Winnie (*Chairwoman*)
Dr. Shao Yan
Mr. Hu Yebi

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AUDITORS

HLB Hodgson Impey Cheng Limited
Certified Public Accountants

LEGAL ADVISERS

As to Bermuda Law:
Conyers Dill & Pearman

As to Hong Kong Law:
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Bank of China
Bank of Communications

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