RESEARCH 1

石四藥集團有限公司 SSY Group Limited

> incorporated in the Cayman Islands with limited liability Stock Code: 2005.HK

2023 Interim Results & Roadshow material

Updated on 29 August 2023





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PART 01 Business Profile PART 02 Competitive Advantages

PART 03 R&D Status and Prospects PART 04 Development Strategies PART 01

Business Profile

 Financial Highlights
 Shareholding & Group Structure Revenue OverviewR&D Overview

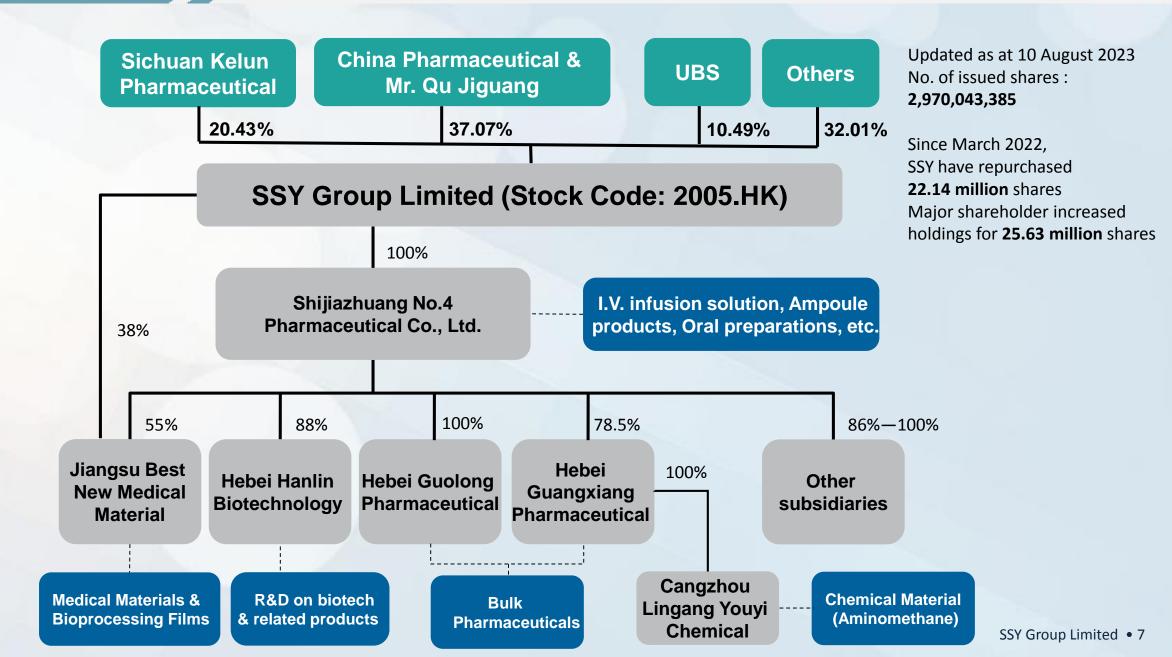
Financial Highlights (1H2023)

(нк\$'000)	1H2023	1H2022	Increase/ (Decrease)
Revenue	3,333,157	3,404,513	(2.1%)
Gross Profit	1,944,751	1,939,447	0.3%
Gross Profit Margin	58.3%	57.0%	1.3%pt
EBITDA	993,861	919,046	8.1%
EBITDA Margin	29.8%	27.0%	2.8%pt
Net Profit	638,611	570,056	12.0%
Net Profit Margin	19.2%	16.7%	2.5%pt
Earning per share (HK\$)	0.2149	0.1906	12.7%
Interim Dividend	207,903	179,205	16.0%
Interim Dividend per share (HK\$)	0.07	0.06	16.7%

Financial Highlights (1H2023)

(HK\$'000)	30 June 2023	31 December 2022	Increase/ (Decrease)
Cash and Cash Equivalent	1,789,616	1,667,547	122,069
Bank Borrowings	3,379,969	3,207,648	172,321
Net Asset Value	6,681,527	6,545,824	135,703
Gearing Ratio	20.1%	19.9%	0.2%pt
Current Ratio	1.87	1.82	0.05
Accounts Receivable Turnover (Day)#	103	110	(7)
Inventory Turnover (Day)	119	104	15
NAV per Share (HK\$)	2.25	2.20	0.05
Return on Equity	19.1%	17.1%	2.0%pt
Remarks: # excluding bills receivables			

Shareholding & Group Structure





Revenue Overview (1H2023)

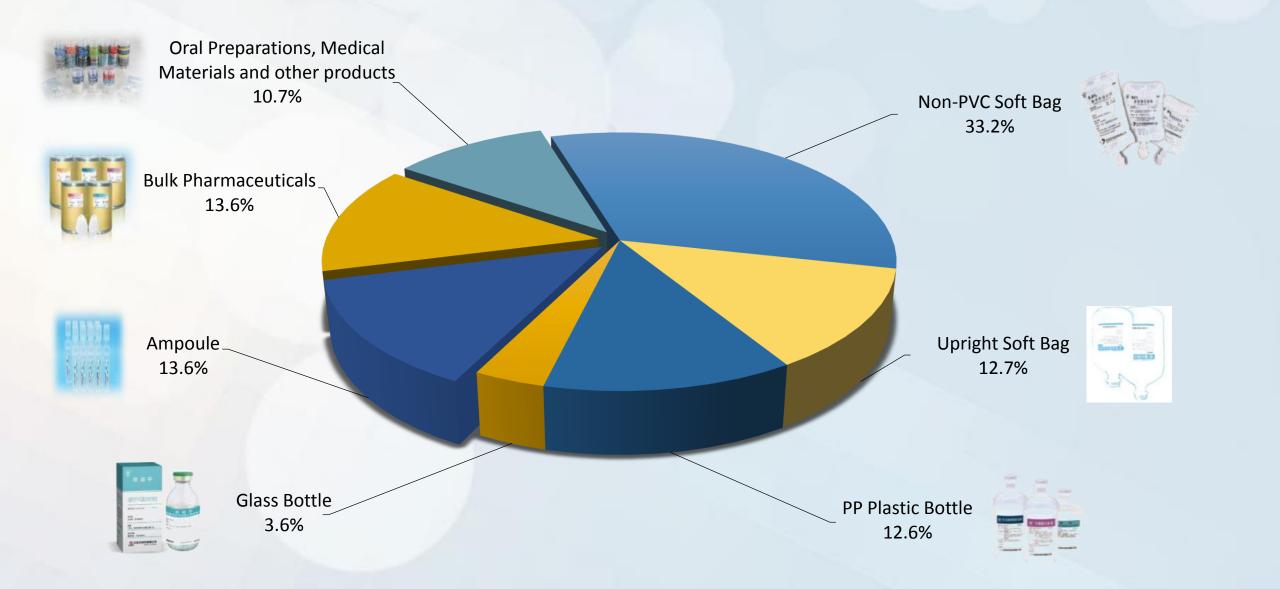
	1H2	.023	1H202	
By Products	Revenue (НК\$'000)	% of Total Revenue	Revenue (НК\$'000)	% of Total Revenue
I.V. Infusion	2,069,115	62.1%	1,833,629	53.8%
Ampoule Injections	453,398	13.6%	510,665	15.0%
Bulk Pharmaceuticals	453,626	13.6%	776,609	22.8%
Oral Preparations	244,391	7.3%	145,088	4.3%
Medical Materials	90,067	2.7%	90,550	2.7%
Other Products	22,560	0.7%	47,972	1.4%
Total	3,333,157	100%	3,404,513	100%

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Revenue Overview (2022FY)

	20	22	2021	
By Products	Revenue (HK\$'000)	% of Total Revenue	Revenue (HK\$'000)	% of Total Revenue
I.V. Infusion	3,510,342	54.6%	3,304,365	61.7%
Ampoule injections	978,707	15.2%	1,093,615	20.4%
Bulk Pharmaceuticals	1,358,949	21.1%	533,860	10.0%
Oral preparations and other products	413,908	6.4%	247,746	4.6%
Medical Materials	172,119	2.7%	177,177	3.3%
Total	6,434,025	100%	5,356,763	100%

Revenue Breakdown by Products (1H2023)



I.V. Infusion

Sales volume increase, Optimise product mix, New types of products rapid growth

- In 1H2023, sales volume of infusion solution reached 936 million bottles (bags), representing an increase of 24.1% y-o-y, revenue reached HKD2,069 million, representing an increase of 12.8% y-o-y
- Production and sales of therapeutic infusion solutions progressed steadily, revenue reached HKD566 million, representing an increase of 24.1% y-o-y, contributed for 27.4% of I.V. sales
- Sales (in RMB) of key products growth rapidly : Ambroxol Hydrochloride + 232%, Moxifloxacin Hydrochloride +222%, Fluconazole +91%, Ciprofloxacin Lactate +45%, Peritoneal dialysis solution +38%
- End of epidemic in 2023, hospitalization rate of large hospitals recovers ; medium and small hospitals, clinics and rural market resume infusion
- For 2023, target sales volume of I.V. infusion no less than 1,900 million bottles (bags)
- By end of 2023, new production lines of upright soft bag with additional production capacity of 600 million bags annually.
 By adopting new technologies and facilities, the production lines will turn to be the most advanced model of intelligent
 manufacturing and digital transformation in the industry, expected to complete construction and start trial production by
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Sales volume of Upright soft bag and PP Plastic bottle increased by 43.0% & 23.6% y-o-y respectively

	I.V. Infusion – 1H2023					
By Packaging	Revenue (HK\$'000)	% of IV Revenue	Average Selling Price (ASP) (HK\$)	GP%		
Non-PVC Soft Bag	1,107,007	53.5%	3.67	67.0%		
Upright Soft Bag	419,490	20.3%	1.70	69.7%		
PP Plastic Bottle	424,088	20.5%	1.23	48.4%		
Glass Bottle	118,530	5.7%	2.73	34.7%		
Total	2,069,115	100%	2.21	61.9%		



- **Proportion of therapeutic infusions (as % of IV revenue) increased by 2.6 %pt**
- Various products' volume entered rapid growth period: Ambroxol Hydrochloride and Sodium Chloride (+294%), Moxifloxacin Hydrochloride & Sodium Chloride (+255%), Fluconazole and Sodium Chloride (+96%), Peritoneal dialysis solution (+36%), Metronidazole (+24%)

Ву	I.V. Infusion – 1H2023				
Pharmaceutical Products	Revenue (HK\$'000)	% of IV Revenue	Average Selling Price (ASP) (HK\$)	GP%	
Basic Infusions	1,179,929	57.0%	1.88	60.8%	
Nutrition Infusions	323,291	15.6%	1.64	51.0%	
Therapeutical Infusions	565,895	27.4%	5.11	70.3%	
Total	2,069,115	100%	2.21	61.9%	



Sales volume of Upright soft bag and PP Plastic bottle increased by 28.1% & 20.1% y-o-y respectively

	I.V. Infusion – 2022FY					
By Packaging	Revenue (HK\$'000)	% of IV Revenue	Average Selling Price (ASP) (HK\$)	GP%		
Non-PVC Soft Bag	1,788,791	51.0%	3.74	62.5%		
Upright Soft Bag	647,621	18.4%	1.79	67.6%		
PP Plastic Bottle	839,750	23.9%	1.30	47.9%		
Glass Bottle	234,180	6.7%	2.65	34.6%		
Total	3,510,342	100%	2.22	58.1%		



Revenue Overview - I.V. Infusion (2022FY)

- **Proportion of therapeutic infusions increased by 4.4 %pt**
- Various products' volume entered rapid growth period: Peritoneal Dialysis
 Solution (+77%), Ambroxol Hydrochloride (+169%), Moxifloxacin Hydrochloride
 (+314%), Ciprofloxacin Lactate (+110%)

Ву	I.V. Infusion – 2022 FY				
Pharmaceutical Products	Revenue (HK\$'000)	% of IV Revenue	Average Selling Price (ASP) (HK\$)	GP%	
Basic Infusions	2,075,133	59.1%	1.99	58.7%	
Nutrition Infusions	535,621	15.3%	1.72	48.3%	
Therapeutical Infusions	899,588	25.6%	4.02	62.5%	
Total	3,510,342	100%	2.22	58.1%	

Ampoule Injections

Increasingly rich in varieties, Production gradually scaled up

- In 1H2023, sales volume reached approx. 131 million, increased by 92% y-o-y; revenue accounted for HK\$453 million, decreased by 11% y-o-y mainly due to change of sales channel of Betahistine, revenue droped (selling expense dropped at the same time, resulting little impact on net profit) and depreciation of RMB (6.5%)
- 7 specifications won the tenders in national centralised procurement : Doxofylline, Ambroxol Hydrochloride, Ropivacaine Hydrochloride, Bromhexine Hydrochloride, Ornidazole, Methylcobalamin, Argatroban injection
- Focus to increase sales volume of national centralized procurement products : Bromhexine Hydrochloride* revenue reached HKD180 million, increased by 4.6 times y-o-y; Ambroxol Hydrochloride* revenue reached HKD 14.67million, increased by 98% y-o-y
- Market share of featured species further expanded : Dexmedetomidine revenue increased by 11.8 times y-o-y; Terbutaline Sulfate Nebuliser Injection revenue increased by 1.2 times y-o-y
- First or exclusive in consistency evaluations : Pentoxifylline injections sales volume expected to reach RMB100 million level
- Further increase in production capacity, from 560 million at the beginning of the year to 1,300 million

*Remark: Bromhexine Hydrochloride is the 7th batch of national centralized procurement products, while Ambroxol Hydrochloride is the 4th batch SSY Group Limited • 16

Solid Preparations

Accelerated upgrade of production & sales scale, revenue contribution increases year by year

- In 1H2023, revenue accounted for HK\$244 million, increased by 68% y-o-y, contributed for 7.3% of total sales, increased by 3%pt y-o-y
- Antiviral drug : Abidol capsules, revenue accounted for RMB37.58 million, increased by 283% y-o-y
- 4 products won national centralised procurement : Prucalopride Succinate tablet, Cefdinir capsule (revenue RMB39.48 million, increased by 4% y-o-y); Cefaclor for Suspension (revenue RMB13.06million, increased by 44% y-o-y); Felodipine/ Felodipine II Sustained-release Controlled-release Tablets
- First approval or consistency evaluation : Blonanserin tablets, Pentoxifylline Sustained-release tablets, Azithromycin for Suspension and Stiripentol for Suspension
- Strengthened business cooperation with the top 100 chain pharmacies, closely linked the commercial chain with the endmarket, accelerated the market layout and promotion among professions of featured oral preparations with high market potential and technological content such as Amlodipine tablets, Rosuvastatin Calcium tablets
- Up to 11 Aug 2023, 20 oral preparations types with 26 specifications passed or regarded as passing consistency evaluation in China
- Annual capacity increased to 3.5billion tablets(pills)

Bulk Pharmaceuticals

Softer market demands and dropped product prices in the first half of the year, successively obtained approvals for featured bulk pharmaceuticals products with high-value added, product mix further diversified

- In 1H2023, revenue accounted for HK\$454 million, decreased by 42% y-o-y. Mainly affected by the decrease in sales of caffeine and methylamine: caffeine sales volume 1,972 tonnes, drop of 39% as y-o-y; methylamine sales volume of 11,262 tonnes, drop of 15% y-o-y
- Key products with revenue growth in first half of the year : Azithromycin up 22%, Theophylline Aminophylline up 381%, Metronidazole up 15%
- 40 types of bulk pharmaceuticals approved with specialised types as follows : Epacistat, Pitavastatin calcium, Rosuvastatin calcium, Blonanserin, Linezolid, Argatroban, Lacosamide, Theobromine, Pentoxifylline,
 Ornidazole, Levonidazole, Tertiary Sulfate Butaline, Cinacalcet Hydrochloride, Lurasidone Hydrochloride,
 Lurasidone Hydrochloride, Tedizolid Phosphate, L-malic acid, Urapidil Hydrochloride, Tofacitinib Citrate

Medical Materials

Steady operating result

- In 1H2023, revenue of external sales accounted for RMB80.04 million, increased by 6.4% y-o-y
- Newly developed products, such as bioprocessing films, specialised films for peritoneal dialysis solution, pistons for pen injectors, rubber plugs with coating and bicolour rubber plugs for blood collection tubes have successively achieved breakthroughs and scaled up in sales.
- Jiangsu Best New Medical Material's listing on the National Equities Exchange and Quotations (NEEQ) transition to Beijing Stock Exchange : In April 2023, application for listing counseling and filing procedures submitted to the Jiangsu Supervision Bureau of the China Securities Regulatory Commission, striving to accelerate the promotion to the A-share market of the Beijing Stock Exchange



Exports of preparations rose against the trend

- In 1H2023, export of infusion solution: volume of 51.08 million bottles (bags), growth of 17% y-o-y, revenue of HK\$80.08 million, growth of 25% y-o-y
- In 1H2023, completed 24 product registrations in foreign countries
- Developed 11 new customers
- Currently exported 28 products and 65 specifications to over 90 countries and regions worldwide

Research and Development

- Up to 11 August 2023, a total of 51 national production approvals were obtained (increased 37% y-o-y), including 43 for preparations and 8 for bulk pharmaceuticals
- Currently 54 product types with 72 specifications passed or regarded as passing consistency evaluation
- Research and development efficiency and quantity of generic drugs are among the best in China's pharmaceutical companies and ranked top 10 chemical drugs research and development capabilities in China. Up to 11 August 2023, 58 applications made to National Drug Administration Center for Drug Evaluation: 51 for preparations (including consistency evaluation), 7 for bulk pharmaceuticals. Currently, 146 items awaiting for approvals : 115 for preparations (including consistency evaluation consistency evaluation), 31 for bulk pharmaceuticals
- The first approval/consistency evaluation in the PRC in 2023 : Pentoxifylline sustained-release tablets, Multiple electrolytes injection II, Stiripentol for suspension
- Group's 1st innovative drug type I anti-tumor NP-01 project achieved positive progress in Phase I clinical trial
- Currently, 212 projects under R&D and 122 products awaiting approval. By end of 2023, target to obtain 47 approvals and make 51 applications for new products

Product passed/regarded passing consistency evaluation

(54 Types, 72 Specifications)

No.	Drug Name	Specification	Remark
1	Fluconazole Tablets	150mg	The First
2	Doxofylline Injection	10ml:0.1g	The First
3	Ropivacaine Hydrochloride Injection	10ml:100mg	The First
4	Ciprofloxacin Lactate Sodium Chloride Injection	100ml	The First
5	Metronidazole Sodium Chloride Injection	250ml	The First
6	Blonanserin tablets	4mg	The First
7	Peritoneal Dialysis Solution (Lactate-G1.5%)	2000ml	The First
8	Peritoneal Dialysis Solution (Lactate-G2.5%)	2000ml	The First
9	Azithromycin dry suspension	0.1g	The First
10	Pentoxifylline Injection	5ml:100mg	The First
11	Pentoxifylline Sustained-release Tablets	400mg	The First
12	Stiripentol for Suspension	250mg	The First
13	Stiripentol for Suspension	500mg	The First
14	Fluconazole Sodium Chloride Injection	50ml	First specification
15	Compound Electrolyte Injection II	1000ml	First specification
16	Fluconazole Tablets	50mg	Second
17	Cefdinir capsule	0.1g	Second
18	Ciprofloxacin Lactate and Sodium Chloride Injection	200ml	Second
19	Fluconazole Sodium Chloride Injection	100ml	Second
20	Metronidazole Sodium Chloride Injection	100ml	Second
21	Bromhexine Hydrochloride Injection	2ml	Second
22	Terbutaline Sulphate Solution for Nebulization	2ml:5mg	Second
23	Acetaminophen Mannitol Injection	100ml : 1g	Second
24	Sorbitol and Mannitol Irrigation Solution	3000ml	Second
25	Sodium Lactated Ringer Injection	500ml	Second
26	Compound Electrolyte Injection II	500ml	Second
27	Terbutaline Sulphate Solution for Nebulization	1ml	Second specification
28	Thioctic Acid Injection	24ml	Second specification
29	Medium and Long Chain Fat Emulsion Injection (C8~24Ve)	250ml	Third
30	Terbutaline Sulphate Injection	1ml:0.5mg	Third
31	Prucalopride Succinate Tablets	1mg	Second
32	Prucalopride Succinate Tablets	2mg	Second

Note: Acetaminophen Mannitol Injection was approved for the indication of relieving fever in adults, and it is the first domestic company to be approved.

Product passed/regarded passing consistency evaluation (54 Types, 72 Specifications)

No.	Drug Name	Specification	No.	Drug Name	Specification
33	Rosuvastatin Calcium Tablets	10mg	53	Ipratropium Bromide Solution for Inhalation	2ml:500µg
34	Rosuvastatin Calcium Tablets	5mg	54	Ipratropium Bromide Solution for Inhalation	2ml:250µg
35	Ropivacaine Hydrochloride Injection	10ml:75mg	55	Azithromycin dispersible Tablets	0.25g
36	Ambroxol Hydrochloride Injection	1ml	56	Lacosamide Injection	20ml
37	Ambroxol Hydrochloride Injection	2ml	57	Felodipine Sustained-Release Tablets	5mg
38	Ambroxol Hydrochloride Injection	4ml	58	Ornidazole Injection	3ml:0.5g
39	Moxifloxacin Hydrochloride & Sodium Chloride Injection	250ml	59	Ornidazole Injection	6ml:1.0g
40	Linezolid and Glucose Injection	100ml	60	Lurasidone Hydrochloride Tablets	40mg
41	Dexmedetomidine Hydrochloride Injection	2ml	61	Azithromycin for Injection	0.5g
42	Dexmedetomidine Hydrochloride Injection	1ml	62	Argatroban Injection	2ml:10mg
43	Lacosamide Tablets	50mg	63	Sodium Acetate Ringer's Injection	500ml
44	Lacosamide Tablets	100mg	64	Cinacalcet Hydrochloride Tablets	25mg
45	Moxifloxacin Hydrochloride Tablets	0.4g	65	Tedizolid Phosphate Injection	200mg
46	Levofloxacin and Sodium Chloride Injection	100ml: 0.5g	66	Urapidil Hydrochloride Injection	5ml
47	Moxifloxacin Hydrochloride Eye Drops	5ml	67	Urapidil Hydrochloride Injection	10ml
48	Cefaclor Dry Suspension	0.125g	68	Citicoline Sodium Injection	4ml:500mg
49	Metronidazole Tablets	0.2g	69	Tirofiban hydrochloride Concentrated Solution Injection	15ml:3.75mg
50	Levofloxacin Injection	20ml:0.5g	70	Pitavastatin Calcium Tablets	2mg
51	Mecobalamin Injection	1ml	71	Pitavastatin Calcium Tablets	1mg
52	Valsartan and Amlodipine Tablets (I)	80mg/5mg	72	Oseltamivir Phosphate Suspension	6mg/ml

PART 02

Competitive Advantages

Competitive Advantages

Bulk Pharmaceuticals, Medical Materials, Preparations and Biotech - Diversified and Coordinated Development



I.V. Infusion Production Line Intelligent Manufacturing , Largest Production Capacity on Single Factory Basis

Numerous Specifications, Complete Preparation Types, Wide Coverage Numerous Prize Recognition, Main subsidiaries are specialized and special new enterprises

Bulk Pharmaceuticals, Medical Materials, Preparations and Biotech - Diversified and Coordinated Development



1 R&D institute, Production Bases: 2 preparation, 2 bulk pharmaceutical, 1 chemical and 1 medical material, forming wholeindustry-chain by preparations + bulk pharmaceuticals + medical materials

- 22 I.V. Infusion production lines, annual 2 billion bottles(bags),
- 8 ampoule production lines, annual capacity 1,300 million,
- 4 oral preparation production lines, annual capacity 3.5 billion,
- 9 bulk pharmaceutical production lines, annual capacity 12,000 tons,
- 1 chemical production line, annual capacity 30,000 tons,
- Non-PVC film production line, annual capacity 25million sq. meters,
- Rubber stopper & gasket production line, annual capacity 3.5 billion units,
- Bioprocessing film production line, annual capacity 2,000 sq. meters,
- Production lines of emulsion, lyophilized powder injection, antitumor drugs, medical equipment and in vitro diagnostic (IVD) reagent under construction

Diversified and Coordinated Development - Pharmaceutical R&D Institute



It covers an area of 85 acres and has advanced equipment such as high-efficiency/ultra-highperformance liquid chromatographs, gas chromatographs, Fourier infrared spectrometers, and the leading hardware level in the country.

It has more than 550 high-level professional research teams led by doctors and masters in synthesis, analysis, preparations and APIs, and has product pipelines in multiple fields such as tumor, antiviral, respiratory, neuropsychiatric, cardiovascular and cerebrovascular, biofilm, etc. Co-founded innovative platforms such as engineering laboratories and technology research centers with numerous universities in China.



Diversified and Coordinated Development – Preparations Production Base





Shijiazhuang No.4 Pharmaceutical
Major products: Non-PVC Soft Bag IV,
Upright Soft Bag IV, PP Plastic Bottle IV, Glass
Bottle IV,
PP Ampoule Injections,
Tablets, Capsule and Granules

Diversified and Coordinated Development – Bulk Pharmaceuticals Production Base

Hebei Guangxiang Pharmaceutical Major products: Caffeine Theophylline , Aminophylline Series Metronidazole, Benzoyl Metronidazole Nifedipine, Xanthinol nicotinate

Cangzhou Lingang Youyi Chemical Major product: Methylamine (API for caffeine and other pharmaceutical/ag ricultural products)





Hebei Guolong Pharmaceutical

Major productis: Hydroxyethyl starch series Respiratory system (Terbutaline, Bromhexine) Anti-biotics (Azithromycin, Moxifloxacin, Linezolid) Mental Nervous system (Lurasidone, Blonanserin) Other (Tirofiban, Prucalopride Succinate)

Specialised Bulk Pharmaceuticals Bulk Pharmaceutials with status A owned by Hebei Guangxiang Pharmaceutical (22)

Serial	Registration No.	Drug Name	Status
1	Y20200001269	Epalrestat	А
2	Y20190007857	Aminophylline	А
3	Y20190007856	Theophylline	А
4	Y20190006345	Niacin	А
5	Y20190002961	Benzoyl metronidazole	А
6	Y20190002960	Nifedipine	А
7	Y20190002959	Caffeine	А
8	Y20190002958	Metronidazole	А
9	Y20200001432	Pitavastatin Calcium	А
10	Y20200001464	Lacosamide	А
11	Y20210000026	Levonidazole	А
12	Y20210000025	Ornidazole	А
13	Y20200001394	Pentoxifylline	А
14	Y20210000024	Rosuvastatin Calcium	А
15	Y20200001465	Argatroban	А
16	Y20210000927	Doxofylline	А
17	Y20210000931	Tinidazole	А
18	Y20210000930	Theobromine	А
19	Y20210000678	Tedizolid Phosphate	А
20	Y20210001076	Tofacitinib Citrate	А
21	Y20210001168	Urapidil Hydrochloride	А
22	Y20210001167	Urapidil	А

Specialised Bulk Pharmaceuticals Bulk Pharmaceutials with status A owned by Hebei Guolong Pharmaceutical (18)

Serial	Registration No.	Drug Name	Status
1	Y20200001123	Cinacalcet Hydrochloride	А
2	Y2020000767	ipratropium Bromide	А
3	Y2020000466	Dexmedetomidine Hydrochloride	А
4	Y20190001004	Blonanserin	А
5	Y20190021513	Linezolid	А
6	Y20190001130	Lurasidone Hydrochloride	А
7	Y20190021527	Terbutaline Sulfate	А
8	Y20190007337	Hydroxyethyl Starch 40	А
9	Y20190007065	Hydroxyethyl Starch 130/0.4	А
10	Y20190006891	Tenofovir Disoproxil Fumarate	А
11	Y20180001418	Prucalopride Succinate	А
12	Y20170001049	Tirofiban Hydrochloride	А
13	Y20170000871	Moxifloxacin Hydrochloride	А
14	Y20170000397	Arbidol Hydrochloride	А
15	Y20170000261	Bromhexine Hydrochloride	А
16	Y20170000185	Hydroxyethyl Starch 200/0.5	А
17	Y20170000182	Azithromycin	А
18	Y20190000687	L-Malic Acid	А

Diversified and Coordinated Development – Medical Materials Production Base







Jiangsu Best New Medical Material Major products: Bioprocessing film series Multi-layer co-extrusion infusion films Rubber stopper series Gasket series

Diversified and Coordinated Development – Biotechnology and product development





Numerous Varieties, Complete Dosage Form, Wide coverage

No. of Production approvals: 391 including

282 Preparations, 40 bulk pharmaceuticals41 medical materials and 28 other products

Distribution of fields of preparation products

27% - cardiovascular system
24% - nervous system
15% - anti-infections
9% - digestive system
8% - respiratory system
6% - electrolyte/nutrition
4% - anti-tumor
7% - other fields

No. of Preparations approved: 282 including 199 in Essential Drug List, 72 passed consistency evaluation, 13 in National Centralised Procurement

Examples of Specialised products

1.000		
R 4'	2013	TH.222223754
	己酮可可碱注射 Pentoxifylline Injectio	
	Ċ	<u>)</u>
5ml:0.1g×50支/盒	★ 石家庄田 古田市法:4	MARCO

Pentoxifylline Injection



Bromhexine Hydrochloride Injection

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		9}<
(mp) 10#	50	家庄茵药有服公司

Blonanserin tablets

Peritoneal Dialysis

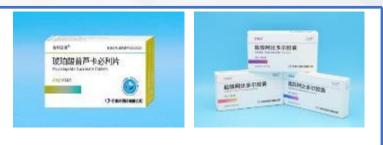
Solution

Arbidol Hydrochloride Capsules

依维多。	BP/#07H20223941
拉考沙胺注	1 射液
Lacosamide Injection	
[ultimat]	
あ品述用于4岁及以上的局害者部分 [検知] 20ml 200mg 20ml 200mg 20ml 20ml 20ml 20ml 20ml 20ml 20ml 20ml 30ml 30ml	4x30808087.
20ml/支	
5支/盒	

Lacosamide Injection

Numerous Varieties, Complete Dosage Form, Wide coverage





Solid preparations

- National Centralised Procurement : Cefaclor for Suspension, Cefdinir capsule, Prucalopride Succinate tablet and Felodipine II Sustained-release Tablets
- 1st approval in PRC: Blonanserin tablets, Azithromycin for suspension, Stipentol for suspension
- 1st passed consistency evaluation : Pentoxifylline Sustained-release tablets



I.V. Infusion

- National Centralised Procurement : Fluconazole Sodium Chloride Injection, Metronidazole Injection
- 1st passed consistency evaluation : Peritoneal Dialysis Solution (Lactate-G1.5%, Lactate-G2.5%), Compound Electrolyte Injection II
- Key products : Ambroxol Hydrochloride, Mannitol, Fluconazole, Moxifloxacin Hydrochloride, Hemofiltration solution, Ciprofloxacin Lactate, Levofloxacin
- Packaging : Non-PVC soft bag, Upright soft bag, PP bottle, Glass bottle



Ampoule Injections

- National Centralised Procurement :
 Doxofylline, Ambroxol Hydrochloride,
 Ropivacaine Hydrochloride, Bromhexine
 Hydrochloride, Ornidazole, Methylcobalamin
 and Argatroban
 - 1st passed consistency evaluation :

Pentoxifylline Injection

Specialised products : Terbutaline Sulfate
 Nebuliser Solution, Dexmedetomidine,
 Moxifloxacin Hydrochloride Eye Drops



Market share increases for products in

national centralised procurement

National centralised procurement batch	Products being selected	Market share in PRC government hospitals		
(Time)		2020	2021	2022
3 rd batch (Aug 2020)	Prucalopride Succinate tablet	1.09%	6.59%	9.44%
	Cefdinir capsule*	2.30%	32.60%	38.56%
4 th batch(Feb 2021)	Doxofylline Injection	0.73%	7.69%	11.67%
	Ambroxol Hydrochloride Injection	0.31%	0.91%	3.10%
5 th batch (Jun 2021)	Fluconazole Sodium Chloride Injection*	0.37%	1.77%	18.88%
	Ropivacaine Hydrochloride Injection*	0.00%	0.38%	12.03%
7 th batch(Jul 2022)	Cefaclor for Suspension	4.84%	3.16%	5.08%
	Bromhexine Hydrochloride Injection	0.00%	16.01%	42.16%
8 th batch(Mar 2023)	Felodipine/Felodipine II Sustained- release Tablets			
	Ornidazole Injection			
	Metronidazole Injection			
	Mecobalamin Injection			
Data source: menet.com.cn	Argatroban Injection			

*In 2022, ranked top 3 in Cefdinir capsule, Fluconazole Sodium Chloride Injection and Ropivacaine Hydrochloride Injection market I.V. Infusion Production Line Intelligent Manufacturing, Largest Production Capacity on Single Factory Basis in PRC

	I.V. Production Capacity Expansion						
No.4 Pharma	Year 2019	Increase / % change	Year 2021	Increase / % change	Year 2022	Increase / % change	Year 2023
Non-PVC Soft Bag (Note1)	750M	-	750M	-	750M	-	750M
Upright Soft Bag (Note2)	300M	-	300M	-	300M	600M/200%	900M
PP Plastic Bottle (Note3)	600M	150M/25%	750M	-	750M	-	750M
Glass Bottle	200M	-	200M	-	200M	-	200M
Total	1,850M	150M/25%	2,000M	-	2,000M	600M/30%	2,600M

(Note1) : Increased 20 million bags in large volume soft bag production line in year 2019

(Note2) : Increased 600 million bags in upright soft bag production line in year 2023

(Note3) : Increased 150 million bottles in plastic bottle production line by technical improvement in year 2021

Awards and recognitions



- Ranked 10 in Chemical Drugs R&D Capabilities in China in 2023
- China pharmaceutical independent innovation pioneer enterprise
- ✓ China innovative pharmaceutical companies
- National-level manufacturing individual champion enterprise
- Selected in the 2022 list of outstanding smart manufacturing scenarios
- ✓ National Intellectual Property Demonstration Enterprise
- ✓ Top 100 Enterprises in China's Pharmaceutical Industry

PART 03

R&D Status and Prospects

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- Strategy in generic drugs R&D
- Specialised drug platform
- Products awaiting approval

- Products for approval application
- Key innovative drug R&D projects
- Strong external R&D support

Strategy in generic drugs R&D

Bulk pharmaceuticals

- Products requires difficult process/ special process products, self-owned patented technology products
- Forming Product series
- Bulk pharmaceuticals in shortage or monopoly
- Industrialization of Microchannel Technology

Basic infusion solutions

- Sourcing domestic raw materials for basic infusion
- Continue to improve and internationalize product
- Facilitate clinical application of basic infusion packaging
- Maintain and consolidate product technology and market advantages

Solid preparations

- Focus on products with large market demand and urgent clinical needs
- Bulk pharmaceuticals + preparation integration
- Extension of drug applications
- Sustained-release technology & product development

Injections

- Complete the consistency evaluations of existing selected therapeutic infusion
- > Diversification in therapeutic fields
- Scale-up of ampoule injections
- Development of anti-tumor, emulsions, lyophilized & long-release injections

Strategy in generic drugs R&D (Key therapeutic fields)

Respiratory system: injections/inhalation/oral

Stimulates lysosomal release from mucus-secreting cells (bromhexine); Phosphodiesterase (PDE) Inhibitors (Doxofylline); Cholinergic Receptor (M Receptor) Antagonist (Ipratropium Bromide); Beta-adrenoceptor agonists (terbutaline, epinephrine)

Cardiovascular system: oral/injection

Hypertension (single prescription, compound preparation); Hyperglycemia (extension of indications); Hyperlipidemia (representative products with different mechanisms); Nephrology field (combination of oral and dialysis); Others (Exclusive in passing consistency evaluation: Pentoxifylline Sustained Release Tablets)

Nervous system : oral/injections

GABA receptors and voltage-gated Na+ channels (stipentol, exclusive product); Dopamine and serotonin receptor antagonists (blonanserin, 1st product); COMT and MAO-B inhibitors (Parkinson, single and combination agents); 5-HT* receptor antagonists (antidepressants)

Anesthesia and Contrast agent: Injection

Caines series (e.g. lidocaine, ropivacaine); Fat emulsion anesthetic preparation (the most advanced domestic production technology); Drugs for anesthesia; Contrast agents (gadolinium and indocyanine green)

Antibacterial & antiviral field: oral/injection

- Cephalosporins (dry suspension for children)
- Macrolides (injection, dry suspension)
- Conazoles (infusion, tablet, dry suspension)
- Floxacin (infusion, tablet, eye drop)
- Oxazolidinones (infusion, lyophilized, tablet, dry suspension)
- Nitazoles (infusion, water injection, tablet)
- > Antivirals (Arbidol, Oseltamivir, etc.)

Bulk Pharmaceuticals under review (Hebei Guangxiang)

No.	Registration No.	Drug Name	Status	Expected approval
1	Y20210000927	Doxofylline	А	Approved
2	Y20210000931	Tinidazole	А	Approved
3	Y20210000930	Theobromine	А	Approved
4	Y20210000678	Tedizolid Phosphate	А	Approved
5	Y20210001167	Uradil	А	Approved
6	Y20210001168	Urapidil Hydrochloride	А	Approved
7	Y20210001076	Tofacitinib Citrate	А	Approved
8	Y20210001074	Entacapone	I	2023.08
9	Y20220000115	Salbutamol Sulfate	I	2023.08
10	Y20220000118	Levosalbutamol Hydrochloride	I	2023.08
11	Y20220000117	Lidocaine Hydrochloride	I	2023.09
12	Y20220000116	Vortioxetine Hydrobromide	I	2023.10
13	Y20220000359	Benserazide Hydrochloride	I	2023.11
14	Y20220000360	Isoproterenol Hydrochloride	I	2023.11
15	Y20220000599	Rasagiline Mesylate	I	2023.12
16	Y20220000836	Norepinephrine Bitartrate	I	2024
17	Y20220000874	Butylphthalide	I	2024
18	Y20220000954	Formoterol Fumarate	I	2024
19	Y20220000958	Adrenaline	I	2024
20	Y20220001108	Phenylephrine Hydrochloride	I	2024

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Bulk Pharmaceuticals under review (Hebei Guolong)

No.	Registration No.	Drug Name	Status	Expected approval
1	Y20190000687	L-malic acid	А	Approved
2	Y20210000821	Stippentol	I	2023.08
3	Y20220000356	Nicorandil	I	2023.11
4	Y20220000426	Etomidate	I	2023.12
5	Y20220000427	Trexagliptin Succinate	I	2023.12
6	Y20220000598	Cisatracurium Besylate	I	2023.12
7	Y20220000597	Alogliptin Benzoate	I	2023.12
8	Y20210000676	Safinamide Mesylate	I	2024
9	Y20220000818	Dapagliflozin	I	2024
10	Y20220000910	Doxazosin Mesylate	I	2024
11	Y20220001251	Betahistine Mesylate	I	2024
12	Y20220001252	Deferasirox	I	2024
13	Y20230000011	Mexartan Potassium	I	2024



Type 3 Preparations under review

Expected to be approved by the end of 2023

No.	Acceptance No.	Drug Name	Specification
1	CYHS2101884	Terbutaline Sulfate Injection	1ml:0.5mg
2	CYHS2102018	Lipoic Acid Injection	24ml:600mg
3	CYHS2101827	Ornidazole Injection	3ml:0.5g
4	CYHS2101828	Ornidazole Injection	6ml:1.0g
5	CYHS2102028	Pentoxifylline Extended Release Tablets	400mg
6	CYHS1600212	Sorbitol Mannitol Rinse	3000ml
7	CYHS2200020	Oseltamivir Phosphate Dry Suspension	6mg/ml
8	CYHS2200546	Ondansetron Hydrochloride Tablets	8mg
9	CYHS2200547	Ondansetron Hydrochloride Tablets	4mg
10	CYHS2200323	Citicoline Sodium Injection	4ml:500mg
11	CYHS2200617	Stipopentol dry suspension	250mg
12	CYHS2200618	Stipopentol dry suspension	500mg
13	CYHS2200496	Tirofiban Hydrochloride Injection	15ml:3.75mg
14	CYHS2200698	Tinidazole Tablets	0.5g
15	CYHS2200719	Ornidazole Tablets	0.5g
16	CYHS2201075	Aminophylline Injection	10ml
17	CYHS2201076	Aminophylline Injection	20ml
18	CYHS2201078	Salbutamol Sulfate Injection	1ml
19	CYHS2200543	Linezolid Sodium Chloride Injection	300ml
20	CYHS2200777	Epalrestat Tablets	50mg
21	CYHS2201031	Arbidol Hydrochloride Tablets	50mg
22	CYHS2201221	Cefuroxime Axetil Dry Suspension	0.125g
23	CYHS2201222	Cefuroxime Axetil Dry Suspension	0.25g
24	CYHS2201219	Ozagrel Sodium Injection	2.5ml
25	CYHS2201220	Ozagrel Sodium Injection	5ml
26	CYHS2201248	Citicoline Sodium Injection	4ml:1g
27	CYHS2201328	Nicorandil for Injection	12mg
28	CYHS2201309	Sodium Bicarbonate Ringer's Injection	500ml
29	CYHS2201365	Magnesium Sulfate Injection	2ml
30	CYHS2201366	Magnesium Sulfate Injection	10ml
31	CYHS2201367	Magnesium Sulfate Injection	20ml



Type 4 Preparations under review

Expected to be approved by the end of 2023

No.	Acceptance No.	Drug Name	Specification
1	CYHS2101193	Lacosamide Injection	20ml : 200mg
2	CYHS2101621	Felodipine sustained release tablets	5mg
3	CYHS2101759	Lurasidone Hydrochloride Tablets	40mg
4	CYHS2102124	Argatroban Injection	2ml: 10mg
5	CYHS2102153	Cinacalcet Hydrochloride Tablets	25mg
6	CYHS2200058	Urapidil Hydrochloride Injection	5ml
7	CYHS2200059	Urapidil Hydrochloride Injection	10ml
8	CYHS1900588	Compound Electrolyte Injection II	500ml
9	CYHS1900589	Compound Electrolyte Injection II	1000ml
10	CYHS2101706	Pitavastatin Calcium Tablets	2mg
11	CYHS2101706	Pitavastatin Calcium Tablets	1mg
12	CYHS2200320	Tedizolid Phosphate for Injection	200mg
13	CYHS2200984	Tedizolid Phosphate Tablets	200mg
14	CYHS2201023	Ropivacaine Hydrochloride Sodium Chloride Injection	100ml
15	CYHS2201044	Rasagiline Mesylate Tablets	1mg
16	CYHS2201195	Propofol Medium / Long Chain Fat Emulsion	10ml
17	CYHS2201196	Propofol Medium / Long Chain Fat Emulsion	20ml
18	CYHS2201268	Vortioxetine Hydrobromide Tablets	5mg
19	CYHS2201269	Vortioxetine Hydrobromide Tablets	10mg



Preparations under consistency evaluation review

Expected to be approved by the end of 2023

No.	Acceptance No.	Drug Name	Specification
1	CYHB2250308	Azithromycin for injection	0.5g
2	CYHB2250342	Sodium Lactated Ringer Injection	500ml
3	CYHB1950801	Peritoneal Dialysis Solution (Lactate - G2.5%)	2000ml
4	CYHB2050115	Sodium Acetate Ringer Injection	500ml
5	CYHB2250493	Low Calcium Peritoneal Dialysis Solution (Lactate - G1.5%)	2000ml
6	CYHB1950835	Sodium Bicarbonate Injection	250ml
7	CYHB1950769	Potassium Chloride Injection	10ml:1.5g
8	CYHB1950790	Potassium Chloride Injection	10ml:1g
9	CYHB2250614	Low Calcium Peritoneal Dialysis Solution (Lactate - G2.5%)	2000ml
10	CYHB2250688	Metoprolol Tartrate Injection	5ml

Production approvals to submit (update: 11 Aug 2023)



To submit soon

- 15 types of bulk pharmaceuticals
- 19 types of liquid preparations with
 - **21** specifications
 - 11 types of oral preparations with
 - **15 specifications**

Major projects of innovative drug development

Type I New Drug

- (a) NP-01: Type I new drug for gastric cancer, expected to complete phase I clinical trial by Nov 2023, start phase II clinical trial in Dec 2023
- (b) ADN-9: Anti-hepatic fibrosis type I new drug, phase I clinical trial expected to start in Dec 2023
- (c) SYN-045: Anti-pulmonary hypertension drug, expected to apply phase I clinical trial Pre-IND in Oct 2023

Type II New Drug

- (a) Miplatin Liposome: Type II new drug for liver cancer, actively promote the phase I clinical trials, and is expected to apply for the phase I clinical trials, and is expected to apply for the phase I clinical trial by the end of 2023
- (b) **TPST Sustained-release preparations**: Hyperuricemia, reduce the number of administrations and fluctuations in blood concentration, under preclinical development
- (c) WNKL Sustained-release Oral Preparation: Atrial fibrillation, changing the route of intravenous administration, improving compliance, under preclinical development
- (d) BWXT Sustained-release Oral Formulation: Epilepsy, reducing dose frequency, plasma concentration fluctuations, under preclinical development
- (e) Compound acetaminophen injection : Antipyretic and analgesic Type II new drug, improving safety, under preclinical development
- (f) Levonidazole injection : Anaerobic bacteria, Type II new drug for small water injections, under preclinical development
- (g) **DBT injection**: Ischemic stroke, Type II new drug for injection small water injection, under preclinical development

Strong External R&D and Industrialization Support/Cooperation



PART 04

Development Strategies

Fields for development
Production chains

Bioprocessing films

> Advanced preparations

> Intelligent production

Fields for development

Generic Drugs : Increase R&D continuously; focus on high-end bulk drugs; integrate specialized bulk drug + preparations
Innovative Drugs : Clinical trials and commercialization to proceed on schedule ; plan on drug development for children and elderly

Bioprocessing films

On the basis of improving existing cell culture and albumin liquid storage bag film product series, to form the core R&D advantages of domestic bioprocessing films

Intelligent production

Using big data, automation and AI to improve efficiency of production and R&D system; Automation in some key /special positions; To build high-end, intelligent and green "lighthouse" factory



Production chains

Expand the Group's production chains to achieve integration of bulk drug+ preparations; Profit maximization for key products

Advanced preparations

Develop high-end/complicated preparations e.g. liposomes, emulsions, microspheres & perforated layered tablets;

Establish a unique competition edge

Prospects for development (2nd half of 2023)

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<u>.</u>

IV : Maintain market leading position; increase proportion of therapeutic and soft bags; potential for higher profits and margins

Ampoule : Continuously enrich in varieties and increase capacity utilization; develop key products with market potential

Bulk pharmaceuticals : Reduce cost + increase efficiency; focus on high value-added specialized products; facilitate domestic and international markets

Oral and other preparations : seize opportunities in national centralised procurement, expand market size and influence on products which have passed consistency evaluation

Medical materials : In-depth development and technology improvement in bio-processing films; speed up the marketing of bio-processing films products



R&D : generic drugs+innovative drugs; external+internal resources; focus on chronic diseases, blood circulatory, emergency & anesthesia, antipyretic & analgesic, new anti-infection and anti-tumor fields



Capital operation : push forward Jiangsu Best transition of listing to Beijing Stock Exchange; actively seek M&A opportunities in pharmaceutical industry



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