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

# 2024 Interim Results & Roadshow material

Updated on 28 August 2024





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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

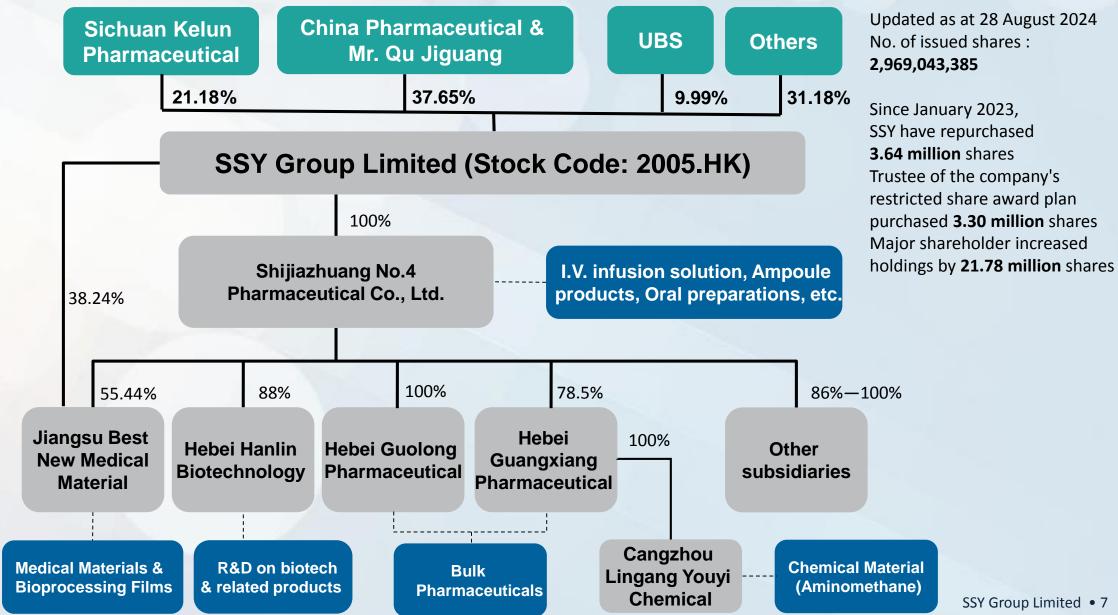
#### Financial Highlights (1H2024)

( HK\$'000 )	1H2024	1H2023	Increase/ (Decrease)
Revenue	3,338,939	3,333,157	0.2%
Gross Profit	1,843,455	1,944,751	(5.2%)
Gross Profit Margin	55.2%	58.3%	(3.1%pt)
EBITDA	1,081,255	993,861	8.8%
EBITDA Margin	32.4%	29.8%	2.6%pt
Net Profit	685,737	638,611	7.4%
Net Profit Margin	20.5%	19.2%	1.3%pt
Earning per share (HK\$)	0.2312	0.2149	7.6%
Interim Dividend	237,523	207,903	14.2%
Interim Dividend per share (HK\$)	0.08	0.07	14.3%

#### Financial Highlights (1H2024)(continued)

( HK\$'000 )	30 June 2024	31 December 2023	Increase/ (Decrease)
Cash and Cash Equivalent	1,564,535	1,615,208	(50,673)
Bank Borrowings	3,607,505	3,368,141	239,364
Net Asset Value	7,569,754	7,268,692	301,062
Gearing Ratio	22.0%	20.2%	1.8%pt
Current Ratio	2.63	2.03	0.60
Accounts Receivable Turnover (Day) <sup>#</sup>	109	110	(1)
Inventory Turnover (Day)	136	122	14
NAV per Share (HK\$)	2.55	2.45	0.10
Return on Equity	18.1%	18.1%	-
Remarks: <sup>#</sup> excluding bills receivables			

#### **Shareholding & Group Structure**



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#### **Revenue Overview (1H2024)**

_	1H2	.024	1H2023		
By Products	Revenue (НК\$'000)	% of Total Revenue	Revenue (НК\$'000)	% of Total Revenue	
I.V. Infusion	2,185,363	65.5%	2,069,115	62.1%	
Ampoule Injections	366,785	11.0%	453,398	13.6%	
Bulk Pharmaceuticals	398,786	11.9%	453,626	13.6%	
Oral Preparations	254,365	7.6%	244,391	7.3%	
Medical Materials	94,480	2.8%	90,067	2.7%	
Other Products	39,160	1.2%	22,560	0.7%	
Total	3,338,939	100%	3,333,157	100%	

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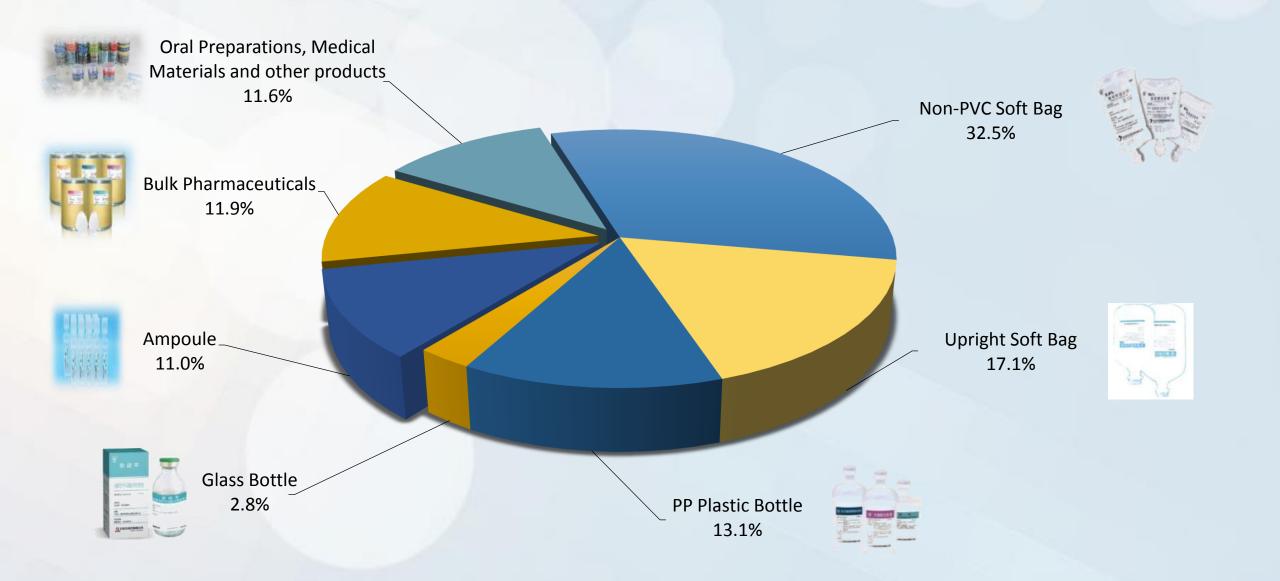


#### Revenue Overview (2023)

	20	23	2022		
By Products	Revenue (НК\$'000)	% of Total Revenue	Revenue (НК\$'000)	% of Total Revenue	
I.V. Infusion	4,040,743	62.5%	3,510,342	54.6%	
Ampoule Injections	826,103	12.8%	978,707	15.2%	
Bulk Pharmaceuticals	888,867	13.8%	1,358,949	21.1%	
Oral Preparations	478,195	7.4%	346,058	5.4%	
Medical Materials	161,629	2.5%	172,119	2.7%	
Other Products	67,472	1.0%	67,850	1.0%	
Total	6,463,009	100%	6,434,025	100%	

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#### **Revenue Breakdown by Products (1H2024)**



#### Sales volume increase, Upright soft bag and Key products continue growth trend in volume

In 1H2024, sales volume of infusion solution reached 1.139 billion bottles (bags), representing an increase of 21.7% y-o-y, revenue reached HKD2,185 million, representing an increase of 5.6% y-o-y (RMB1,986 million, representing an increase of 8.0% y-o-y)

**I.V. Infusion** 

- Outstanding performance of Upright soft bag due to the increase in production capacity and efficiency after the high-end smart production line put into production. Sales volume increased by 51.5% y-o-y, sales revenue increased by 37.9% y-o-y, and contributed for 26.2% of I.V. sales increasing by 5.7%pt
- Therapeutic infusion solutions: revenue reached HKD551 million, representing a decrease of 2.59% (HKD14.63 million) y-o-y, contributed for 25.2% of I.V. sales decreasing by 2.2%pt. Since most therapeutic infusions are packaged in non-PVC soft bags, sales of non-PVC soft bags decreased by 1.9% y-o-y, but selling expenses reduced, net profits improved
- Volume of key products : Ambroxol Hydrochloride +135%, Peritoneal Dialysis Solution +83%, Moxifloxacin Hydrochloride +72%, Mannitol +69%,
- Sales (in RMB) of key products : Ambroxol Hydrochloride +94%, Peritoneal Dialysis Solution +73%, Mannitol +23%, Moxifloxacin Hydrochloride +17%

_		I.V. Infusio	I.V. Infusion – 1H2024			
By Packaging	Revenue (HK\$'000)			GP%		
Non-PVC Soft Bag	1,085,468	49.7%	3.28	58.2%		
Upright Soft Bag	571,771	26.2%	1.53	69.1%		
PP Plastic Bottle	435,357	19.9%	1.09	46.1%		
Glass Bottle	92,768	4.2%	2.61	27.3%		
Total	2,185,363	100%	1.92	57.4%		

Ву	I.V. Infusion – 1H2024					
Pharmaceutical Products	Revenue (HK\$'000)	% of IV Revenue	Average Selling Price (ASP) (HK\$)	GP%		
Basic Infusions	1,298,333	59.4%	1.70	59.5%		
Nutrition Infusions	335,766	15.4%	1.49	48.0%		
Therapeutical Infusions	551,264	25.2%	3.71	58.0%		
Total	2,185,363	100%	1.92	57.4%		

Dec	I.V. Infusion – 2023					
By Packaging	Revenue (HK\$'000)			GP%		
Non-PVC Soft Bag	2,094,847	51.8%	3.51	65.1%		
Upright Soft Bag	880,556	21.8%	1.66	68.3%		
PP Plastic Bottle	827,264	20.5%	1.21	47.3%		
Glass Bottle	238,076	5.9%	2.44	34.1%		
Total	4,040,743	100%	2.12	60.3%		

**Revenue Overview - I.V. Infusion (2023)** 

- Proportion of therapeutic infusions (as % of IV revenue) increased by 2.2 %pt
- Various products' volume entered rapid growth period: Ambroxol Hydrochloride (+215%), Moxifloxacin Hydrochloride (+233%), Fluconazole (+295%), Peritoneal dialysis solution (+24%)

Ву	I.V. Infusion –2023					
Pharmaceutical Products	Revenue (HK\$'000)	% of IV Revenue	Average Selling Price (ASP) (HK\$)	GP%		
Basic Infusions	2,292,129	56.7%	1.84	60.5%		
Nutrition Infusions	627,729	15.5%	1.64	51.5%		
Therapeutical Infusions	1,120,885	27.8%	3.99	65.1%		
Total	4,040,743	100%	2.12	60.3%		

#### Ampoule Injections

# Increasingly rich in varieties, Production gradually scaled up, Increasing in centralised procurement

- In 1H2024, sales volume reached 167 million, increased by 26.9% y-o-y; revenue accounted for HK\$367 million, decreased by 19.1% y-o-y (RMB333 million, decreased by 17.3% y-o-y) mainly due to decrease in price of Bromhexine Hydrochloride, a centralised procurement product
- High volume products : sales volume of Betahistine Hydrochloride Injection reached 12.94 million, increased by 41% y-o-y; sales volume of Doxofylline Injection reached 15.26 million, increased by 31% y-o-y; sales volume of Ambroxol Hydrochloride Injection reached 36.79 million, increased by 19% y-o-y; sales volume Urapidil Hydrochloride Injection reached 5.02 million, achieved faster growth
- 8 specifications won the tenders in national centralised procurement : Doxofylline, Ambroxol Hydrochloride, Ropivacaine Hydrochloride, Ornidazole, Methylcobalamin, Argatroban, Urapidil Hydrochloride, Citicoline Sodium
- Proportion of National centralized procurement products in ampoule revenue : 55%
- National centralized procurement products contribute to ampoule revenue : HK\$200 million, increased by 19% y-o-y

#### **Oral Preparations**

#### Accelerated upgrade of production & sales scale, revenue contribution gradually increase

- In 1H2024, sales volume reached 800 million tablets/capsules, increased by 8% y-o-y; revenue accounted for HK\$254 million, increased by 4.1% y-o-y (RMB231 million, increased by 6.4% y-o-y); contributed for 7.6% of total sales, increased by 0.3%pt y-o-y
- Azithromycin for Suspension 53.22 million bags (+962%), Rosuvastatin Calcium tablets 66.95 million tablets (+128%), Lodipine Sustained-release tablets 72.62 million tablets (+106%), Azithromycin Dispersible tablets 60.07 million tablets (+73%)
- 5 products won national centralised procurement : Prucalopride Succinate tablet, Cefdinir capsule, Cefaclor for Suspension, Felodipine/ Felodipine II Sustained-release tablets, Azithromycin for Suspension. National centralized procurement products contributed 44% oral preparations revenue
- Revenue contribution by top national centralised procurement products (in RMB) : Cefdinir capsules RMB49.63 million (+26%), Azithromycin for Suspension RMB19.60 million (+503%), Cefaclor for suspension RMB18.56 million (+42%), Felodipine Sustained-release tablets RMB13.08 million (+81%). National centralized procurement oral preparations products contributed RMB102 million in revenue, increased by 60% y-o-y
- First approval or consistency evaluation : Blonanserin tablets, Pentoxifylline Sustained-release tablets, Azithromycin for Suspension, Stiripentol for Suspension, Linezolid for Oral Suspension, Levodopa-Carbidopa Sustained-release Tablets
- Up to 30 Jun 2024, 35 oral preparations types with 45 specifications passed or regarded as passing consistency evaluation in China

#### **Bulk Pharmaceuticals**

#### Sales volume of caffeine increased, volume and price of azithromycin increased

- In 1H2024, revenue accounted for HK\$399 million, decreased by 12.1% y-o-y (RMB362 million, decreased by 10.1% y-o-y ).
- **32** new bulk pharmaceutical customers, including 13 new caffeine customers
- Caffeine : sales volume increased by 28% y-o-y, but unit price at a low level, lead to decrease in revenue by 1% y-o-y; contributed for 47% of bulk pharmaceutical sales, increased by 4.5%pt y-o-y
- Azithromycin : sales volume increased by 33% y-o-y, revenue increased by 55% y-o-y, contributed for 40.1% of bulk pharmaceutical sales, increased by 16.9%pt y-o-y
- There are 60 bulk pharmaceutical products with Status A. Refer details to "Bulk Pharmaceutials with status A owned by Hebei Guangxiang Pharmaceutical" & "Bulk Pharmaceutials with status A owned by Hebei Guolong Pharmaceutical"

### Medical Materials

Improve in medical materials and lyophilized powder products

- In 1H2024, revenue of external sales accounted for HK\$94.48 million, increased by 4.9% y-o-y (RMB85.86 million, increased by 7.3% y-o-y), benefit from increased market penetration and coverage.
- Other product and services: revenue accounted for HK\$39.16 million, increased by 73.6% y-o-y (RMB35.59 million, increased by 77.5% y-o-y). The main reason is that lyophilized powder for injection series contributed nearly half (48%) of revenue, while there was no sales of lyophilized powder for injection in the same period.

## Foreign exports

#### **Preparation exports maintain stable**

- In 1H2024, export of infusion solution: volume of 51.72 million bottles (bags), growth of 1.3% y-o-y, revenue of HK\$77.62 million, roughly the same y-o-y (RMB70.55 million, roughly the same y-o-y)
- Developed 13 new customers
- Completed 17 product registrations in 6 countries, obtained 405 product registration certificates in nearly 100 countries
- Recently 37 products and 84 specifications exported to over 100 countries and regions in the world

#### **Research and Development**

- Up to 30 June 2024, a total of 66 national production approvals were obtained (increased 43% y-o-y), including 51 for preparations and 15 for bulk pharmaceuticals. Research and development efficiency and quantity of generic drugs are among the best in China's pharmaceutical companies
- Up to 30 June 2024, the Group has a total of 94 product types with 126 specifications passed or regarded as passing consistency evaluation. 1<sup>st</sup> : 19 products; 1<sup>st</sup> 3<sup>rd</sup> : 60 products
  - The first PRC company passing consistency evaluation in 2024: anti-infective drug linezolid dry suspension, Parkinson's drug carbodopa sustained-release tablets, acidosis drug sodium bicarbonate injection 50ml
  - The first and only: Stiripentol for suspension for the treatment of severe myoclonic epilepsy in infants (orphan drug)
  - Antihypertensive series: Nifedipine sustained-release tablets (II), felodipine sustained-release tablets, valsartan and amlodipine tablets (I), urapidil hydrochloride injection, esmolol hydrochloride injection
  - Anti-Parkinson's disease drug series: Carbopol levodopa sustained-release tablets, Rasagiline mesylate tablets, Entacapone levodopa tablets (II), Dopamine hydrazine tablets
- Up to 30 June 2024, 65 applications made to National Drug Administration Center for Drug Evaluation: 51 for preparations (including consistency evaluation), 14 for bulk pharmaceuticals; 147 items awaiting for approvals : 111 for preparations (including consistency evaluation), 36 for bulk pharmaceuticals
- Innovative drug SYN-045 (type I new drug for pulmonary arterial hypertension) phase I clinical trial is underway
- Target to obtain 29 approvals and make 53 applications for new products from 30 June 2024 to the end of 2024.
  Currently, 202 projects under R&D and 134 products awaiting approval.
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## **V**

#### Product passed/regarded passing consistency evaluation

(94 Types, 126 Specifications)

No.	Drug Name	Specification	Approval Date	Approval in PRC	Treatment Category
1	Fluconazole Tablets	150mg	28/04/2019	The First	Systemic anti-infectives
2	Doxofylline Injection	10ml:0.1g	21/01/2020	The First	Respiratory system
3	Ropivacaine Hydrochloride Injection	10ml:100mg	17/03/2020	The First	Nervous system
4	Ciprofloxacin Lactate Sodium Chloride Injection	100ml	05/01/2021	The First	Systemic anti-infectives
5	Metronidazole Sodium Chloride Injection	250ml	26/02/2021	The First	Systemic anti-infectives
6	Blonanserin tablets	4mg	16/06/2022	The First	Nervous system
7	Peritoneal Dialysis Solution (Lactate-G1.5%)	2000ml	28/06/2022	The First	Blood and hematopoietic organs
8	Peritoneal Dialysis Solution (Lactate-G2.5%)	2000ml	11/04/2023	The First	Blood and hematopoietic organs
9	Azithromycin dry suspension	0.1g	30/08/2022	The First	Systemic anti-infectives
10	Pentoxifylline Injection	5ml:100mg	30/09/2022	The First	Cardiovascular System
11	Pentoxifylline Sustained-release Tablets	400mg	21/03/2023	The First	Cardiovascular System
12	Stiripentol for Suspension	250mg	25/07/2023	The First	Nervous system
13	Stiripentol for Suspension	500mg	25/07/2023	The First	Nervous system
14	Fluconazole Sodium Chloride Injection	50ml	31/12/2021	First specification	Systemic anti-infectives
15	Compound Electrolyte Injection II	1000ml	17/04/2023	First specification	Blood and hematopoietic organs
16	Fluconazole Tablets	50mg	28/04/2019	Second	Systemic anti-infectives
17	Cefdinir capsule	0.1g	08/07/2020	Second	Systemic anti-infectives
18	Ciprofloxacin Lactate and Sodium Chloride Injection	200ml	16/12/2022	Second	Systemic anti-infectives
19	Fluconazole Sodium Chloride Injection	100ml	12/01/2021	Second	Systemic anti-infectives
20	Metronidazole Sodium Chloride Injection	100ml	26/02/2021	Second	Systemic anti-infectives
21	Bromhexine Hydrochloride Injection	2ml	23/03/2021	Second	Respiratory system
22	Terbutaline Sulphate Solution for Nebulization	2ml:5mg	07/04/2021	Second	Respiratory system
23	Acetaminophen Mannitol Injection	100ml : 1g	16/06/2022	Second	Nervous system
24	Sorbitol and Mannitol Irrigation Solution	3000ml	21/03/2023	Second	Blood and hematopoietic organs
25	Sodium Lactated Ringer Injection	500ml	20/03/2023	Second	Blood and hematopoietic organs
26	Compound Electrolyte Injection II	500ml	17/04/2023	Second	Blood and hematopoietic organs
27	Terbutaline Sulphate Solution for Nebulization	1ml	07/04/2023	Second specification	Respiratory system
28	Thioctic Acid Injection	24ml	31/01/2023	Second specification	Digestive system and metabolic
29	Medium and Long Chain Fat Emulsion Injection (C8~24Ve)	250ml	28/01/2021	Third	Blood and hematopoietic organs
30	Terbutaline Sulphate Injection	1ml:0.5mg	19/01/2023	Third	Respiratory system
31	Prucalopride Succinate Tablets	1mg	16/07/2020	Second	Digestive system and metabolic drugs
32	Prucalopride Succinate Tablets	2mg	16/07/2020	Second	Digestive system and metabolic drugs

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

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#### Product passed/regarded passing consistency evaluation

(94 Types, 126 Specifications)

No.	Drug Name	Specification	Approval Date	Approval in PRC	Treatment Category
33	Rosuvastatin Calcium Tablets	10mg	17/08/2020		Cardiovascular System
34	Rosuvastatin Calcium Tablets	5mg	09/06/2022		Cardiovascular System
35	Ropivacaine Hydrochloride Injection	10ml:75mg	16/06/2023		Nervous system
36	Ambroxol Hydrochloride Injection	1ml	22/12/2020		Respiratory system
37	Ambroxol Hydrochloride Injection	2ml	22/12/2020		Respiratory system
38	Ambroxol Hydrochloride Injection	4ml	22/12/2020		Respiratory system
39	Moxifloxacin Hydrochloride & Sodium Chloride Injection	250ml	23/11/2020		Systemic anti-infectives
40	Linezolid and Glucose Injection	100ml	29/06/2021		Systemic anti-infectives
41	Dexmedetomidine Hydrochloride Injection	2ml	07/09/2021		Nervous system
42	Dexmedetomidine Hydrochloride Injection	1ml	30/01/2022		Nervous system
43	Lacosamide Tablets	50mg	30/09/2021		Nervous system
44	Lacosamide Tablets	100mg	30/09/2021		Nervous system
45	Moxifloxacin Hydrochloride Tablets	0.4g	07/01/2022		Systemic anti-infectives
46	Levofloxacin and Sodium Chloride Injection	100ml : 0.5g	16/03/2022		Systemic anti-infectives
47	Moxifloxacin Hydrochloride Eye Drops	5ml	16/03/2022		Systemic anti-infectives
48	Cefaclor Dry Suspension	0.125g	30/03/2022		Systemic anti-infectives
49	Metronidazole Tablets	0.2g	30/03/2022		Systemic anti-infectives
50	Levofloxacin Injection	20ml:0.5g	16/06/2022		Systemic anti-infectives
51	Mecobalamin Injection	1ml	05/09/2022		Blood and hematopoietic organs
52	Valsartan and Amlodipine Tablets (I)	80mg/5mg	20/09/2022		Cardiovascular System
53	Ipratropium Bromide Solution for Inhalation	2ml:500µg	30/09/2022		Respiratory system
54	Ipratropium Bromide Solution for Inhalation	2ml:250µg	30/09/2022		Respiratory system
55	Azithromycin dispersible Tablets	0.25g	08/11/2022		Systemic anti-infectives
56	Lacosamide Injection	20ml	30/12/2022		Nervous system
57	Felodipine Sustained-Release Tablets	5mg	30/12/2022		Cardiovascular System
58	Ornidazole Injection	3ml:0.5g	31/01/2023		Systemic anti-infectives
59	Ornidazole Injection	6ml:1.0g	31/01/2023		Systemic anti-infectives
60	Lurasidone Hydrochloride Tablets	40mg	14/02/2023		Nervous system
61	Azithromycin for Injection	0.5g	21/03/2023		Systemic anti-infectives
62	Argatroban Injection	2ml:10mg	24/03/2023		Blood and hematopoietic organs
63	Sodium Acetate Ringer's Injection	500ml	04/05/2023		Blood and hematopoietic organs
64	Cinacalcet Hydrochloride Tablets	25mg	12/05/2023		Non-sex hormones and insulin-based hormonal systemic drugs

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#### Product passed/regarded passing consistency evaluation

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(94 Types, 126 Specifications)

No.	Drug Name	Specification	Approval Date	Approval in PRC	Treatment Category
65	Tedizolid Phosphate Injection	200mg	26/05/2023		Systemic anti-infectives
66	Urapidil Hydrochloride Injection	5ml	29/05/2023		Cardiovascular System
67	Urapidil Hydrochloride Injection	10ml	29/05/2023		Cardiovascular System
68	Citicoline Sodium Injection	4ml:500mg	07/06/2023		Nervous system
69	Tirofiban hydrochloride Concentrated Solution Injection	15ml:3.75mg	27/06/2023		Blood and hematopoietic organs
70	Pitavastatin Calcium Tablets	2mg	30/06/2023		Cardiovascular System
71	Pitavastatin Calcium Tablets	1mg	30/06/2023		Cardiovascular System
72	Oseltamivir Phosphate Suspension	6mg/ml	11/07/2023		Systemic anti-infectives
73	Low Calcium Peritoneal Dialysis Solution (Lactate-G1.5%)	2000ml	21/08/2023	Second	Blood and hematopoietic organs
74	Low Calcium Peritoneal Dialysis Solution (Lactate-G2.5%)	2000ml	28/08/2023	Second	Blood and hematopoietic organs
75	Tinidazole Tablets	0.5g	28/09/2023		Systemic anti-infectives
76	Ornidazole Tablets	0.5g	28/09/2023		Systemic anti-infectives
77	Linezolid Sodium Chloride Injection	300ml	12/10/2023	Third	Systemic anti-infectives
78	Salbutamol Sulfate Injection	1ml:0.5mg	23/10/2023	Second	Respiratory system
79	Ondansetron Hydrochloride Tablets	8mg	24/10/2023	Third	Digestive system and metabolic
80	Ondansetron Hydrochloride Tablets	4mg	24/10/2023	Third	Digestive system and metabolic
81	Epalrestat Tablets	50mg	24/10/2023		Digestive system and metabolic
82	Metoprolol Tartrate Injection	5ml	26/10/2023	Third	Cardiovascular System
83	Potassium Chloride Injection	10ml:1g	02/11/2023	Third	Blood and hematopoietic organs
84	Aminophylline Injection	10ml	27/10/2023		Respiratory system
85	Aminophylline Injection	20ml	27/10/2023		Respiratory system
86	Tirofiban Hydrochloride and Sodium Chloride Injection	100ml	20/11/2023		Blood and hematopoietic organs
87	Tedizolid Phosphate Tablets	200mg	28/11/2023		Systemic anti-infectives
88	Nifedipine Sustained-release Tablets	20mg	25/12/2023	Third	Cardiovascular System
89	Ropivacaine Hydrochloride and Sodium Chloride Injection	100ml	29/12/2023	Third	Nervous system
90	Chlorpheniramine Maleate Injection	1ml	04/01/2024	Second	Respiratory system
91	Chlorpheniramine Maleate Injection	2ml	04/01/2024	The First	Respiratory system
92	Vortioxetine Hydrobromide Tablets	10mg	09/01/2024		Nervous system
93	Magnesium Sulfate Injection	2ml	09/01/2024		Cardiovascular System
94	Magnesium Sulfate Injection	10ml	09/01/2024		Cardiovascular System
95	Magnesium Sulfate Injection	20ml	09/01/2024		Cardiovascular System
96	Potassium Chloride Injection	20ml	16/01/2024		Blood and hematopoietic organs



#### Product passed/regarded passing consistency evaluation

(94 Types, 126 Specifications)

No.	Drug Name	Specification	Approval Date	Approval in PRC	Treatment Category
97	Propofol Medium/Long Chain Fat Emulsion Injection	20ml	06/02/2024		Nervous system
98	Propofol Medium/Long Chain Fat Emulsion Injection	10ml	06/02/2024		Nervous system
99	Sodium Bicarbonate Ringer's Injection	500ml	20/02/2024		Blood and hematopoietic organs
100	Gliclazide Tablets	80mg	23/02/2024		Digestive system and metabolic
101	Nicorandil for injection	12mg	23/02/2024		Cardiovascular System
102	Cefuroxime Axetil Dry Suspension	0.125g	29/03/2024	Second	Systemic anti-infectives
103	Cefuroxime Axetil Dry Suspension	0.25g	29/03/2024	The First	Systemic anti-infectives
104	Lidocaine Hydrochloride Injection	5ml	29/03/2024		Cardiovascular System
105	Lidocaine Hydrochloride Injection	10ml	29/03/2024		Cardiovascular System
106	Lidocaine Hydrochloride Injection	20ml	29/03/2024		Cardiovascular System
107	Cephalexin Capsules	0.125g	28/03/2024		Systemic anti-infectives
108	Cephalexin Capsules	0.25g	28/03/2024		Systemic anti-infectives
109	Linezolid Dry Suspension	5ml:100mg	17/04/2024	The First	Systemic anti-infectives
110	Compound Electrolyte Injection	500ml	07/05/2024	Second	Blood and hematopoietic organs
111	Rasagiline Mesylate Tablets	1mg	15/05/2024		Nervous system
112	Ondansetron Hydrochloride Injection	4ml:8mg	21/05/2024		Digestive system and metabolic
113	Ondansetron Hydrochloride Injection	2ml:4mg	21/05/2024		Digestive system and metabolic
114	Sodium Bicarbonate Injection	8.4%, 50ml	23/05/2024	The First	Blood and hematopoietic organs
115	Acetaminophen Mannitol Injection	50ml:500mg	27/05/2024	Second	Nervous system
116	Peritoneal dialysis solution (Lactate-G4.25%)	2000ml	28/05/2024		Blood and hematopoietic organs
117	Bisoprolol Amlodipine Tablets	5mg	28/05/2024	Second	Cardiovascular System
118	Entacapone Tablets	0.2g	28/05/2024	Third	Nervous system
119	Esmolol Hydrochloride and Sodium Chloride Injection	100ml	11/06/2024	Second	Cardiovascular System
120	Esmolol Hydrochloride Injection	10ml:0.1g	25/06/2024		Cardiovascular System
121	Isoproterenol Hydrochloride Injection	1ml:0.2mg	28/06/2024		Cardiovascular System
122	Carbendazim Sustained-Release Tablets	50mg/200mg	28/06/2024	The First	Nervous system
123	Dapagliflozin Tablets	5mg	28/06/2024		Digestive system and metabolic
124	Dapagliflozin Tablets	10mg	28/06/2024		Digestive system and metabolic
125	Isosorbide Nitrate Injection	10ml:10mg	28/06/2024		Cardiovascular System
126	Etomidate Medium/Long Chain Fat Emulsion Injection	10ml:20mg	28/06/2024	Third	Nervous system



#### Products considered as catalyst of growth

(34 Types, 47 Specifications)

#### **Catalyst products**

It is considered to have room for great growth as it meets the following conditions at the same time: Bulk pharmaceuticals + preparation integration (Self-bulk pharmaceuticals supply)

- & Five or more companies passed Consistency Evaluation (including our Group)
- & Room for growth from existing revenue

No.	Drug Name	Specification	Approval Date	Approval in PRC	Treatment Category
1	Rosuvastatin Calcium Tablets	10mg	17/08/2020		Cardiovascular System
2	Rosuvastatin Calcium Tablets	5mg	09/06/2022		Cardiovascular System
3	Dexmedetomidine Hydrochloride Injection	2ml	07/09/2021		Nervous system
4	Dexmedetomidine Hydrochloride Injection	1ml	30/01/2022		Nervous system
5	Epalrestat Tablets	50mg	24/10/2023		Digestive system and metabolic
6	Moxifloxacin Hydrochloride & Sodium Chloride Injection	250ml	23/11/2020		Systemic anti-infectives
7	Terbutaline Sulphate Solution for Nebulization	2ml:5mg	07/04/2021	Second	Respiratory system
8	Azithromycin dry suspension	0.1g	30/08/2022	The First	Systemic anti-infectives
9	Urapidil Hydrochloride Injection	5ml	29/05/2023		Cardiovascular System
10	Urapidil Hydrochloride Injection	10ml	29/05/2023		Cardiovascular System
11	Doxofylline Injection	10ml:0.1g	21/01/2020	The First	Respiratory system
12	Azithromycin for Injection	0.5g	21/03/2023		Systemic anti-infectives
13	Pitavastatin Calcium Tablets	2mg	30/06/2023		Cardiovascular System
14	Pitavastatin Calcium Tablets	1mg	30/06/2023		Cardiovascular System
15	Linezolid and Glucose Injection	100ml	29/06/2021		Systemic anti-infectives
16	Metronidazole Sodium Chloride Injection	100ml	26/02/2021	Second	Systemic anti-infectives
17	Ipratropium Bromide Solution for Inhalation	2ml:500µg	30/09/2022		Respiratory system
18	Ipratropium Bromide Solution for Inhalation	2ml:250µg	30/09/2022		Respiratory system

#### Products considered as catalyst

(34 Types, 47 Specifications)

No.	Drug Name	Specification	Approval Date	Approval in PRC	Treatment Category
19	Moxifloxacin Hydrochloride Tablets	0.4g	07/01/2022		Systemic anti-infectives
20	Bromhexine Hydrochloride Injection	2ml	23/03/2021	Second	Respiratory system
21	Tirofiban Hydrochloride and Sodium Chloride Injection	100ml	20/11/2023		Blood and hematopoietic organs
22	Tirofiban Hydrochloride and Sodium Chloride Injection	250ml	20/11/2023		Blood and hematopoietic organs
23	Azithromycin dispersible Tablets	0.25g	08/11/2022		Systemic anti-infectives
24	Aminophylline Injection	10ml	27/10/2023		Respiratory system
25	Aminophylline Injection	20ml	27/10/2023		Respiratory system
26	Cinacalcet Hydrochloride Tablets	25mg	12/05/2023		Non-sex hormones and insulin-based hormonal systemic drugs
27	Terbutaline Sulphate Injection	1ml:0.5mg	19/01/2023	Third	Respiratory system
28	Lacosamide Tablets	50mg	30/09/2021		Nervous system
29	Lacosamide Tablets	100mg	30/09/2021		Nervous system
30	Lurasidone Hydrochloride Tablets	40mg	14/02/2023		Nervous system
31	Tinidazole Tablets	0.5g	28/09/2023		Systemic anti-infectives
32	Prucalopride Succinate Tablets	1mg	16/07/2020	Second	Digestive system and metabolic drugs
33	Prucalopride Succinate Tablets	2mg	16/07/2020	Second	Digestive system and metabolic drugs
34	Moxifloxacin Hydrochloride Eye Drops	5ml	16/03/2022		Systemic anti-infectives
35	Nifedipine Sustained-release Tablets	20mg	25/12/2023		Cardiovascular System
36	Tedizolid Phosphate Injection	200mg	26/05/2023		Systemic anti-infectives
37	Tedizolid Phosphate Tablets	200mg	28/11/2023		Systemic anti-infectives
38	Vortioxetine Hydrobromide Tablets	10mg	09/01/2024		Nervous system
39	Nicorandil for injection	12mg	23/02/2024		Cardiovascular System
40	Lidocaine Hydrochloride Injection	5ml	29/03/2024		Cardiovascular System
41	Lidocaine Hydrochloride Injection	10ml	29/03/2024		Cardiovascular System
42	Lidocaine Hydrochloride Injection	20ml	29/03/2024		Cardiovascular System

## Products considered as catalyst

(34 Types, 47 Specifications)

No.	Drug Name	Specification	Approval Date	Approval in PRC	Treatment Category
43	Rasagiline Mesylate Tablets	1mg	15/05/2024		Nervous system
44	Ondansetron Hydrochloride Injection	4ml:8mg	21/05/2024		Digestive system and metabolic drugs
45	Ondansetron Hydrochloride Injection	2ml:4mg	21/05/2024		Digestive system and metabolic drugs
46	Dapagliflozin Tablets	5mg	28/06/2024		Digestive system and metabolic drugs
47	Dapagliflozin Tablets	10mg	28/06/2024		Digestive system and metabolic drugs

PART 02

# Competitive Advantages

#### **Competitive Advantages**

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



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

Numerous Specifications, Complete Preparation Types, Wide Coverage Increase in market share for products under centralized procurement Numerous Prize Recognition, Main subsidiaries awarded "Specialised and special new enterprises" in China

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



Production Bases: 2 preparation, 2 bulk pharmaceutical, 1 chemical and 1 medical material, forming synergy and whole-industry-chain by preparations + bulk pharmaceuticals + medical materials + biotech

	Production Lines	Annual Capacity
	25 I.V. Infusion production lines	2.6 billion bottles(bags)
	9 ampoule production lines	1.3 billion ampoules
	4 oral preparation production lines	5.0 billion tablets/capsules
ALCONTRACTOR AND	<ul><li>9 bulk pharmaceutical production lines (Guangxiang)</li><li>6 bulk pharmaceutical production lines (Guolong)</li></ul>	12,000 tons 600 tons
	Chemicals production line	30,000 tons
	Non-PVC film production line	25 million sq. meters
	Bioprocessing film production line	20 million sq. meters
	Rubber stopper & gasket production line	3.5 billion units
	Emulsion production line	50 million units
	Lyophilized powder injection production line	30 million units
	Medical equipment production line	5 new products

In vitro diagnostic (IVD) reagent production line 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, Freeze-dried powder injection, Tablets, Capsule and Granules

#### **Diversified and Coordinated Development – Bulk Pharmaceuticals Production Base**

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

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





#### **Hebei Guolong Pharmaceutical**

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

# **Specialised Bulk Pharmaceuticals** Bulk Pharmaceuticals with status A owned by Hebei Guangxiang Pharmaceutical (34)

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Serial	<b>Registration No.</b>	Drug Name	Status
1	Y20200001269	Epalrestat	А
2	Y20190007857	Aminophylline	А
3	Y20190007856	Theophylline	A
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	A
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
23	Y20210001074	Entacapone	А
24	Y20220000115	Salbutamol Sulfate	А
25	Y20220000118	Levalbuterol Hydrochloride	А
26	Y20220000116	Vortioxetine Hydrobromide	A

#### **Specialised Bulk Pharmaceuticals** Bulk Pharmaceuticals with status A owned by Hebei Guangxiang Pharmaceutical (34) 13

Serial	<b>Registration No.</b>	Drug Name	Status
27	Y20220000360	Isoproterenol Hydrochloride	А
28	Y20220000117	Lidocaine Hydrochloride	А
29	Y20220000599	Rasagiline Mesylate	А
30	Y20220000359	Benserazide Hydrochloride	А
31	Y20220000836	Norepinephrine Bitartrate	А
32	Y20220000874	Butylphthalide	А
33	Y20220000954	Formoterol Fumarate	А
34	Y20220000958	Adrenaline	А

# **Specialised Bulk Pharmaceuticals** Bulk Pharmaceuticals with status A owned by Hebei Guolong Pharmaceutical (26)

Serial	<b>Registration No.</b>	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
19	Y20210000821	Stiripentol	А
20	Y20220000356	Nicorandil	А
21	Y20220000818	Dapagliflozin	А

# **Specialised Bulk Pharmaceuticals** Bulk Pharmaceuticals with status A owned by Hebei Guolong Pharmaceutical (26)

Serial	<b>Registration No.</b>	Drug Name	Status
22	Y20220000426	Etomidate	А
23	Y20220000427	Trelagliptin Succinate	А
24	Y20220000910	Doxazosin Mesylate	А
25	Y20220001251	Betahistine Mesylate	А
26	Y20220001252	Deferasirox	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





### Hebei Hanlin Technology

#### Major products :

In vitro diagnostic reagents, Cosmetic Peptide, Medical Ultrasound Coupling Agent and Medical Radiation Protection Spray







Numerous Varieties, Complete Dosage Form, Wide coverage

## No. of Production approvals: 436 including

331 Preparations, 63 Bulk Pharmaceuticals,42 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: 331 including 206 in Essential Drug List, 126 passed Consistency Evaluation, 17 in National Centralised Procurement

## Examples of Specialised products

		- 41
<b>R</b> 4*	面积189+20223704	SALAS
	己酮可可碱注射液 Pentoxifylline Injection	1
	8	
5ml:0.1g×50支/盒	5 石家庄園師有限公司 吉治电话: 400-6168689	11

Pentoxifylline Injection Blonanserin tablets



Bromhexine Hydrochloride Injection

+	вижношие:
市南色林 Bionanserin Ta	的 國際
4mp 10#	1.7石家庄茵药有赖公司

**Peritoneal Dialysis** 

Solution

Arbidol Hydrochloride Capsules

依维多*	BIR/8/#H01223941
拉考沙胺》	主射液
Lacosamide Injectio	
[48:00:00]	
市正进程于4岁及以上的标卷者部分 [建物]	HERDERART.
20mi:200mg	
20ml/支	
5支/盒	
	大学石家庄园药有酬公司

Lacosamide Injection

## Numerous Varieties, Complete Dosage Form, Wide coverage



### **Oral preparations**

- National Centralised Procurement : Prucalopride Succinate Tablets, Cefdinir Capsule, Cefaclor for Suspension and Felodipine II Sustained-release Tablets
- 1<sup>st</sup> approval in PRC: Blonanserin tablets, Azithromycin for suspension, Stipentol for suspension
- 1<sup>st</sup> passed consistency evaluation : Pentoxifylline Sustained-release tablets Levodopa-Carbidopa Sustained-release Tablets



#### I.V. Infusion

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



### Ampoule Injections & Lyophilized powder

- National Centralised Procurement :
   Doxofylline, Ambroxol Hydrochloride, Ropivacaine Hydrochloride, Ornidazole, Methylcobalamin, Argatroban, Urapidil Hydrochloride, Tedizolid Phosphate for Injection (lyophilized powder)& Citicoline Sodium
- 1<sup>st</sup> 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 selected in tender	Change ir	are*	
(Date of Result)		2020	2021	2022
$2^{rd}$ batch (Aug 2020)	Prucalopride Succinate tablet	1.09%	6.59%	9.44%
3 <sup>rd</sup> batch(Aug 2020)	Cefdinir capsule	2.30%	32.60%	38.56%
4 <sup>th</sup> batch(Feb 2021)	Doxofylline Injection	0.73%	7.69%	13.28%
	Ambroxol Hydrochloride Injection	0.31%	0.91%	2.57%
$E^{th}$ batch ( lup 2021 )	Fluconazole Sodium Chloride Injection	0.37%	1.77%	18.63%
5 <sup>th</sup> batch ( Jun 2021 )	Ropivacaine Hydrochloride Injection	-	0.38%	12.01%
7 <sup>th</sup> batch (Jul 2022)	Cefaclor for Suspension	4.84%	3.16%	5.92%
	Felodipine/Felodipine II Sustained-release Tablets	-	-	-
8 <sup>th</sup> batch (Mar 2023)	Ornidazole Injection	-	-	-
	Metronidazole Injection	11.61%	21.50%	29.07%
	Mecobalamin Injection	-	- 10	-
	Argatroban Injection	-	-	-
9 <sup>th</sup> batch (Nov 2023)	Azithromycin for Suspension	-	-	-
` /	Urapidil Hydrochloride Injection	-	-	-
	Tedizolid Phosphate for Injection	-	-	-
	Citicoline Sodium Injection	-	-	-

\*Data source: menet.com.cn

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
<b>PP Plastic Bottle</b> (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*, 1<sup>st</sup> 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	A	Approved
6	Y20210001168	Urapidil Hydrochloride	A	Approved
7	Y20210001076	Tofacitinib Citrate	А	Approved
8	Y20210001074	Entacapone	А	Approved
9	Y20220000115	Salbutamol Sulfate	А	Approved
10	Y20220000118	Levosalbutamol Hydrochloride	A	Approved
11	Y20220000117	Lidocaine Hydrochloride	А	Approved
12	Y20220000116	Vortioxetine Hydrobromide	А	Approved
13	Y20220000359	Benserazide Hydrochloride	А	Approved
14	Y20220000360	Isoproterenol Hydrochloride	А	Approved
15	Y20220000599	Rasagiline Mesylate	А	Approved
16	Y20220000836	Norepinephrine Bitartrate	А	Approved
17	Y20220000874	Butylphthalide	А	Approved
18	Y20220000954	Formoterol Fumarate	А	Approved
19	Y20220000958	Adrenaline	А	Approved
20	Y20220001108	Phenylephrine Hydrochloride	I	2024
21	Y20230000238	Vonoprazan Fumarate	I	2024

Limited • 49

## Bulk Pharmaceuticals under review (Hebei Guangxiang)

No.	<b>Registration No.</b>	Drug Name	Status	Expected approval
22	Y20230001010	Nikethamide	I	2025
23	Y20230001037	Benidipine Hydrochloride	I	2025
24	Y20230001109	Benidipine Hydrochloride	I	2025
25	Y20230001169	Nimodipine	I	2025
26	Y20230001287	Morpholinazole	I	2025
27	Y20230001288	Allopurinol	I	2025
28	Y20230001289	Dyphylline	I	2025
29	Y20230001344	Felodipine	I	2025
30	Y20240000021	Drotaverine Hydrochloride	I	2025
31	Y20240000115	Acipimox	I	2025

## Bulk Pharmaceuticals under review (Hebei Guolong)

No.	<b>Registration No.</b>	Drug Name	Status	Expected approval
1	Y20190000687	L-malic acid	А	Approved
2	Y20210000821	Stippentol	А	Approved
3	Y20220000356	Nicorandil	А	Approved
4	Y20220000818	Dapagliflozin	А	Approved
5	Y20220000910	Doxazosin Mesylate	А	Approved
6	Y20220000426	Etomidate	А	Approved
7	Y20220000427	Trexagliptin Succinate	A	Approved
8	Y20220000597	Alogliptin Benzoate	I	2024
9	Y20230000179	Betahistine Hydrochloride	I	2024
10	Y20220001251	Betahistine Mesylate	А	Approved
11	Y20220001252	Deferasirox	А	Approved
12	Y20230000011	Mexartan Potassium	I	2024
13	Y20220000598	Cisatracurium Besylate	I	2024
14	Y20210000676	Safinamide Mesylate	I	2024
15	Y20230000733	Dronedarone Hydrochloride	I	2024
16	Y20230000361	Lactose Monohydrate	I	2024

## Bulk Pharmaceuticals under review (Hebei Guolong)

No.	Registration No.	Drug Name	Status	Expected approval
17	Y20230000948	L-Lysine	l l	2025
18	Y20230001087	Piribedil	I	2025
19	Y20230001251	Indocyanine Green	I	2025
20	Y20230001271	Lornoxicam	I	2025
21	Y20230001345	Riluzole	I	2025
22	Y20240000182	Azilsartan	I	2025
23	Y20240000374	Cupric Chloride	I	2025
24	Y20240000375	Vitamin A Palmitate	I	2025
25	Y20240000427	Fampridine	I.	2025



## **Type 3 Preparations under review**

No.	Acceptance No.	Drug Name	Specification
1	CYHS2201367	Magnesium Sulfate Injection	20ml
2	CYHS2201366	Magnesium Sulfate Injection	10ml
3	CYHS2201365	Magnesium Sulfate Injection	2ml
4	CYHS2201309	Sodium Bicarbonate Ringer's Injection	500ml
5	CYHS2201328	Nicorandil for Injection	12mg
6	CYHS2201221	Cefuroxime Axetil Dry Suspension	0.125g
7	CYHS2201222	Cefuroxime Axetil Dry Suspension	0.25g
8	CYHS2201460	Lidocaine Hydrochloride Injection	20ml:0.4g
9	CYHS2201458	Lidocaine Hydrochloride Injection	5ml:0.1g
10	CYHS2201459	Lidocaine Hydrochloride Injection	10ml:0.2g
11	CYHS2301331	Cycloserine Capsules	250mg
12	CYHS2300060	Esmolol Hydrochloride Injection	10ml:0.1mg
13	CYHS2300340	Isoprenaline Hydrochloride Injection	1ml:0.2mg
14	CYHS2300853	Norepinephrine Bitartrate Injection	1mg/ml(4ml)
15	CYHS2300901	Phenylephrine Hydrochloride Injection	1ml:10mg
16	CYHS2300956	Sodium Potassium Magnesium and Calcium Concentrated Solution for Injection	20ml
17	CYHS2301154	Acetylcysteine Injection	25ml:5g
18	CYHS2301104	Acetic Acid Maintenance Solution (Containing Glucose)	500ml
19	CYHS2301103	Acetic Acid Maintenance Solution (Containing Glucose)	200ml
20	CYHS2301442	Epinephrine Hydrochloride Injection	1ml:1mg
21	CYHS2301676	Composite Potassium Hydrogen Phosphate Injection	5ml
22	CYHS2302249	Sodium Bicarbonate Injection	10ml:0.42g
23	CYHS2301989	Sodium Bicarbonate Injection	10ml:0.84g



## **Type 4 Preparations under review**

No.	Acceptance No.	Drug Name	Specification
1	CYHS2201023	Ropivacaine Hydrochloride Sodium Chloride Injection	100ml
2	CYHS2302754	Vortioxetine Hydrobromide Tablets	10mg
3	CYHS2201196	Propofol Medium / Long Chain Fat Emulsion	20ml
4	CYHS2201195	Propofol Medium / Long Chain Fat Emulsion	10ml
5	CYHS2201787	Linezolid for Oral Suspension	5ml:100mg
6	CYHS2201917	Entacapone Tablets	0.2g
7	CYHS2202089	Entacapone, Levodopa and Carbidopa Tablets $(~\Pi~)$	100mg/25mg/200mg
8	CYHS2300412	Betahistine Mesylate Tablets	6mg
9	CYHS2300266	Carbidopa and Levodopa Extended-release Tablets	50mg/200mg
10	CYHS2300518	Bisoprolol Fumarate and Amlodipine Besilate Tablets	5mg/5mg
11	CYHS2300686	Nicorandil Tablets	5mg
12	CYHS2301077	Levodopaand Benserazide Tablet	0.2g/0.05g
13	CYHS2300928	Dapagliflozin Tablets	5mg
14	CYHS2300929	Dapagliflozin Tablets	10mg
15	CYHS2301358	Fluvoxamine Maleate Tablets	100mg
16	CYHS2301960	Vonoprazan Fumarate Tablets	10mg
17	CYHS2301959	Vonoprazan Fumarate Tablets	20mg
18	CYHS2201678	Ondansetron Hydrochloride Injection	4ml:8mg
19	CYHS2201677	Ondansetron Hydrochloride Injection	2ml:4mg
20	CYHS2300010	Lipid Emulsion(10%) /Amino Acids(15%) and Glucose (20%) Injection	1500ml
21	CYHS2300011	Lipid Emulsion(10%) /Amino Acids(15%) and Glucose (20%) Injection	1000ml
22	CYHS2300581	Esmolol Hydrochloride and Sodium Chloride Injection	100ml
23	CYHS2300750	Etomidate Medium and Long Chain Fat Emulsion Injection	10ml:20mg
24	CYHS2301123	Isosorbide Dinitrate Injection	10ml:10mg
25	CYHS2301147	Lornoxicam for Injection	8mg



## **Type 4 Preparations under review**

No.	Acceptance No.	Drug Name	Specification
26	CYHS2201044	Rasagiline Mesylate Tablets	1mg
27	CYHS2301413	Phloroglucinol Injection	4ml : 40mg
28	CYHS2301960	Vonolazen Fumarate Tablets	10mg
29	CYHS2301959	Vonolazen Fumarate Tablets	20mg
30	CYHS2302139	Tofacitinib Citrate Extended Release Tablets	11mg
31	CYHS2302754	Vortioxetine Hydrobromide Tablets	5mg



## **Preparations under consistency evaluation review**

No.	Acceptance No.	Drug Name	Specification
1	CYHB2350257	Chlorpheniramine Maleate injection	1ml:10mg
2	CYHB2350256	Chlorpheniramine Maleate injection	2ml:20mg
3	CYHB2350237	Potassium Chloride Injection	20ml:3g
4	CYHB2350498	Gliclazide Tablets	80mg
5	CYHB2350184	Cefalexin Capsules	0.125g
6	CYHB2350185	Cefalexin Capsules	0.25g
7	CYHB2350446	Multiple Electrolytes Injection ( $\Pi$ )	500ml
8	CYHB2350502	Sodium Bicarbonate Injection	8.4% · 50ml
9	CYHB2350602	Peritoneal Dialysis Solution (Lactate-G4.25%)	2L
10	CYHB2350704	Nefopam Hydrochloride Injection	2ml:20mg
11	CYHB2350781	Glycerol Fructose and Sodium Chloride Injection	250ml

Production approvals to submit by end of 2024 (updated as of 30 Jun 2024)



## To submit soon

- 17 types of bulk pharmaceuticals
- 23 types of liquid preparations with
  - **26 specifications**
  - 13 types of oral preparations with

## **15 specifications**

## • Major projects of innovative drug development

## **Type I New Drug**

(a) SYN-045: Anti-pulmonary hypertension drug, Phase I clinical trial is underway, expected to be completed by the end of the year and is currently in good progress

(b) ADN-9: Anti-hepatic fibrosis type I new drug, expected to apply for Phase I clinical trial in 2024

## **Type II New Drug**

(a) Miplatin Liposome: Type II new drug for liver cancer, actively promote the phase I clinical trials, under preclinical development

- (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 preparation : 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 ampoule injection, under preclinical development
- (g) **DBT injection**: Ischemic stroke, Type II new drug for ampoule 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**



IV : Further expand market share of basic therapeutic infusion in hospitals of different tiers, focus on increasing the sales volume of key infusion products, consolidate its market share



Ampoule : Explore the market potential of dominant products, step up effort to increase sales of new products, increase the proportion of ampoule products in sales



Bulk pharmaceuticals : stabilise customer base, strengthen the development of domestic customers, accelerate the sales of products with distinctive strengths, improve the product mix



Oral and other preparations : seize opportunities in national centralised procurement, expand market size and influence on products which have passed consistency evaluation accelerate the optimisation and upgrading of the production and sales mix



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



R&D : "Combination of generic and innovative drugs" , accelerate the development of specialised generic drug, high-end complex preparations and innovative drugs, leverage on the cooperation mechanism with universities and scientific research institutes and talent recruitment mechanism to explore more high-quality research projects



Construction-in-progress : New construction of production lines for PP bottles injections with annual capacity of 600 million bottles in view of market condition, double-chamber bags of infusion with annual capacity of 15 million bags, sterile preparations of hormones with annual capacity of 200 million units



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